E. Provisions of the Final Rule

FDA selected each of the restrictions that it included in the 1995 proposed rule based on its tentative view that the particular restriction is necessary to providing a comprehensive response to the appeal of tobacco advertising to young people. Each proposed restriction was intended to address an aspect of this advertising that contributes to its appeal. The agency tentatively concluded that, together, these restrictions will ensure that advertising is not used to undermine the access restrictions that FDA proposed and thus will help to protect the health of children and adolescents under the age of 18.

In this section of the document, FDA will respond to comments on each element of this comprehensive approach, including comments on whether the regulations are legally supportable. A key question about the agency's approach is whether there is a reasonable fit between the agency's interest and the means that it has chosen to accomplish it; that is, between the agency's interest and the specific restrictions that it proposed. This inquiry involves consideration of the restrictions under the third and final prong of *Central Hudson*.

FDA will first consider comments that raised general concerns about its approach under the third prong of *Central Hudson*. It will then consider comments that raised concerns about specific restrictions under this aspect of *Central Hudson* as part of its discussion of the comments on each restriction.

1. Are FDA's Regulations Narrowly Drawn?

In the preamble to the 1995 proposed rule, FDA stated that the regulations that it was proposing met the final prong of the *Central Hudson* test (60 FR 41314 at 41355). In *Central Hudson,* the Supreme Court stated that the First Amendment mandates that speech restrictions be ''narrowly drawn.'' The Court continued:

> The regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger to the asserted State interest, * * * nor can it completely suppress information when narrower restrictions on expression would serve its interest as well.

(447 U.S. at 565, n.7) FDA pointed out, however, that: ''The Supreme Court has made it clear that this prong does not require a 'least restrictive means test,' but rather that there be a 'reasonable fit' between the government's regulation and the substantial governmental interest sought to be served'' (*Board of Trustees of State University of New York* v. *Fox,* 492 U.S. 469, 480 (1989); (60 FR 41314 at 41355).

(23) This statement by FDA provoked a significant amount of comment. Several comments said that FDA had mischaracterized its burden. These comments argued that *Fox* did not dilute the *Central Hudson* analysis, and that any restriction on commercial speech must be narrowly tailored. One comment pointed out that, in *Rubin* v. *Coors,* the Supreme Court made no mention of reasonable fit. The comment stated that in Rubin v. Coors, the Supreme Court said that *Central Hudson* requires that a valid restriction be no more extensive than necessary to serve the governmental interest (115 S.Ct. at 1591). Finally, one comment said that FDA was arguing that courts have applied a rational basis standard to restrictions on commercial speech, but the comment stated that FDA was wrong because courts have rejected this notion.

In response to these comments, FDA has carefully evaluated the relevant case law. The agency does not agree that it mischaracterized its burden in the 1995 proposed rule.

It is true that in *Rubin* v. *Coors* the Supreme Court found that the challenged statutory provision violated the First Amendment's protection of commercial speech, at least in part, because it was more extensive than necessary (115 S.Ct. at 1594). However, the Court also stated that its inquiry under the last two steps of *Central Hudson* involves ''a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends'' (*Id.* at 1391 (quoting *Posadas De Puerto Rico Associates* v. *Tourism Co. of Puerto Rico,* 478 U.S. at 341); (See also *44 Liquormart, Inc.* v. *Rhode Island,* 116 S.Ct. at 1510 (''As a result, even under the less than strict standard that generally applies in commercial speech cases, the state has failed to establish a reasonable fit between its abridgment of speech and its temperance goal.'')).

Moreover, the Court's statement in *Rubin* v. *Coors* that a restriction on commercial speech must be no broader than necessary, which was cited by a comment, must be read in light of the Court's discussion of this requirement in *Board of Trustees of State University of New York* v. *Fox,* 492 U.S. at 476–481. In *Fox,* the Supreme Court concluded from its consideration of how this phrase has been used in its case law and in the related case law on time, place, and manner restrictions, that what is required, exactly as the agency said in the 1995 proposed rule, is a fit between the Government's ends and the means chosen to accomplish those ends that is not necessarily perfect but reasonable (492 U.S. at 480). The Supreme Court reiterated this point in *Florida Bar* v. *Went For It, Inc.,* 115 S.Ct. at 2380 (citations omitted):

> With respect to this prong, the differences between commercial speech and noncommercial speech are manifest. In *Fox,* we made clear that the ''least restrictive means'' test has no role in the commercial speech context * * * ''What our decisions require,'' instead, ''is a 'fit' between the legislature's ends and the means chosen to accomplish those ends,'' a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served' that employs not necessarily the least restrictive means but * * * a means narrowly tailored to achieve the desired objective.

Thus, FDA did not mischaracterize its burden in the 1995 proposed rule. Moreover, in any event, FDA has narrowly tailored its provisions.

Before turning to the question of whether there is a reasonable fit between FDA's interest in the health of children and the restrictions that FDA proposed on tobacco advertising, the agency wishes to make clear that, contrary to the claim of one comment, it recognizes that courts have not equated the reasonable fit test with rational basis review. (See, e.g., *Florida Bar* v. *Went For It, Inc.*) FDA recognizes that the reasonable fit test requires that the Government goal be substantial, and that the cost of achieving that goal be carefully calculated. (See *Board of Trustees of State University of New York* v. *Fox,* 492 U.S. at 480.) It also recognizes that this test requires that the agency consider whether there are less burdensome alternatives to restrictions on speech.

Having already established that its goal is substantial (see section VI.C.4. of this document), FDA will consider the issues of the costs of the restrictions and alternatives to these restrictions in its analysis of the comments that follows.

(24) Several comments argued that the restrictions on cigarette and smokeless tobacco advertising that FDA proposed are not narrowly tailored. One comment said that the premise of the narrow tailoring requirement is that commercial speech is valuable, and that it may only be restricted when it is necessary to do so. Other comments argued that restrictions on speech must attack only problem speech, and that FDA had failed to prove that this is what the proposed restrictions did. These

comments stated that FDA's proposed restrictions are more extensive than necessary to achieve the agency's asserted interest, particularly because the agency had failed to show that the advertising restrictions will have any effect on underage smoking. Some comments argued that the restrictions that FDA proposed were tantamount to a ban because they will prevent the advertiser's message from reaching consumers.

Other comments disagreed. These comments said that FDA's proposed action is narrowly tailored. They argued that FDA had steered clear of imposing a categorical ban on tobacco advertising, or even broad prophylactic rules. One comment said that tailored prohibitions, instead of all-out bans, are important signposts indicating a measured response.

FDA disagrees with the comments that claimed that the restrictions were not narrowly tailored. The agency recognizes, as the Supreme Court said in *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985), that it has the burden of distinguishing the harmless from the harmful. FDA has met this burden.

The restrictions that FDA is adopting are not like those in *Central Hudson*, which, even though the Public Service Commission's interest was limited to energy conservation, reached all promotional advertising, regardless of the impact of the touted service on energy use. (See 447 U.S. at 570.) Rather, FDA's restrictions are carefully crafted to focus on those media and aspects of advertising that children are routinely exposed to and that the available evidence shows has the greatest effect on youngsters, while leaving the informational aspects of advertising largely untouched. FDA is not banning outdoor advertising; it is restricting it so that it does not unavoidably confront children when they play. It is not banning print advertising. It is restricting the use of images and color, which are particularly appealing to children, in publications that have a large number of young readers under the age of 18 and in other forms of advertising to which children are routinely exposed but permitting unrestricted advertising in adult publications and adult venues. It is restricting cigarette and smokeless tobacco companies' use of brand names and product identifications in sponsored events, but again in a way that reflects the agency's concern about children and adolescents under the age of 18. That is, it is permitting companies to sponsor in the corporate name in order to engender good will, but preventing them from using the brand specific attractive imagery that is influential with young people. Finally, it is prohibiting the use of branded promotional items because it is the young who find particular value in these items. In each of these respects, the agency has gone no further than it has found, based on the evidence, is necessary to meet its ends. (See *Dunagin* v. *City of Oxford, Miss.*, 718 F.2d at 751.)

Under the restrictions that FDA is adopting, firms will remain free to disseminate advertising that performs all the informational functions that are protected by the First Amendment. They will be able to disseminate information on what they are selling, for what reason, and at what price. (See *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 364 (1977).) Thus, the situation here is analogous to that in *Friedman* v. *Rogers*, 440 U.S. 1 (1979), where the Supreme Court found that a restriction on the use of optometrical trade names had only an incidental effect on the content of commercial speech. The Court said that ''the factual information associated with trade names may be communicated freely and explicitly to the public'' (440 U.S. at 16). So, here, any information that firms wish to communicate to adults may still be communicated by use of words. Indeed, the tobacco industry has used text-only advertising successfully in the past. [196]

It may be true, as some of the comments state and as the agency recognized above, that it will be more difficult for adult consumers to find cigarette and smokeless tobacco advertising without images and color, but willingness to search for information is one of the things that adults will do when they need information about price, quality, or product performance. Moreover, as discussed above, adult tobacco users are particularly interested in information on price, ''safer'' cigarettes, and new products, information that can be freely conveyed under FDA's regulations.

(25) The effect of the proposed restrictions on cigarette and smokeless tobacco product manufacturers' ability to communicate with adults was the subject of a number of comments. These comments argued that the proposed restrictions would not only preclude speech that may be perceived by young people, it would preclude speech that would be received by adults. The restrictions, these comments asserted, would deprive adults, who are legally entitled to smoke, of their right to the free flow of relevant commercial information. Other comments, relying on several cases, said that the First Amendment does not countenance wholesale censorship of speech for adults under the guise of protecting children. Many comments, for example, quoted a statement from *Butler* v. *State of Michigan*, 352 U.S. 380, 383 (1957) (''Surely, this is to burn the house to roast the pig.'') in support of this point. One comment said that FDA's purpose of reducing tobacco use by minors cannot support massive censorship between tobacco advertisers and adults.

One comment, however, argued that FDA's proposed restrictions are narrowly tailored to the specific types of advertising that are most effective with children. This comment said that these restrictions permit companies to continue marketing practices that do not appeal to children.

FDA has considered the concerns expressed in the comments. First, FDA does not agree that its interest is limited. As discussed above, the agency's interest is compelling. Nonetheless, the agency has tried very hard to tailor the restrictions on advertising in this final rule to focus them in order to limit the appeal of advertising to the young and ensure that the restrictions on access to cigarettes and smokeless tobacco will not be undermined, while at the same time, minimizing their effect on adults. Given this approach, FDA's restrictions differ significantly from those struck down in *Butler* v. *State of Michigan*, where the Court overturned conviction of a bookseller for selling a book to adults that contained some portions that might be objectionable to young people. In that case, the Supreme Court stated:

> We have before us legislation not reasonably restricted to the evil with which it is said to deal. The incidence of this enactment is to reduce the adult population of Michigan to only what is fit for children. (352 U.S. at 383)

This statement clearly does not describe the situation under the restrictions FDA is adopting. Except for limits on images and colors, the restrictions that FDA is adopting do not limit what cigarette and smokeless tobacco manufacturers, distributors, or retailers may say. As stated above, they are free to put into words any nondeceptive message that they would have communicated by color or image.

[196] As discussed more fully elsewhere, advertising for low-tar products is generally more reliant on text than on imagery.

FDA's restrictions, as one comment stated, restrict only those advertising techniques that have the most appeal. Thus, contrary to the situation in *Butler* v. *Michigan*, these restrictions are reasonably restricted to the harms they are intended to address.

Nor are the restrictions that FDA is imposing like the one struck down in *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60 (1983), which was cited by several comments. In that case, a Federal statute prohibited the mailing of unsolicited advertisements for contraceptives. The Postal Service sought to justify this restriction as aiding parents' efforts to discuss birth control with their children. While the Court found this interest to be substantial, it found the restriction to be more extensive than the Constitution permits (463 U.S. at 73). The Supreme Court struck down the restrictions, stating: ''The level of discourse reaching the mailbox simply cannot be limited to that which would be suitable for a sandbox'' (*Id.* at 74). It is in this respect that FDA's restrictions differ from those in *Bolger*. While FDA may limit the type of color or imagery, or the use of noncommunicative media, i.e., hats, FDA's restrictions do not limit the types of information that can be disseminated, except within 1,000 feet of schools and playgrounds.

(26) Other comments cited *Sable Communications* v. *FCC*, 492 U.S. 115 (1989), in which the Supreme Court struck down an outright ban on indecent as well as obscene interstate commercial telephone messages. This case is not relevant here because FDA is not imposing an outright ban on cigarette and smokeless tobacco advertising,[197] and because in contrast to Congress's failure to make findings that would justify the ban in *Sable*, FDA is fully explaining the basis for each of the restrictions that it is adopting here.

Other comments cited *Erznoznik* v. *City of Jacksonville*, 422 U.S. 205 (1975), in which the Supreme Court struck down an ordinance that, to protect minors, made it illegal to exhibit a motion picture visible from public streets in which female buttocks and bare breasts were shown. In doing so, the Supreme Court stated that: ''Speech * * * cannot be suppressed solely to protect the young from ideas or images that a legislative body thinks unsuitable for them'' (422 U.S. at 213).

Again, however, FDA is imposing restrictions on the manner and, to a limited extent, places in which cigarettes and smokeless tobacco are advertised, not content restrictions. Moreover, FDA is restricting commercial speech, which, as stated in section VI.C.1. of this document, is subject to a subordinate position in the scale of First Amendment values to the noncommercial expressions involved in *Erznoznik*. Thus, this case has no application here.

(27) Finally, a few comments cited *Project 80's, Inc.* v. *City of Pocatello*, 942 F.2d 635 (9th Cir. 1991), a case in which the U.S. Court of Appeals for the Ninth Circuit struck down ordinances that prohibited door-to-door solicitation because they restricted both wanted and unwanted solicitations. (See 942 F.2d at 638–639.) The municipalities sought to defend these ordinances on the grounds that they did not prohibit in-home sales. However, the court said that residents who wanted to receive unwanted solicitors had to post a ''Solicitors Welcome'' sign, and that the Government's imposition of affirmative obligations on the residents' First Amendment rights to receive speech is not permissible (*Id.* at 639).

Presumably, the comments cited this case as evidence that FDA's restrictions on tobacco advertising sweep too broadly because they affect the rights of both minors and adults to receive speech. Again, however, the case is distinguishable. Under FDA's restrictions, adults will be able to continue to receive tobacco advertising without any obligation to take any affirmative steps. They will have to look a little harder because, to advance FDA's interest in protecting the health of minors, advertisements will generally not have images or color, and such advertising will not be around schools or playgrounds. However, the advertising should otherwise continue to be available in newspapers, magazines, and billboards and appear unrestricted in adult publications and venues. There is no indication in *Project '80, Inc.* v. *City of Pocatello*, that the Ninth Circuit would find in such restrictions an undue burden under the First Amendment.

This review of the case law shows that FDA's effort to tailor the restrictions that it is adopting for cigarette and smokeless tobacco advertising that clearly distinguishes them from the governmental efforts to protect minors that have been struck down as sweeping too broadly and as impinging on the rights of adults. Under FDA's restrictions, there will still be a free flow of information to adults and not massive censorship as some comments allege. Thus, these comments do not provide a basis to conclude that FDA's restrictions fail the third prong of the *Central Hudson* test.

(28) Several comments pointed out that the Supreme Court has stated on several occasions that regulations that disregard numerous and obvious less restrictive and more precise means of achieving the government's asserted objectives are not narrowly tailored. These comments suggested that there are several less restrictive alternatives to the restrictions on advertising that FDA had proposed. One alternative pointed to by the comments was better enforcement of laws prohibiting sales to minors. The comments pointed out that Congress passed legislation as part of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, that prohibits DHHS from providing block grants for the prevention and treatment of substance abuse unless the State prohibits the sale and distribution of tobacco products to persons under 18. The comments said that FDA should give this new law a chance to work before imposing restrictions on speech, particularly in light of the fact that DHHS itself said in its 1995 proposed rule to implement this new law that ''[e]liminating virtually all sales [of tobacco products] to minors does not even present particularly difficult enforcement problems'' (see 58 FR 45156 at 45165, August 26, 1993).

The other alternative, according to the comments, that exists to the restrictions is an educational campaign that is sponsored either by the Government or that is provided through voluntary counter speech by the tobacco industry.

The agency recognizes that the various opinions by the Justices in *44 Liquormart* reiterate the need to consider nonspeech restrictions. Justice Stevens, speaking for himself and Justices Kennedy, Ginsburg, and Souter stated that the legislature ''cannot satisfy the requirement that its restriction on speech be no more extensive than necessary,'' given that alternative forms of regulation, such as taxation or limits on purchases that did not involve restrictions on speech, could achieve the goal of promoting temperance as well as, or better, than,

[197] The Court specifically distinguished *FCC* v. *Pacifica Foundation*, 438 U.S. 726 (1978), because that case did not involve a total ban on broadcasting indecent material. The Court pointed out that the FCC rule in that case sought to channel the indecent material to times of the day when children most likely would not be exposed to it (*Sable Communications* v. *FCC*, 492 U.S. at 127). FDA's intention here is to impose a similar type of focused and tailored restriction on tobacco advertising to limit the appeal of such advertising to children.

its ban. Moreover, Justice O'Connor in a concurrence, joined by the Chief Justice, and Justices Souter and Breyer stated:

> The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny.

(116 S.Ct. at 1521)

(29) One comment, however, argued that, for two reasons, there is no plausible claim that FDA has disregarded reasonable alternatives. First, the comment pointed out that the Federal Government has engaged in an incremental effort for 30 years to strike the appropriate balance in regulating the sale of tobacco products. This effort was successful in bringing down overall smoking rates, but youth smoking rates remained stable during the 1980's and have recently begun to rise. Because previous measures have failed, the comment said, it was now appropriate for FDA to take stricter action to reduce the use of tobacco products by minors. Second, the comment noted that a lack of narrow tailoring often manifests itself in a restraint that is either grossly underinclusive or overinclusive. The comment said that FDA had been neither here.

In *Florida Bar* v. *Went For It, Inc.*, 115 S.Ct. at 2380, the Supreme Court made clear that the question whether a restriction on commercial speech is reasonably well-tailored turns, at least in part, on the existence of ''numerous and obvious less burdensome alternatives to restrictions on commercial speech * * *.'' (See 115 S.Ct. at 2380 (citing *Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. 410, 418 n.13 (1993)).) FDA has considered the alternatives suggested by the comments and finds that none of them is an appropriate alternative to the restrictions that FDA is adopting.

First, the Government has engaged in a 30-year effort to eliminate young people's access to and use of tobacco products. The industry, through its voluntary code and various education programs, has professed to be part of the solution. However, tobacco can be easily obtained by young people (between 516 million and 947 million packs of cigarettes sold illegally per year to children (1992–1993) (60 FR 41314 at 41315)). Moreover, although adult smoking rates have declined dramatically since the publication of the first Surgeon General's Report in 1964 (from over 42.4 percent in 1965 to 25 percent in 1993) (60 FR 41314 at 41317), young people's smoking rates failed to decline during the decade of the 1980's and began to rise in 1991. Between 1991 and 1995, the proportion of 8th and 10th graders who reported smoking in the 30 days before the survey had risen by one-third, to about 19 percent and 28 percent, respectively. Smoking among high school seniors had increased by more than one-fifth since 1992, with 33.5 percent saying that they had smoked in the 30 days before the survey.[198] Thus, past efforts involving age restrictions and warning messages on packages and advertising have not been sufficient to reduce the demand for tobacco by young people. The restrictions on advertising are designed to affect the demand.

Second, the agency proposed a sufficiently comprehensive set of regulatory restrictions to address the problem of tobacco use by young people, to wit: (1) Provisions that restrict and prevent sales of tobacco products to young people; (2) provisions that reduce the appeal of tobacco products for young people that is created by advertising and promotions; and (3) a program to provide educational messages for young people to help them resist tobacco use. Thus, the agency has not relied solely on regulations that have an impact upon the speech of the tobacco industry but has included provisions to address the activity itself.

Third, while it is true that better enforcement of laws restricting sales to minors is complementary to FDA's approach, it does not eliminate the need for this action. As DHHS recognized in its final rule implementing the ADAMHA Reorganization Act of 1992, DHHS's action under that statute and FDA's regulations both address the need to reduce minors' access to tobacco products. FDA's action, however, in addition to reducing access, attempts, through the restrictions on advertising, to reduce ''the powerful appeal of tobacco products to children and adolescents'' (61 FR 1492, January 19, 1996).[199]

Advertising, as explained in sections VI.B. and VI.D. of this document, plays a role in the decision of children and adolescents to use cigarettes and smokeless tobacco. As long as advertising continues to play that role, young people will be motivated to obtain access to tobacco products and to attempt to circumvent any access restrictions. Thus, the restrictions on speech are necessary to prevent advertising from undermining FDA's proposed restrictions on access. First, the agency notes that the voluntary educational campaigns conducted by tobacco companies have not been effective in reducing underage tobacco use. This fact is evidenced by the increase in prevalence of tobacco use among young people. (See, e.g., 60 FR 41314 at 41315.) Second, the agency finds that any educational campaign is likely to be undermined if the young people to whom it is aimed continue to be the target of advertising that fosters the perception that experimentation with tobacco by young people is expected and accepted.

The U.S. Court of Appeals for the Fifth Circuit considered a suggestion similar to that of an educational campaign in *Dunagin* v. *City of Oxford, Miss.* and found it not to be an alternative to restrictions on advertising:

> We do not believe that a less restrictive time, place, and manner restriction, such as a disclaimer warning of the dangers of alcohol, would be effective. The state's concern is not that the public is unaware of the dangers of alcohol * * * The concern instead is that advertising will unduly promote alcohol consumption despite known dangers.

(See 718 F.2d at 751; see also *Posadas de Puerto Rico Ass'n* v. *Tourism Co. of Puerto Rico*, 478 U.S. at 344.) This is exactly FDA's concern about the effect of advertising on underage tobacco use, and why an educational campaign, which may complement advertising restrictions, is not an alternative to them.

Thus, the agency concludes that there are no less burdensome alternatives to restrictions on advertising. In this respect, this proceeding is distinguishable from that considered in *Rubin* v. *Coors*, which was cited by a number of the comments. In *Rubin* v. *Coors*, the Supreme Court pointed to the fact that the respondent cited several options that could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights than the

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[198] ''Teen Smoking, Marijuana Use Increase Sharply, Study Shows; HHS Sees Alarming 'Culturewide' Change in Progress,'' *The Washington Times*, p. A2, December 16, 1995; quoting from ''Results from the 1995 Monitoring the Future Survey,'' National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

[199] It is true that in its August 25, 1993, proposal (58 FR 45156), DHHS stated, as the comments say, that eliminating virtually all sales to minors does not present particularly difficult enforcement problems. This statement did not imply, however, that achieving this goal would be easy, nor did it reflect consideration of what ancillary measures would be useful to help to achieve this goal. It was, rather, a statement of DHHS' view that this goal could be achieved.

statutory provision the Government had adopted (115 S.Ct. at 1593).[200] Here, as in section VI.E. of this document, there are none believed to be nearly as effective.

In *U.S.* v. *Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993), the Supreme Court said that ''the requirement of narrow tailoring is met if 'the * * * regulation promotes a substantial Government interest that would be achieved less effectively absent the regulation,' provided that it did not burden substantially more speech than necessary to further the government's legitimate interests.''

FDA's restrictions on cigarette and smokeless tobacco advertising clearly meet this test. FDA's restrictions directly and materially advance its compelling interest in the health of children and adolescents under the age of 18. The discussion of the lack of less restrictive alternatives demonstrates that the agency's goals would be achieved less effectively in the absence of these restrictions. Finally, as the discussion on narrow tailoring and in the review of the comments on each of the regulations on advertising that follows makes clear, FDA is restricting only those aspects of advertising that have particular appeal to the young. Thus, the agency has crafted the advertising provisions with specificity to allow unrestricted advertising in those venues that are not seen by or used by children and adolescents. Accordingly, publications with adult readership and adult establishments may have unlimited print advertising. Moreover, companies are free to offer nontobacco items and events in their corporate names or unbranded. Companies, thus, can reward adult usage by providing these incentives but may not do so in a format (with brand identification and imagery) which is appealing to young people.

However, the agency has been unable to determine additional areas for unrestricted advertising. Thus, other than adult establishments, such as bars, there are no areas at other retail establishments that are not visible to young people. Billboards are ubiquitous and accessible to all ages. Nontobacco items can be restricted to dissemination to adults, but they would still serve as walking billboards. Finally, there are no adult only sponsored events—children are at the events or watching them on television. As described more fully in section VI.E.8. of this document, in the case of auto racing, attendance by young people is on the rise.

2. Section 897.30(a)—Permissible Forms of Labeling and Advertising

Proposed § 897.30(a) would have established the scope of permissible forms of labeling and advertising for cigarettes and smokeless tobacco. Proposed § 897.30(a)(1) would have defined permissible forms of advertising as newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution); billboards, posters, placards; and nonpoint of sale promotional material (including direct mail). Proposed § 897.30(a)(2) would have defined permissible forms of labeling as point of sale promotional material; audio and/or video formats delivered at a point of sale; and entries and teams in sponsored events.

In response to the comments, FDA has revised § 897.30(a) so that it no longer distinguishes between advertising and labeling, deletes teams and entries as permissible advertising, describes the procedure that FDA will follow when it is informed by advertisers of their intent to advertise in a medium not listed in the regulation.

In addition, the first sentence of § 897.30(a), which states that this subpart does not apply to cigarette or smokeless tobacco product package labels, has been redesignated as § 897.30(c).

(30) Several comments were received addressing the issue of permissible advertising outlets. Comments from the tobacco and advertising industries opposed the 1995 proposed rule. These comments criticized the 1995 proposed rule for not defining the term ''advertising'' and called the 1995 proposed rule unprecedented in the scope of its limitations on the forms of media, a violation of the First Amendment, a violation of the Administrative Procedure Act (APA), and beyond FDA's statutory authority. Supporters of the 1995 proposed rule, including health and public interest groups, stated that it is a reasonable measure given the effect of advertising on children and that it provides manufacturers with a wide variety of means for communicating with their customers. Some supporting comments urged that the prohibition of certain media, such as the Internet, be stated explicitly.

Several comments from the tobacco industry expressed concern that FDA did not define the term ''advertising'' ''because § 897.30(a)(1) would limit the media in which cigarettes may be 'advertised,' the definition of 'advertising' as used by FDA is crucial; yet the term is not defined in the proposed regulations.''

Moreover, they expressed concern that the definition was so sweeping that it could literally ''include reports to shareholders or potential shareholders; communications among manufacturers, wholesalers, distributors, and retailers; or even communications to the news media insofar as they might be deemed a 'commercial use.'''

Other comments requested that the agency clarify the definition to ban product placements in movies and commercials shown in movie theaters. Several comments stated that § 897.30 should be extended to include tobacco product packages to reduce the means of a child expressing affinity with the image associated with a particular brand. One comment recommended tombstone packaging without an identifiable logo.

The agency carefully considered whether it should attempt to define the term ''advertising'' more explicitly than it did. ''Advertising'' as a term is constantly evolving, as new media and new techniques of marketing emerge. Although its boundaries are understood (and were provided in the preamble to the 1995 proposed rule), there is no one accepted definition. FTC is the Federal agency with general responsibility for regulating most consumer advertising. Yet neither FTC nor any of its rules define the general term ''advertising.'' The agency agrees with the approach taken by FTC and continues to believe that the term ''advertising'' should not be defined any more specifically. Thus, FDA finds that the description of advertising in the preamble to the 1995 proposed rule is appropriate:

> Labeling and advertising are used throughout this subpart to include all commercial uses of the brand name of a product (alone or in conjunction with other words), logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product. However, labeling and advertising would exclude package labels, which would be covered under proposed subpart C.

(60 FR 41314 at 41334)

The agency also agrees with comments that state that it must provide some context for the application of so open ended a definition. For example, comments contended that ''commercial use'' could be interpreted to include such items as trade advertising (communication between

[200] One alternative that the respondents in *Rubin* v. *Coors* advanced was prohibiting marketing efforts emphasizing high alcohol strength (115 S.Ct. at 1593.) What FDA is doing here is analogous to that alternative. It is restricting marketing efforts that have particular appeal to the young.

manufacturers, wholesalers, distributors, and retailers), shareholder reports, and possibly even communications with the news media. This was not FDA's intent. This rule is a consumer based regulation; it is not the intention of FDA to include purely business related communications. Thus, noncommercial uses would not be affected. These would include such uses as unpaid press statements, signs on factories noting locations, business cards, and stockholder reports. While many of these uses would be ordinary and necessary business expenses, they would not be commercial uses in the context of the rule's restrictions on tobacco advertising affecting minors' tobacco use.

Furthermore, the preamble to the 1995 proposed rule explained that the agency intends to permit advertising with imagery and color in publications that are read primarily by adults. For that reason, under § 897.32(a), advertisements in publications (whether periodic or limited distribution) with primarily adult readership are not restricted to a text-only format. Trade advertising in trade press publications and trade show publications, trade catalogs, price sheets, and other publications for wholesalers, distributors, and retailers that will not be seen by consumers, including minors, are unaffected by the rule.

Also, the agency does not believe that the term ''advertising'' needs to be defined to clarify what is *not* a permissible advertising outlet. The 1995 proposed rule clearly specifies what advertising outlets are included within the regulation's coverage. However, the agency has been persuaded to make more clear its procedures for new or uncovered media. These procedures are described in this section.

The agency does not agree with comments that the rule needs to be clarified regarding infomercials or advertorials (program length commercials). Television infomercials are not allowed under the statutory broadcast ban, and magazine advertorials would be treated like any other magazine advertising. The agency recognizes that commercial advertising messages (videos) shown in a movie theater are not addressed by the 1995 proposed rule. If this becomes a desired medium, the companies would need to notify FDA 30 days prior to using a new medium. Finally, product placements in movies, music videos, and television, if not placed at the expense of a tobacco manufacturer, distributor, or retailer, would not be affected by this rule. The agency does not intend to regulate a film producer's artistic expression—i.e., what the producer chooses to display in movies.

The agency has decided not to include restrictions on tobacco product packaging. The agency has attempted to narrowly tailor this rule and therefore has not included packaging restrictions at this time.

(31) Several comments from the advertising industry expressed concern that the wording of § 897.30(a)(1) would ban all advertising for tobacco products that is not expressly permitted. If so, the comment states, the rule would be arbitrary and capricious because the agency did not present evidence that these unnamed advertising techniques influence young people. Another comment pointed out that the channels available to tobacco companies for communicating with adults already have been severely restricted by Congress' ban on television and radio advertising.

In contrast, comments from organizations of health professionals and a public interest group supported the scope of permissible advertising. One specific comment stated that, ''The media listed in § 897.30 provide manufacturers with a wide variety of means for communicating with their customers.''

The agency has determined that the scope of the permissible outlets for tobacco advertising in the 1995 proposed rule is reasonable. The permissible forms are the known current forums for tobacco labeling and advertising and account for the vast majority of advertising expenditures. While the format of much of current tobacco advertising is being restricted to a text-only format, almost all of the current media outlets being used for tobacco advertising will still be permissible. Legal users will continue to be able to receive information about cigarettes and smokeless tobacco, in a text-only format in most cases, in virtually all the same media currently used for tobacco advertising. Moreover, if an advertiser intends to use a new media outlet not included in the list of permissible advertising, its responsibility is to notify FDA and provide the agency with information about the media and the extent to which the advertising is seen by young people. FDA will review any submission and make a determination whether provisions of the final regulation provide sufficient information for the advertiser to know how to disseminate its advertising or whether the regulations need to be amended. Advertising in any new media will be subject to the text-only format requirement if it is a medium used by young people. Therefore, FDA has created a new § 897.30(a)(2) to reflect this new process.

The agency believes this approach is reasonable and is fully consistent with its statutory authority and with the First Amendment. In *Central Hudson Gas & Electric Co.*, 447 U.S. at 571, n.13, the Supreme Court suggested that the Public Service Commission might consider a system of previewing advertising campaigns to ensure that they will not defeat conservation policy. The Court pointed out that ''commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it'' (*Id.*). Given the agency's significant interest in ensuring that the restrictions on access that it is imposing are not undermined, FDA finds that the requirement that firms consult with it before using a new advertising medium is a limited means of regulating commercial expression that is likely to vindicate FDA's public health interests. This approach will not prohibit the tobacco industry from advertising in new media but will protect young people by giving the agency an opportunity to review the problems presented by a new media and to design new regulations or adapt current ones.

(32) One comment from a public interest group concerned with electronic media urged FDA to explicitly prohibit tobacco advertising over the Internet, Worldwide Web, and other on-line services and interactive media. The comment stated that children and adolescents are increasingly using on-line services with up to 4 million Americans under age 18 using, or with access to, on-line services. The comment stated further that the interactive nature of the on-line services gives advertisements numerous advantages over traditional print advertisements. The comment emphasized that a ban on tobacco advertising over these media is necessary because the text-only format would not be as effective in reducing the appeal of tobacco advertising to minors given the interactive nature of these media.

One comment from an organization of health professionals stated that one tobacco company advertises its mail-order business through a Web site on the Internet and offers links to other tobacco-related sites. The comment wondered why this type of advertisement was not banned by FCC

since the Internet operates over telephone lines, a form of electronic media that is regulated by FCC and from which cigarette advertising is banned.

A few comments dealt with on-line advertising and recommended that the rule should limit format to black text on a plain background, require advertisers to demonstrate that significant numbers of children do not access ad sites, require use of any available blocking technology, and define ''conspicuous'' and ''prominent'' as they pertain to interactive media.

Some of these comments have suggested that advertising of tobacco products in on-line media should be banned under the Federal Cigarette Labeling and Advertising Act's (the Cigarette Act) (15 U.S.C. 1331) and the Comprehensive Smokeless Tobacco Health Education Act of 1996's (the Smokeless Act) (15 U.S.C. 4401) prohibition of advertising on any media subject to the jurisdiction of FCC. The agency leaves the issue of jurisdiction and the applicability of the broadcast ban to the Department of Justice, which has the appropriate jurisdiction over the Cigarette Act, and to FTC, which has along with the Department of Justice jurisdiction over the Smokeless Act. Were these agencies not to take action and were, tobacco advertising to continue in on-line media, then FDA is available to meet with advertisers regarding their responsibility under the final rule.

The agency recognizes the growing importance and use of on-line media and the Internet for communications of all sorts, including tobacco sales and advertising. On-line media are not included within the list of permissible outlets for tobacco advertising because the agency does not have sufficient information on the technology to include regulations in the final rule. However, advertisers interested in advertising on the Internet should notify the agency, after the rule is final, and provide the agency with sufficient information about use by young people so that the agency can make a proper determination. This notification is for discussion purposes only, and is not in any way intended to imply, or create a need for, prior approval.

The agency recognizes the concern expressed by one comment that a text-only format, without additional requirements, may not be as effective in protecting young people from on-line advertising as it would be for print advertising because of the interactive nature of on-line media. The agency would consider the unique qualities of on-line media and the Internet in evaluating any requests to use these media. Any other statement about specific requirements for this new media or any other media would constitute speculation at this point. [201]

Section 897.30(a)(1) provides a comprehensive listing of the permissible forms of advertising and labeling. The evidence that FDA has gathered in this proceeding establishes the need for and importance of such a comprehensive listing. In addition to the general evidence and support provided by expert opinion, advertising theory, studies and surveys, empirical studies, anecdotal evidence, industry statements, and two consensus reports (the IOM Report and the 1994 SGR) described in section VI.D.5. of this document, FDA has found specific support for a comprehensive listing in:

Empirical Studies—Various economic and econometric studies of international and cross-country data show that restrictions on advertising and promotional activities can result in a decline in tobacco use (see section VI.D.6.a. of this document).

Country Experience—The experience of countries, such as Norway and Finland, shows that comprehensive advertising restrictions can positively affect the smoking rates of young people over time (see section VI.D.6.a. of this document).

Advertising Theory—Each separate advertising media plays a critical role in shaping young people's beliefs about tobacco use, and ultimately their use of tobacco products (see sections VI.D.3.a. through VI.D.3.e. of this document). Therefore, regulation of advertising must address each type of media. As will be described in the following sections of the regulation, the restrictions on each media are necessary to reduce the appeal of tobacco for young people and to prevent unrestricted tobacco advertising from undermining the regulation's access provisions. Moreover, as international experience indicates (see section VI.D.6. of this document), when regulations that are not comprehensive are implemented, tobacco money can migrate to unregulated advertising venues (e.g., if publications are prohibited, money expended on sponsorship will increase) and can undermine the force of the regulation. Thus, in order to be effective, restrictions must be as comprehensive as possible.

Based on all of the foregoing, FDA concludes that the comprehensive listing of permissible advertising in § 897.30(a)(1) will directly and materially advance the agency's efforts to reduce consumption of tobacco products by children and adolescents under the age of 18.

3. Section 897.30(b)—Billboards

The agency proposed in § 897.30(b) to prohibit outdoor advertising, including but not limited to billboards, posters, or placards, placed within 1,000 feet of any public playground or playground in a public park, elementary school, or secondary school. FDA proposed this provision because these are places where children and adolescents spend a great deal of time and should therefore be free of advertising for these products. The agency tentatively concluded that this was a reasonable restriction and noted that the cigarette industry's voluntary ''Cigarette Advertising and Promotion Code,'' (the Code) revised in 1990, contains a similar provision concerning schools and playgrounds (60 FR 41314 at 41334 through 41335).

(33) FDA received over 2,500 comments concerning this part of the 1995 proposed rule. Comments opposing this measure pointed out that the tobacco industry has established a voluntary code similar to the proposed provision with which advertisers already comply, and that therefore, there is no reason to make this measure mandatory. These comments also stated that outdoor advertising does not target children and adolescents, and that parents, siblings, and friends have a much greater influence than billboards and posters on a young person's desire to start smoking. Further, they stated that there is no evidence that this measure would reduce any teenager's desire to smoke.

Most comments supported this provision, stating that children and adolescents should not be subjected to visual images promoting tobacco use around those areas where they attend school or play. The comments argued that children and adolescents want to be like the attractive models in the advertising, and, thus, the advertisements directly influence them to start using tobacco.

In the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period for the August 1995 proposed rule to place on the public record a memorandum that provided further explanation of the

[201] In addition to the substantive changes, the following changes in language have been made: (1) Deletion of ''only'' in § 897.30(a)(1); (2) substitution of (a)(2) for (b) in 897.30; and (3) deletion of ''and'' before ''in point of sale'' in § 897.30(a)(1).

agency's proposal to ban outdoor advertising within 1,000 feet of schools and playgrounds. The document provided an additional 30 days in which to comment on this new information. The memorandum stated that the agency was aware of the industry's voluntary 500-foot ban on advertising from schools and playgrounds but also that it was cognizant, based on the experience of its employees, that billboards can loom large in the sight of children and adolescents at that distance and thus would be able to capture their attention. The agency also noted that 1,000 feet is about 3 blocks and that signage kept that far away from schools and playgrounds would not loom as large, if it would be visible at all. Moreover, the 1,000 feet will protect children as they travel to and from these locations.

In response to the comments, FDA has modified the provision to clarify the coverage of the provision. Thus, the final rule states that the 1,000-foot area is to be measured from the perimeter of the playground or school. Moreover, a definition of playground is included as well as an indication that the relevant area of a playground in a larger public park is limited to the play area itself. Section 897.30(b) reads:

No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(34) Several comments asked FDA to define what is meant by the term ''playground.'' The comments stated that the term could be construed to include literally any place of outdoor recreation where children may play (i.e., a paved parking lot, a tennis court, or a city park), even places used primarily by persons 18 years of age or older. One of the comments noted that the industry code refers to ''children's playgrounds'' (i.e., playgrounds designed primarily for use by children), but that § 897.30(b) refers to ''any playground.''

Some comments suggested that the term ''playground'' should include the playgrounds of city parks, recreation facilities, theme parks (e.g., Disneyland), and national parks.

The agency agrees that it needs to clarify what is meant by the term ''playground.'' A typical dictionary definition of ''playground'' states that it is: (1) An outdoor area set aside for recreation and play, especially one having equipment such as seesaws and swings; or (2) a field or area of unrestricted activity. The intent of the proposal was not to preclude outdoor advertising within 1,000 feet of any area that would fall under this broad definition, but to preclude cigarette and smokeless tobacco advertising around those areas where children and adolescents are likely to spend a lot of time. Clearly, areas around schools with equipment such as swings and seesaws are areas where children are likely to play. Public parks for family recreational purposes with play equipment, and facilities for activities such as baseball or basketball are also areas where children and adolescents are likely to be present for hours at a time.

However, private enterprises, such as theme parks and recreational facilities, are not necessarily intended only for children and adolescents. Those that are, may require the presence of an adult for entry. There are usually entrance fees or required purchases for use of these areas. In addition, children and adolescents may not be present in these areas on any regular basis (e.g., an annual visit to a theme park). Therefore, the agency will not include these areas in the regulation. Moreover, because all outdoor advertising must be in black and white text, the agency sees no need to extend the prohibition beyond elementary and secondary schools and public playgrounds at this time.

The concern expressed that a decision by private parties to build a playground could destroy the value of a billboard sign should no longer exist. Because the agency is limiting its definition of playground to those publicly owned playgrounds, any interested party could object to the establishment of the playground.

FDA is modifying § 897.30(b) to state that outdoor advertising is prohibited within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., areas with equipment such as swings and seesaws, baseball diamonds, basketball courts), elementary school or secondary school. The agency concludes that this modification in § 897.30(b) is adequate to clarify the term ''playground,'' and that a more specific definition for ''playground'' is not necessary at this time.

The agency notes that the definition makes clear that, when an area is set aside for a playground within a public park, the 1,000 feet is measured from the perimeter of the play area and not from the larger park.

(35) Several comments contended that the regulation should specify that the 1,000-foot rule should be measured from the perimeter of the property to avoid confusion. One comment asked that the provision be more clear as to what types of schools would be included within the definition.

The agency agrees with the first comment. The intent of the 1995 proposed rule was that the distance would be measured from the perimeter of the school or playground. Any other measurement could defeat the purpose of the regulation. For example, measuring from the edge of a building or from the center of a playground could allow outdoor advertising to be placed closer to the perimeter where children may be assembled or playing. In addition, for large schools or playgrounds, the outdoor advertising could feasibly be near the perimeter of the school or playground if the distance is measured from somewhere other than the perimeter. Therefore, to clarify the intent of the provision, FDA is modifying § 897.30(b) to state that no outdoor advertising may be placed within 1,000 feet of the perimeter of any playground, elementary school, or secondary school.

However, the agency does not believe that it needs to provide a definition of elementary and secondary schools, as those terms, as commonly used, include all such schools (kindergarten through 12th grade) whether public, private, or parochial.

(36) One comment stated that the tobacco industry Code of Advertising Practices (the Code) applies to outdoor advertising on billboards, and that § 897.30(b) applies to all outdoor signage, including signage on the exterior of retail establishments that sell tobacco, and conceivably even to advertising on buses, taxis, and other vehicles that might venture within the 1,000-foot zone.

Another comment stated that FDA should consider regulations that eliminate tobacco advertising via traveling vans and trailers because trailers and vans are mobile billboards and can be strategically placed to gain maximum exposure among young people.

FDA agrees that § 897.30(b) applies to more forms of advertising media than does the tobacco industry code (i.e., all outdoor advertising, not just billboards). FDA's regulation restricts all outdoor advertising of tobacco products, including, but not limited to, billboards, posters, and placards. However, the intent and purpose of § 897.30(b) is not

to prohibit signage on taxis and buses that are not located in, but may pass through, the school or play zone. Such signage is usually temporary or transient and does not present the same concern of a permanent sign.

(37) Several comments questioned the factual basis for the proposed ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and playgrounds and stated that ''employee'' experience is not a sufficient basis. One comment argued that FDA should give little weight to employee experience in light of the fact that cigarette manufacturers submitted expert testimony that children and adolescents pay relatively little attention to billboard advertising at any distance. In addition, some comments argued that FDA's analysis related solely to billboards, and that it had presented no evidence or analysis justifying a ban on store signage. Finally, several comments stated that the agency failed to take into account the ''visibility'' of the outdoor advertising. These comments suggested that any regulation must take into account whether obstructions exist (e.g., trees, winding roads, signage placed facing away from the prohibited area).

The agency disagrees that it has not provided an adequate basis for its proposed regulation. In addition to the analysis provided by the agency in its March 20, 1996, Federal Register document, the agency received two comments during the comment period with evidence regarding this issue. A professor of biophysics and optometry stated that he believed that there was a rational and quantitative basis for deciding on a given distance if that distance was to be based on the visibility of words on a billboard. Specifically, he stated that children and adolescents typically have 20/15 visual acuity. Therefore, it is possible, using a mathematical formula using a right-angled triangle and the definition of the tangent trigonometric function to compute the distance at which words are visible. He computed the distances from which it would be possible to see both words 1 foot high and 2 feet high. In addition, he computed the distances for a ''normal'' visual acuity of 20/20. If one were to average these numbers, the result would be approximately 1,200 feet, which could be rounded to 1,000 feet.

Table 1a.

	1-foot high letters	2-foot high letters
20/15 vision	917 feet	1,833 feet
20/20 vision	687.8 feet	1,376

(38) Another comment reminded the agency that two separate laws passed by Congress had provided for a 1,000-foot zone around schools as a means to protect youngsters from dangerous and unsafe behavior. The Controlled Substances Act (21 U.S.C. 860) provides additional penalties for anyone distributing or manufacturing drugs within 1,000 feet of schools, playgrounds, and universities, and 18 U.S.C. 922 prohibited possession of a firearm within 1,000 feet of schools. [202] Moreover, the comment contained scores of pictures of advertising billboards and signs within 500 and 1,000 feet of school and playgrounds as well as statements by children indicating that the signs are ubiquitous and attractive. The pictures and statements may only be anecdotal evidence of the proliferation of tobacco advertising near schools and playgrounds, but the number of children who provided pictures in such a short period of time indicates that the problem of advertising in proximity to schools and playgrounds is not isolated.

Moreover, the agency also disagrees that it has no basis for including other outdoor signage, including signs on stores, in the regulation. The agency provided evidence in the administrative record and comments refer to evidence, [203] which showed that in a test area, those stores within 1,000 feet of schools had a significantly greater percentage of windows covered with tobacco signs than those further away. Moreover, the two RJR memoranda by sales representatives, described in section VI.D.3.d. of this document, mention the importance of supplying stores near high schools with ''young adult'' material.

This provides sufficient support for the agency's concern with signage on stores near schools. Young people are more likely to frequent stores near schools, especially older adolescents, and these venues should therefore be free of advertising for tobacco products.

The agency also finds that it cannot address the comments' concerns with obstructions. It would not be possible to qualify a regulation to account for the fact that trees may obstruct a sign when they are in full bloom but not in winter, or that children may be able to see signage as streets wind or that face away from the school or playground as they walk to and from school. The line that the agency has drawn is narrowly tailored (see *Board of Trustees of State University of New York* v. *Fox* 492 U.S. at 480) and consistent with how a standard needs to be crafted for it to be enforceable.

Finally, FDA finds that the expert testimony referred to in the industry comment that indicates that young people do not pay attention to billboards is contradicted by other evidence in the record. The Roper Starch study mentioned in section VI.D.3.d. of this document, submitted by RJR, reported that 51 percent of 10 to 17 year olds surveyed reported that they had seen or heard of Joe Camel from a billboard advertisement. For this reason, FDA is not accepting the suggestion in the comment.

(39) A number of comments from the tobacco and outdoor advertising industries stated that the tobacco industry had adopted a code in 1990, which encouraged all billboard companies to establish and manage a program to prohibit alcohol and tobacco advertisements within 500 feet of places of worship and primary and secondary schools. They noted that over 16,000 billboards nationwide have been voluntarily identified as ''off limits'' for these categories of advertising. As a consequence, the comments asserted that Government action is unnecessary.

One of the comments stated that the fact that members of an industry have elected to submit to a code of advertising practices does not make it reasonable for the government to impose mandatory advertising restrictions backed by criminal sanctions. It stated that private parties may voluntarily take actions that the Constitution forbids the Government to mandate. The comment argued that few industries would risk any self-regulation if their decision to do so might establish a predicate for even greater Federal regulation.

Conversely, several comments raised concerns about the voluntary code and cited numerous examples of violations that continued after the sponsors and the billboard companies had been informed of the violations. One

[202] Although this statute was overturned in *United States* v. *Lopez*, 115 S.Ct. 1624 (1995), as inappropriate under the Commerce Clause, the congressional determination that 1,000 feet was an appropriate distance was not disturbed.

[203] Rogers, T., E. C. Teighey, E. M. Tencoti, J. L. Butler, and L. Weiner, ''Community Mobilization to Reduce Point-of-Purchase Advertising of Tobacco,'' *Health Education Quarterly*, 1995, in press.

comment stated that a survey found that in California tobacco advertising is more prevalent at stores within 1,000 feet of schools than at stores farther from schools. The comment asserted that statewide findings also revealed that there is more exterior store advertising in areas where at least 30 percent of the neighborhood is 18 years old or younger, and that the advertisements are placed near the candy or at a child's eye view (3 feet or below).

The agency is aware that the Code of Advertising Practices has not been uniformly observed, as several comments pointed out. Moreover, the industry code is significantly less inclusive than the proposed regulation as it covers only billboard advertising and not other forms of outdoor advertising such as posters and placards. These other forms are likely to be placed near retail establishments and in some cases, according to comments, have appeared on school fences. The agency finds that all outdoor advertising must be included in the regulation in order to provide comprehensive coverage. There is little difference between a billboard and a large poster to a child. Both are advertisements, and both are visible, so that children see them as they go to and from school and play.

In addition, the Code prohibits outdoor advertising only within 500 feet of schools, an area only a block or a block and a half from the school (there are 10 to 12 city blocks to a mile). One block will not provide sufficient protection as it would not cover the areas where many children congregate with their friends. Moreover, a child's vision does not stop at one block from school. A prohibition of 1,000 feet will ensure the absence of signs for 2 to 3 blocks from a school or playground which can be seen from these locations where children spend a significant amount of time each day. (Several comments stated that FDA had misused its math to calculate block distances in its March 20, 1996, Federal Register document (61 FR 11349).) If the misstatement caused any confusion, the agency regrets it but does not believe that the one-half block difference undermined the rationale.)

(40) One series of comments supported FDA's 1995 proposal, stating that the restriction on billboards near schools should not be compromised, nor the distance reduced.

A number of comments argued that the proposed regulation did not go far enough. One comment recommended excluding outdoor tobacco advertising from neighborhoods where children live. Another comment stated the belief that the ban on billboards should be at least double the proposed 1,000 feet from schools, while others argued that outdoor advertising should be prohibited completely.

These comments stressed the importance of billboards and other outdoor advertising in creating cigarette brand awareness among children. For example, one comment discussed the results of a survey conducted for *Advertising Age*, which showed that 46 percent of children 8 to 13 years old said they most often saw cigarette advertising on billboards, outpacing magazines. It stated that 34 percent of children 14 to 18 years old cited billboards as the predominant advertising medium for tobacco products.[204] The comment stated further that all billboards, regardless of placement, are seen by significant numbers of children, therefore, it clearly makes sense that, as a means to protect children from tobacco advertising, such advertisements should be prohibited from billboards and other outdoor advertisements. The comment emphasized its point by quoting from the billboard industry's own marketing material (''Outdoor: It's not a medium, it's a large''), ''You can't zap it. You can't ignore it * * * It asks little time, but leaves a long impression.'' The comment stated that the same publication notes, ''Outdoor is right up there. Day and night. Lurking. Waiting for another ambush.''

One tobacco company presented evidence of the effectiveness of billboards in bringing tobacco advertising to children. RJR, in its comment on the 1995 proposed rule, as stated in section VI.D.3.d. of this document, attached a study conducted for it to test children's recognition of advertising characters and slogans (Roper Starch study). This study involved 1,117 children 10 to 17 years of age, with 86 percent of them recognizing Joe Camel using aided and unaided recall. When asked where they had seen Joe Camel, 51 percent said on billboards.[205] That amount of recall shows that billboards represent a very effective advertising medium and belies the industry's assertion that billboards are not an effective source of advertising information for children.

Finally, one comment from a public interest group warned that, the more complex a rule is, the more difficult enforcement becomes. It stated that spacing limitations, such as the proposed 1,000-foot zone around schools, begs a series of questions, for example: How is that distance measured, from what point to what point. It stated that these questions would make it virtually impossible for citizens to play an active role in enforcing this rule. The comment stated that without citizen participation, billboard control is extremely difficult, and that this situation has, in fact, contributed to the industry's disregard for local and State billboard control laws.

The agency finds that the comments, as well as the evidence spelled out in the 1995 proposal, have provided ample support to establish that outdoor advertising has a significant impact on children and adolescents. While the comments have presented significant evidence in support of a ban on all outdoor advertising, the agency is not convinced that a ban or a restriction on tobacco advertising of more than 1,000 feet would be appropriate. As discussed elsewhere in this document, the agency is requiring that all permissible outdoor advertising be in a black and white, text-only, format. Therefore, some of the concerns raised by the comments requesting a complete ban on outdoor tobacco advertising or of expanding the ban are addressed by that provision. Moreover, the agency's regulations are an attempt to balance the rights of adults to receive information about a legal product with its desire to protect children from the unavoidable appeal of advertising. Thus, although the line could be drawn elsewhere, the agency finds that the 1,000 feet limitation should ensure adequate protection from visible advertising where children spend a significant amount of time but will permit adults to get information.

(41) One comment stated that FDA's action violated the APA because the agency offered no evidence in support of its claim that children spend a great deal of time in areas as far as 1,000 feet from the places specified in § 897.30(b). It added that the justification for text-only advertising undercuts FDA's justification for its 1,000-foot ban.

Another comment stated that although tobacco product advertising is disseminated through a broad spectrum of media, outdoor advertising is the only such medium that is subject to additional specific prohibitions under the 1995 proposed rule beyond the

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[204] Levin, G., ''Poll Shows Camel Ads are Effective With Kids; Preteens Best Recognize Brand,'' *Advertising Age*, p. 12, April 27, 1992.

[205] ''Advertising Character and Slogan Survey,'' pp. 10, 22.

prohibitions applicable to all tobacco product advertising. It stated that the record does not contain evidence that would establish either that these prohibited outdoor advertising signs are viewed more often by minors than other advertising media, or that outdoor advertising in general has a greater impact on minors than other media. There is nothing, the comments argued, that indicates that the mandatory content restrictions and affirmative disclosure requirements imposed by the proposal would be less effective in outdoor advertising of tobacco products than when such an advertisement is placed in a rock and roll magazine, or in an exempt publication with 1 million adolescent readers.

One of the comments stated that because the text-only requirement itself is intended to render the advertising unattractive to young people, the additional ''protection'' offered by the 1,000-foot rule would be wholly gratuitous.

Several comments argued that there is no proof that this additional area of ban will reduce any teenager's desire to use tobacco: a desire that has withstood the ban of TV and radio advertisements and a massive educational program. The comment stated that the 1,000-foot rule seems particularly gratuitous in view of the fact that it would ban advertising that FDA, by virtue of its proposed text-only requirement, already has stripped of the features FDA deems make it appealing to young people.

FDA disagrees with these comments. The agency's bases for the text-only requirement for billboards and for the 1,000-foot ban are reasonable and supportable, and they are not in conflict. The text-only format requirement will reduce the appeal of cigarette and smokeless tobacco product advertising to persons younger than 18 years of age without affecting the information conveyed to adults (60 FR 41314 at 41335). It is an attempt to narrowly tailor the restriction by balancing the need to restrict advertising's appeal to children with the preservation of the informational function of advertising for adults.

The prohibition on outdoor advertising within 1,000 feet of schools and playgrounds is designed to address a different problem. The concern is not the appeal of the advertising. If the problem were only appeal, the 1,000-foot restriction would not be necessary because the text-only requirement would eliminate this concern. The concern is the nature of billboards themselves. Billboards near schools and playgrounds ensure that children are exposed to their messages for a prolonged period of time. As the Supreme Court recognized in *Packer Corp*. v. *Utah*, 285 U.S. 105, 110 (1934), billboards are seen without the exercise of choice or volition, and viewers have the message thrust upon them by all the arts and devices that skill can produce. This is particularly true of billboards that are readily visible (i.e., within 1,000 feet) when children play or study at a playground or school, places where by design children spend a lot of time, or when children walk to and from a school or playground. Confronted daily and unavoidably with the advertised message, even in text-only, a child gets a sense of familiarity, normalcy and acceptability of the message and the product that is advertised.

(42) Several comments stated that placing a circle with a radius of 1,000 feet drawn from the perimeter of each school and playground would establish a ''forbidden zone'' that would be at least 2,000 feet in diameter (i.e., over one-third of a mile). They stated that in many communities, this would be tantamount to a de facto ban, for there would be virtually no outdoor location that could escape the rule's prohibition.

Several comments pointed out that even if advertisers wanted to disseminate advertisements on billboards that complied with the FDA proposal, there would be virtually no locations where such outdoor advertising signs could be located in some cities. They submitted results of computer assisted surveys of nine cities showing the areas where outdoor advertising of tobacco products would be allowed under the 1995 proposal. The survey showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the proposal. The comment stated that this range approximates the high and low percentages that could be anticipated in other metropolitan areas in the United States. Moreover, when it correlated the data collected from the study and other data regarding the actual location of billboards, the comment found that, even under the most expansive view, not a single billboard in Manhattan (including the commercial corridor of Times Square), and no more than 24 actual billboard locations in the entire city of Boston, would be permitted to display tobacco advertisements.

The comment stated further that even if the rule permits a few locations where tobacco advertising would be allowed in a given municipality, there is no commercial utility in a limited number of outdoor advertising signs where the location of the advertisement is dictated by the 1,000-foot rule, rather than by market demographics and vehicle circulation. According to the comments, these latter factors are what actually control billboard placement. It concluded that, as a practical matter, FDA's proposed outdoor advertising restrictions would eliminate billboards as a medium for tobacco advertising even in those jurisdictions where a small number of such signs theoretically would be available.

FDA has carefully considered the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas. The agency has concluded, however, that if this situation comes to pass, it would be a consequence of the density of population in cities. FDA's intent in adopting § 897.30(b) is to restrict the accessible and intrusive communication of information about cigarettes and smokeless tobacco to children and adolescents at school and at play. It was not to provide for distances that would have the effect of banning outdoor signs from urban areas. By limiting the restriction to 1,000 feet, FDA has tried to make it no more extensive than necessary to achieve its intended end. FDA has considered the cost of its restriction but concludes that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising in settings in which they are essentially a captive audience.

The 1,000-foot restriction on outdoor advertising will serve to remove what has been shown is an effective means for tobacco companies to communicate with young people in a direct and unavoidable manner. Eliminating such billboards will thus mean eliminating a means by which the industry has influenced young people to engage in tobacco use behavior. Therefore, the agency concludes that § 897.30(b) is a necessary part of its effort to reduce underage use of tobacco products.

Several comments from the tobacco industry and from retailers pointed out that § 897.30(b) would prevent retail establishments within the 1,000-foot zone from informing potential customers that tobacco (or particular brands thereof) are available for purchase therein and at what prices. These comments stated that this restriction not only would hurt the retailers but would increase, in turn, the

search costs for adult smokers. The comments stated that retailers in the small slivers of a city in which outdoor advertising would continue to be permitted would be afforded an unfair competitive advantage.

One comment added that convenience stores located within 1,000 feet of a school or playground would not even be able to put a small black on white placard on top of a gas pump that merely indicates the price of tobacco, but that a billboard across the street and located a little over 1,000 feet away from the same school or playground could carry the brand name of a tobacco product in black letters as tall as the store's front door. The comment urged FDA to recognize this distinction.

The agency acknowledges that some retailers may be prohibited from placing advertising concerning tobacco products on or around their retail establishments, while others, perhaps just across the street, can. Any minimum distance that the agency establishes will preclude some retailers from outdoor advertising at their retail establishments but not others. However, FDA has determined that it is necessary to keep outdoor advertising away from areas where children are likely to congregate daily.

FDA notes that the Supreme Court cases that have considered restrictions on speech have recognized that such restrictions may not be perfectly tailored, see, e.g., *Board of Trustees of State University of NY* v. *Fox*, 492 U.S. at 479. Thus, while in a few instances there may be inequities created by the line FDA has drawn, because there is a reasonable fit, as explained in section VI.E.1. of this document, between FDA's ends and the restrictions that it is adopting, these minor problems do not doom FDA's rule (*Id*. at 480).

FDA's prohibition on signage on stores within 1,000 feet of schools and playgrounds will advance the agency's interest in protecting the health of children. Several of the studies submitted with comments showed that there is more signage in and around stores near schools and playgrounds than in stores generally. The ban on outdoor advertising within 1,000 feet of schools and playgrounds will ensure that signage near schools will be removed and thus minimize any sense of familiarity that would develop.

Thus, even though the agency has carefully considered these comments, it concludes that it is appropriate to establish a minimum distance from schools and playgrounds within which all outdoor advertising is prohibited.

(43) A number of comments argued that the prohibition on tobacco billboards within 1,000 feet of schools violates the Commerce Clause as recently interpreted by the Supreme Court in *United States* v. *Lopez*, 115 S.Ct. 1624 (1995). In *Lopez*, the Supreme Court held that Congress lacked the power under the Commerce Clause to criminalize the possession of a gun within 1,000 feet of a school. One comment argued that the Congress's commerce power only permits it to regulate, for example, the interstate transit of advertisements, but that once the advertisement is within a state, it is private property and not subject to regulation under the Commerce Clause.

The agency disagrees. Under the Commerce Clause, Congress may ''regulate those activities having a substantial relation to interstate commerce, * * *, i.e., those activities that substantially affect interstate commerce.'' (See *Lopez*, 115 S.Ct. at 1629-30 (citation omitted).) As the Supreme Court noted in *Lopez*, ''the possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce'' (*Id*. at 1634; see also *id*. at 1640 (Kennedy, J., concurring)). As all advertising is inherently commercial in that it proposes a sale, the placement of tobacco billboards in a local school zone is economic activity that does substantially affect interstate commerce because it affects the demand for tobacco and smokeless tobacco. That the advertisements are private property after transportation in interstate commerce does not alter this analysis. Indeed, ''[a]ctivities conducted within State lines do not by this fact alone escape the sweep of the Commerce Clause. Interstate commerce may be dependent upon them.'' (See *United States* v. *Rock Royal Co-op., Inc*., 307 U.S. 533, 569 (1939); see also *Wickard* v. *Filburn*, 317 U.S. 111, 127–28 (1942) (holding that, under Commerce Clause, Congress could control farmer's production of wheat for home consumption because cumulative effect of such consumption by many farmers might alter supply and demand in interstate wheat market).) As such, regulation of the placement of billboards advertising tobacco products does not violate the Commerce Clause. [206]

(44) A number of comments argued that § 897.30(b) would violate the First Amendment. These comments argued that, given the requirement for black text-only on a white background, the restriction on billboards within 1,000 feet of schools and playgrounds would not directly and materially advance a substantial government interest. The comments also argued that the billboard restriction could not be considered to be narrowly tailored. One comment from a public interest group, however, argued that FDA's proposal is fully constitutional because it is much more limited than the restrictions on billboards upheld in *Penn Advertising* v. *Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995) vacated, remanded 64 U.S.L.W. 3868 (U.S. July 1, 1996), and *Metromedia, Inc*. v. *San Diego*, 453 U.S. 490 (1981). The comment pointed out that in *Metromedia, Inc*., the Supreme Court held that the City's interest in traffic safety and aesthetics were sufficient to justify a ban on commercial outdoor advertising (453 U.S. at 551, n. 23). Here, the comment said, the interest that FDA has asserted is more weighty.

FDA disagrees with the comments that argued that § 897.30(b) violates the First Amendment. As explained, this restriction does advance FDA's interest beyond what is accomplished by the text-only restriction. As explained in sections VI.B. and VI.D. of this document, the regular exposure of children to tobacco advertising, even in text-only form, builds a sense of familiarity and acceptability that, reports and studies say, contributes materially to the decisions of young people to experiment with and use tobacco products. Thus restrictions that eliminate such exposure will eliminate one factor that contributes to the process by which children and adolescents decide to smoke or use smokeless tobacco and, consequently, will directly advance FDA's interest.

Moreover, the restriction that FDA is adopting is narrowly tailored to advance its interest. FDA's concern is with the advertising that can be seen from schools and playgrounds, the place at which children and adolescents spend a significant amount of time each day. Three blocks or 1,000 feet is about the distance at which signs are readily visible. Thus, FDA has restricted outdoor advertising within this distance of schools and playgrounds.

[206] Moreover, cigarettes and smokeless tobacco products are nicotine delivery devices. Congress plainly provided for medical devices to be federally regulated as indicated by the provision allowing seizure of devices without proof of interstate shipment (section 304 of the act) (21 U.S.C. 334)) and by a presumption that devices are in interstate commerce (section 709 of the act (21 U.S.C. 379)).

The result of FDA's restriction is that children will not be confronted with tobacco advertising as they study and play, and thus there will be a corresponding reduction in the ability of tobacco advertisers to create the impression of acceptance and familiarity that is influential with youngsters. Consequently, there is a reasonable fit between FDA's interest in protecting the health of children and the restriction on outdoor advertising that it is adopting (see *City of Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. at 416; *Board of Trustees of State University of New York* v. *Fox*, 492 U.S. at 480).

Thus, FDA concludes that, in fashioning the restriction on billboards, it has fully met its obligations under the First Amendment.

In summary, FDA finds that § 897.30(b) will contribute in a direct and material way to reducing underage tobacco use. The evidence establishes that billboards are one of the most effective forms of advertising for young people, and that their elimination near schools and playgrounds will directly and materially advance FDA's goals.

Studies—A Roper Starch survey submitted by R. J. Reynolds found that billboards were the most mentioned source of information about Joe Camel for children (see section VI.D.3.d. of this document), and a study conducted for *Advertising Age* (April 27, 1992) discussed in this section showed that 46 percent of children 8 to 13 and 34 percent of children 14 to 18 said that billboards are a predominant form of advertising for tobacco.

Advertising Theory—Billboards near schools and playgrounds give the child a sense of familiarity, normalcy, and acceptability of the message on the product. Therefore, regulation of the format and even the location of some billboards and other outdoor signs within 1,000 feet of a school or playground, is essential. As discussed in this section, comments submitted in this rulemaking include photographs that evidence the intrusive effect of billboards and signage around schools and playgrounds.

Evidence of Children's Visual Range—Data provided by a professor of biophysics and optometry, detailed in this section, support a finding that 1,000 feet is an appropriate distance to remove signage that would be visible and readable to students.

Congressional Finding—As detailed in this section, Congress mandated a 1,000 foot drug free zone around schools and playgrounds (Controlled Substances Act (21 U.S.C. 860)) as an appropriate area in which to protect young people from drug dealing near schools and playgrounds.

Finally, the agency has tailored the ban as narrowly as possible by defining playgrounds narrowly and, as noted above, by restricting the area of the ban to that consistent with children's visual range.

4. Section 897.32(a)—Text-Only Format

Under proposed § 897.32(a), cigarette and smokeless tobacco product labeling and advertising, as described in § 897.30(a) and (b), would be required to use black text on a white background and nothing else. The agency tentatively concluded that this text-only requirement would reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 years of age and preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products.

In response to comments, the agency has decided to permit another exception to the requirement that all permissible advertising appear in text-only. Thus, it has created an exception for advertising in adult facilities that meet the criteria of § 897.16(c)(2)(ii) provided the advertising is affixed to the wall or fixture in the facility and is not visible from outside the facility. FDA has added this provision, as paragraph (a)(1) of § 897.32 and renumbered the exception for adult publications as § 897.32(a)(2)(i) and (a)(2)(ii).

Several comments suggested that FDA should provide an appropriate definition of ''text-only'' for permissible audio and video advertising, specifically static black text on a white background with no music or sounds. Therefore, proposed § 897.32 has been revised in consideration of comments received. A new § 897.32(b) has been added to provide guidance for audio/video advertising. Proposed § 897.32(b) has been redesignated as (c), and proposed § 897.32(c) and (d) have been eliminated. New § 897.32(b) has been added to provide explicit format requirements for one form of permissible advertising that had been left out of the proposed regulation.[207]

Many comments were received specifically addressing the text-only proposal. That children and adolescents should not use tobacco products was the one point of agreement among them. However, many comments from adult smokers and nonsmokers, retailers, tobacco farmers, elected officials, and the tobacco, advertising, newspaper, and magazine industries strongly objected to the text-only requirement. Their major objections were that: (1) Cigarette advertising does not cause young people to start smoking; (2) the proposed advertising restrictions would violate the First Amendment; and (3) the restrictions would have the effect of a virtual ban on cigarette advertising. Some comments expressed the concern or suspicion that FDA was using this proposal, ostensibly directed at minors, as a pretext to try to ban cigarette advertising generally.

In contrast, nearly three-quarters of the comments—mostly from parents, teenagers, public health officials, teachers, doctors, public interest groups, medical organizations, and some individuals in the advertising business—supported the proposal for text-only advertisements. The major reason presented for their support was the need to eliminate the appeal for tobacco that the advertising creates among children and adolescents. Some supporters urged even stronger action such as a total ban on all tobacco advertising. Some comments expressed the opinion that even though the proposed regulations may also affect adults, any resulting reductions in smoking by adults would not necessarily be bad.

(45) A number of comments questioned the validity of the evidence cited by FDA as support for the proposal. Many of these comments came from groups representing the tobacco, advertising, and publishing industries. These comments argued that there is no evidence that advertising with color and images encourages use of tobacco by minors or that advertising converts nonsmokers or nonchewers into smokers or chewers. Moreover, these other comments argued that there is no evidence that limiting advertisements to text-only is essential to reduce youth smoking and that there is no evidence that black and white text will reduce underage smoking.

In contrast, a number of supportive comments stated that the evidence cited by FDA, as well as studies published

[207] In addition to the substantive changes made to § 897.32, the following changes in language have been made: (1) Addition of ''Except as provided.* * * section,'' to § 897.32(a); (2) addition of ''any'' to § 897.32(a); (3) amended language in § 897.32(a)(2) starting with ''any publication'' and ending with ''an adult publication'' and, in the last sentence, ''an adult publication,''; (4) two changes to § 897.32(a)(2)(i) ''younger than 18 years of age'' and ''15 percent or less''; and (5) deletion of ''labeling'' from § 897.32(c).

since the proposal, demonstrate the special susceptibility of children and adolescents to pictures, cartoons, photographs, other graphic images and colors.

Specifically, many comments observed that the appearance of Joe Camel in traditional advertising forums (magazines, billboards) attracts children and adolescents. One child wrote that his father gave him two sports magazines. ''There were eight smoking ads in them * * * the last one had two pictures of Joe Camel smoking. This can attract kids to start smoking.''

Studies cited in the preamble to the 1995 proposed rule and in section IV.B. of this document, demonstrate the impact that images and colors, cartoons, and pictures and other graphic material have on children and adolescents. This does not mean that the same characteristics of advertising do not appeal to or affect adults. However, the effect of these techniques on children and adolescents is magnified because of their usual level of involvement in advertising as in everything else. [208] As detailed more fully in section VI.B. of this document, children and adolescents respond to stimuli that interest them, and that provides them with information that is important. Young people do not have the information processing skills that adults possess, and as a result more often than not, the information that is relevant to them comes in the form of images and colors rather than with a lot of words. This fact provides an explanation why 86 percent of children and adolescents smoke the three most heavily advertised brands (all are promoted with attractive imagery), even though they are generally price sensitive. [209] Adults buy generic products for price reasons or low tar brands for health concerns. [210] Advertising's colorful images are not as relevant to them as cost. Given these factors, FDA finds that the text-only requirement will significantly reduce the appeal of cigarette and smokeless tobacco advertising to young people and reduce its influence on them.

(46) Many comments, especially from the magazine, newspaper, advertising, and tobacco industries, stated that the proposal will operate as a virtual ban on most types of cigarette and smokeless tobacco advertisements. These comments argued that the text-only format requirement will eliminate tobacco companies' ability to attract the attention of potential customers and to convey brand messages and will render advertising invisible to adults. Therefore, tobacco advertisers would be far less likely to advertise in the text-only format. Also, not having a clear standard for when the text-only requirement applies (see also definition of adult publication) will cause tobacco advertisers to avoid more publications than may be necessary to ensure that they do not violate the rule. Many of these comments also argued that advertising would become ineffective. One comment said that advertising that passes unnoticed amounts to no advertising at all. This comment also asserted that, as a result of the text-only proposal, no viable alternative channels of communication would exist.

Comments from the tobacco and advertising industry suggested that the advertising industry would suffer revenue, profit, and job losses as a result of the text-only format; employees involved in graphics arts would especially be affected; and suppliers providing services and products to advertising agencies would also be adversely affected.

A number of comments supporting the proposal recommended a total ban on all tobacco advertising. Many comments stated that a ban on all tobacco advertising and marketing would be reasonable because the tobacco industry will use any available loopholes to market tobacco products and will test any partial ban.

Tobacco companies will be able to continue advertising in most of the same forums in a text-only format. Advertising with colors, pictures, and graphics will still be allowed in adult publications. Tobacco advertisers will still be able to convey information to adults about taste, price, and product development using text-only advertising. Many current advertisements for low tar cigarettes rely heavily on text formats.

The agency is not limiting fonts, font styles, or size of type because it believes that the tobacco industry and its advertising firms can use their creativity with a variety of print formats to produce text-only advertising that will effectively communicate their messages, including brand messages, to adults. However, the agency is also convinced that print advertising, no matter how creative, will not be able to provide the attractive imagery that young people look for in advertising to explain the importance of a product to them, e.g., what to wear, whom to hang out with, how to look cool (see discussion of the importance of color and imagery in the introduction to this section).

Moreover, although the restriction to text-only advertisements may tend to solidify market position, it will not give any one company new competitive advantage over another since all companies must play by the same rules. Thus, the economic impact of the rule on the advertising business will be mitigated by a shifting of resources to create new advertising in compliance with the rule and to advertising for other businesses (see section XV. of this document entitled ''Analysis of Impacts'' for more information).

The agency does not support a total ban on all tobacco advertising as was suggested by a number of comments. The agency has been able to tailor the restrictions that it is adopting, by requirements such as the text-only advertisements requirement, to eliminate the appeal of tobacco advertising for children and adolescents while still allowing a means for companies to communicate with adult tobacco users. The use of text-only will mean that there can be continued advertising that is less likely to attract young people but that can convey information to adults.

(47) Several comments stated that limiting point of sale advertising to text-only would effectively ban point of sale advertising and impair retailers' ability to market tobacco products to adult customers.

Many comments noted the places one sees (and placement of) Joe Camel at point of sale, the nature of the items on which his image appears, and his ubiquitousness in and around stores, as evidence of the intent of at least one tobacco company to try to attract young people. A physician commented that he:

> recently was returning from an evening [of] helping to care for [a] patient who was dying of emphysema [a lung ailment caused by cigarette smoking]. I decided to stop at a convenience store * * * I was confronted with no less than 14 advertisements for cigarettes. From the Camel Joe sign beckoning in the parking lot * * * a customer is bombarded with ads urging them to buy cigarettes.

Another comment stated that ''advertisements on convenience store doors are placed well below adult eye-level and features such popular advertising cartoons as Joe and

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[208] One such study tested the effect of different forms of advertising on children and found that they preferred pictures to text-only. (See Huang, P. P., D. Burton, H. L'Howe, and D. M. Sosin, ''Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents,'' *Tobacco Control*, vol. 1, pp. 249–255; 1992.)

[209] ''Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993,'' in *MMWR*, CDC, DHHS, vol. 43, pp. 577–581, 1994.

[210] Teinowitz, I., ''Add RJR to List of Cig Price Cuts,'' *Advertising Age*, pp. 3, 46, April 26, 1993.

Josephine Camel. It seems counter-intuitive to assume that such advertising is intended for adults.'' Another comment stated, ''Tobacco companies say they do not want to entice our children to smoke, then why are Joe Camel ads above the candy counters?'' One comment noted that at a major retailer near the commenter's neighborhood, Joe Camel posters are right behind an exhibit of pogs, a popular children's collectible toy.

Manufacturers and retailers are not prohibited from promoting tobacco products at the retail level. Adult consumers looking for price and product information about cigarettes and smokeless tobacco will be able to find that information by searching even without the images to attract them. Text-only point of sale advertising, like magazines or billboards, will be effective in communicating this information. Thus, FDA is not banning point of sale advertising.

While text-only point of sale advertising can be effective with adults, it will have less allure and be less appealing to children and adolescents. Children and adolescents, who are less willing to process print information in a leisurely setting (such as reading a magazine), will not find textual material appealing in the momentary time setting of a retail purchase.

(48) A comment from an advertising industry association stated that:

> * * * FDA's prohibition on all direct mail promotion of tobacco products except for ''tombstone'' messages * * * is even more onerous than that imposed on publications, since at least some publications will be permitted to carry non-tombstone advertising. The disparate treatment of direct mail exposes the real purpose of the FDA to censor messages to adults, because that medium by definition can be addressed to a specific audience, i.e., adults, with little risk of inadvertent viewing by minors.

This comment also noted that this form of direct advertising is not insignificant to the industry and given the small likelihood of youth access to it, should not be severely restricted. The comment noted that total industry spending on direct mail advertising was $33 million in 1993.

Some comments from mail-order firms noted that the text-only requirement would adversely affect catalogs for tobacco and related products, making them less appealing and less effective for marketing to adult smokers. One comment from the owner of a small (55 employees) tobacco products manufacturing business said the text-only requirement for its catalog, along with several other aspects of the 1995 proposed rule, would destroy his business:

> It offends me as a good American running a clean, honest business that a cadre of bureaucrats in Washington, DC would propose a rule that could ruin my life's work. FDA has given no more thought to the impact on my business than I might give to swatting a mosquito.

A supportive comment stated that the tobacco industry has made increasing use of direct mail promotions, including contests, questionnaires, coupons, offers, and even birthday cards. It stated that no company can be certain its mailing lists do not include minors. In a 1993 survey of 12 to 17 year olds, 7.6 percent indicated they had received mail personally addressed to them from a tobacco company. This could project out to 1.6 million persons aged 12 to 17. This comment noted that a major tobacco company sent free packs of cigarettes to people on its mailing list as a holiday present ''from the Camel family'' and has not changed its practice despite the fact that as many as 1.6 million 12 to 17 year olds could be on tobacco company mailing lists.

Direct mail is a high involvement medium, that is, it requires the recipient to study the text in order to get the central message. In those circumstances, text-only can be effective with recipients who have an interest in the offer. There is less of a need to attract a consumer's attention with a direct mail promotion, including a catalog, than with a point of sale or magazine advertisement. A consumer opening a direct mail promotion he/she is interested in is in a high-involvement mode and is prepared to read the enclosed material and catalog. Although the material may be more easily ignored, current tobacco users who want to buy by direct mail can get the information from textual material.

Mailings in text-only to current customers and to other adult smokers are permitted under the rule. On the other hand, if a direct mail promotion or catalog is seen by a child, the text-only format would make it much less appealing and less interesting. This is especially important since there is evidence that as many as 1.6 million children aged 12 to 17 receive direct mail tobacco promotions. Thus, text-only direct mail is important to accomplish the purpose of this rulemaking. Moreover, contrary to being censorship, as some comments stated, the text-only format for direct mail will allow advertisers to send adults an encyclopedia of information about any aspect of smoking or tobacco products while protecting children from the effects of advertising.

Although direct mail catalog advertising will be less interesting, sales should only be minimally affected. As the final rule does not include a prohibition on mail-order sales, the only restriction will be the text-only format. In addition, this should be less of an impediment than a total ban to small mail order company owners such as the commenter.

This compromise represents the agency's attempt to narrowly tailor its rule. Based on comments received from the industry, most mail-order customers purchase tobacco products for price, convenience, and uniqueness and to stockpile a long term supply. The agency believes that creative and effective advertising for adults can be designed in the text-only format for catalogs, especially for catalogs targeted to consumers purchasing tobacco products for these reasons. Therefore, FDA is not exempting direct mail promotion of tobacco products from the text-only requirement.

(49) One comment suggested that FDA create an exception for direct mail similar to that for publications. The comment said that direct marketers can target mailings so that children and adolescents are protected to, at the very least, the same degree that the regulations provide for the publishing industry.

FDA has considered this request but finds that it cannot grant it. The agency based the threshold for publications on the ground that publications with youth readership of less than 15 percent are not of interest to young people and thus would be unlikely to be read by them. The same cannot be said of direct mail advertisements that come addressed with the child's name on it. (As explained in this section, surveys show that a significant portion of tobacco direct mail advertising is sent directly to individuals under the age of 18.) The appearance of the child's name in the address will cause the child to look at the advertisement and thus will cause the message to be thrust on the child in a manner similar to messages on billboards or point of purchase (see *Packer Corp*. v. *Utah*, 285 U.S. 105, 110 (1934)). Thus, direct mail advertising is more similar in nature to billboards and point of purchase advertising than are publications. Consequently, as with the former types of advertising, FDA has concluded that to reduce the appeal of direct mail advertising to those youngsters who view it, it is appropriate

to require that this type of advertising be in the text-only format.

(50) A few comments said that in the same way the agency attempted to carve out an exception for publications with primarily adult readers, it should permit a similar exception for advertising in bars, clubs, etc., with customers over 21 years of age.

The agency agrees with these comments. The agency recognizes the need to precisely tailor its regulations and thus, has created an exception for advertising in adult only (18 years of age and older) facilities permitted to sell tobacco products from vending machines and self-service under § 897.16(c)(2)(ii). These facilities, which are required to ensure that no one under the age of 18 is present, or permitted to enter, the facility at any time, may display permissible advertising, i.e., with color and imagery, provided that the advertising is not visible from outside the facility and is affixed to a wall or fixture within the facility. These conditions will ensure that the advertising does not become a surrogate for outdoor advertising and is not carried from the facility.

(51) The agency received some comments from opponents and supporters of the 1995 proposed rule that stated that this provision might be counterproductive and result in increased demand for cigarettes and smokeless tobacco by minors. One comment from an association of advertising agencies stated that a reduction in spending on cigarette advertising, resulting from the proposal, could make cigarettes less expensive and increase demand for these products. In contrast, another comment from a tobacco company stated that reduced competition due to the text-only restrictions could lead to price increases for some brands which would harm the adult purchasers of those brands.

Some comments stated that the health warnings in cigarette advertising would become less effective in the proposed text-only format. This consequence could result in fewer people giving up smoking because of information in the health warnings. Some comments argued that the text-only format might actually attract more attention from minors because these advertisements would be so different from most advertising.

The agency finds that, on balance, the evidence does not support a conclusion that the text-only requirement will be counterproductive. This finding is based in part on the contradictory comments regarding the price of cigarettes. Some comments from the advertising industry argued that tobacco companies would use the savings from doing less advertising to reduce the price of cigarettes, which would increase demand especially among young people who are price sensitive. Other comments from the tobacco industry argued that the requirement would reduce competition, which could lead to higher prices for adult consumers. This conflict points out the speculative, and therefore unconvincing, nature of the claims that the restrictions will be counterproductive.

Also, despite concerns expressed by the tobacco industry and others that the text-only format would make the Surgeon General's health warning less effective, there is evidence from the focus groups conducted by the agency that this warning is not very effective with young people now.[211] The text-only format will not interfere with the ability of the Surgeon General's warning to warn adults of the health hazards of smoking. This format will, however, reduce the appeal to young people that advertising creates and therefore will lessen the need for the warning for young people.

The agency has considered the concern of some comments that the text-only format will be so unlike most advertising that young people will be attracted to it. Whatever attraction the novelty has for young people, the agency has concluded that it should be less than the attraction of the current imagery in tobacco advertising.

(52) A number of comments, especially from the tobacco industry, expressed concern about the 1995 proposed rule's adverse impact on competition. Many comments stated that advertising is critical to competition, brand choice, and product innovation. Comments from the tobacco industry stated that the primary purposes of its advertising are to promote brand competition and to maintain brand loyalty. Many of these comments argued that the text-only format would stamp out competition and freeze market shares. Some comments also stated that the 1995 proposed rule would serve as a barrier to new and improved products and product innovation, especially to products like lower tar cigarettes.

Although all firms will be subject to the same rules, some firms may still gain an advantage by dominant market position or by being more creative in their text-only advertising or more effective in their placement of advertising. Tobacco companies will still be able to advertise in virtually all the same forums they use now, but companies may gain competitive advantages by developing new marketing techniques aimed at adults that are within the rules. All industries have to adapt to changing competitive circumstances, whether caused by government regulations, demanded by the public, self-imposed as in professional sports, affected by international competition and changing technologies, or in reaction to changes in consumer preferences. Creative companies can succeed by adapting better than their competitors within the new framework.

Additionally, these advertising restrictions could make it more difficult for a new competitive tobacco company to be formed and to enter the market. But, there are much greater barriers to entry for a new firm in terms of the nature of the tobacco business, capital requirements, and the existing large firms already in the business. Nevertheless, to the extent that the regulations do produce anticompetitive effects, these are outweighed by the public health benefits of the rule.

Finally, information on new products and on product innovations need not be ''stamped out.'' This kind of information can be conveyed in the text-only format. One example of a new product that the tobacco industry claims might not have been developed if this rule had been in effect is the low tar cigarette. Yet advertising for low tar brands tends to use much more text than regular brands because the information is factual and specific. Therefore, the agency continues to find the text-only requirement to be an appropriately tailored remedy.

(53) Comments offered differing views on the function of advertising. Some stated that imagery is necessary to attract and hold the attention of adult smokers in order to convey useful information about the product and to effectively differentiate brands, while others saw images as being too appealing to children. These latter comments argued that FDA's rule is seeking to regulate only the presentation of the advertising that attracts children (the imagery), not its content.

One small business owner said the proposed ban on imagery would make established advertising logos with pictures worthless, not just for the major tobacco companies but also for small firms in tobacco related businesses. Others stated that the 1995 proposed

[211] Focus group report in administrative record, December 1, 1995, 60 FR 61670.

rule is not strong enough. One comment said that FDA is mistaken in asserting that the black and white text format removes imagery and emotive content from the advertisement. It said that the regulation should also limit the type styles, font sizes, and shapes of borders and letters.

The agency continues to believe that it has created an appropriately tailored remedy. The tobacco and advertising industries argue that FDA's ban on imagery and color is overinclusive and not narrowly tailored. FDA disagrees, however. The restriction on the use of images and color preserves informational advertising because of its utility to adults while eliminating the aspects of advertising that are most attractive to young people. The agency is regulating only the manner in which advertising is presented, not the information contained in it. Also, the agency is allowing imagery in advertising in adult publications.

There is undoubtedly an impact on businesses that have established logos, pictures, and other graphics associated with their businesses or products. However, all businesses are subject to the same requirements, and thus no one business should receive any competitive advantage.

The agency does not agree with comments recommending restrictions on type styles, fonts, etc. Such a restriction on advertising is, given the currently available evidence, more restrictive than necessary. Text-only advertising should be sufficient to reduce the appeal of advertising based on imagery to children and adolescents, however creatively the text is displayed. The agency concludes that the elimination of imagery and color directly and materially advances its interest in protecting the health of young people by making tobacco advertising much less appealing to them and, therefore, it makes it less likely that they will be influenced to use tobacco products.

(54) Several comments requested that FDA provide specific regulation for audio and video formats. Specifically, the comments requested that audio be confined to a text-only format appropriate for audio (words) unaccompanied by music or sound and that video be limited to black text on a white background only. Restrictions, such as these, the comments continued, would apply the spirit of the text-only format to these media. Finally, one comment expressed the concern that without these restrictions, tobacco companies might create and disseminate music tapes, similar to one distributed by RJR with music by ''The Hard Pack.'' This would, the comment stated, provide aural imagery for young people.

The agency agrees that it should provide more specific guidance for permissible audio and video media and that this guidance should be a logical application of the text-only requirement. Therefore, the agency has amended § 897.32 to add a new paragraph (b), which requires text-only black and white text in video advertising, which should be static, and text-only, no music, in audio advertisements.

(55) Several comments challenged FDA's proposal to limit most advertising to the use of the text-only, black print on white background format on the grounds that this limitation would violate the First Amendment. These comments relied most heavily on three cases: *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626 (1985), in which the Supreme Court struck down a restriction on the use of pictures in attorney advertising; *Shapero* v. *Kentucky Bar Association*, 486 U.S. 466 (1988), in which the Supreme Court held that the State may not restrict lawyer solicitations to those least likely to be read by the recipient; and *In re R. M. J.*, 455 U.S. 191 (1984), a case in which the Court struck down a requirement that lawyers use a fixed format in their advertising. One comment, however, argued that FDA's restriction is fully consistent with the First Amendment.

In *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. at 647, the Supreme Court said that ''the burden is on the State to present a substantial governmental interest justifying the restriction * * * and to demonstrate that the restriction vindicates that interest through [narrowly tailored] means.'' [212] FDA will apply this test here.

As explained in section VI.C.4. of this document, FDA has not merely a substantial, but a compelling, interest in the health of minors. It is this interest that led it to propose the restriction on the use of images and color in cigarette and smokeless tobacco advertising.

Several comments argued, however, that the restriction on images and color do not further FDA's interest. These comments argued that there is no evidence that the use of color and images in advertising increases tobacco use among young people.

FDA has fully addressed this assertion. The available evidence demonstrates that pictures and colors have particular appeal to children and adolescents under 18 years of age, and that they are more important to underage individuals than other aspects of the advertisement. [213] Young people pay attention to peripheral cues in an advertisement, such as the models that appear in them, color, and scenery, and it is these components that tobacco advertisers use to create the images that are so important to people under the age of 18. Thus, the restriction on images and colors will have a particular effect on the appeal of advertisements to young people and make these advertisements a significantly less effective means of communicating to this group.

(56) Several comments also argued that FDA's restriction on the use of colors and images is not narrowly tailored, pointing to the fact that the agency proposed to eliminate the use of all visual images and graphic designs in cigarette and smokeless tobacco advertisements.

These comments misinterpret the rule. FDA has not restricted all use of color and images. FDA has provided that these mechanisms may continue to be used in publications with primarily adult readership and in adult-only establishments. The agency has endeavored to restrict as little speech as possible. FDA has found, however, that it could not limit the appeal of cigarette and smokeless tobacco advertising to the young if it did not restrict the use of image and color.

Each of the cases relied upon by the comments is fundamentally distinguishable from the current situation. In each of these cases, the body seeking to restrict the advertising in question failed to present any evidence that the restriction was addressing an actual harm (see *Zauderer*, 471 U.S. at 648–649; *Shapero*, 486 U.S. at 479–80; (see also *Florida Bar* v. *Went For It, Inc.*, 115 S.Ct. at 2378 (''Finally, the State in Shapero assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail.''); *In re R. M. J.*, 455 U.S. at 206). Here, in contrast, the record fully establishes the reality of the harm, and that FDA's interest will be directly and materially advanced by the

[212] *Zauderer* actually states ''* * * through the least restrictive available means.'' However, in *Board of Trustees of State University of N.Y.* v. *Fox*, 492 U.S. at 479–481, the Court clarified this phrase as requiring narrowly tailored means.

[213] See, e.g., Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, 1986.

restriction on colors and images. For these reasons, FDA finds no merit to these comments.

In summary, FDA finds that the evidence amassed during this investigation and provided by comments provides ample support for its requirement that all forms of advertising that children see and are exposed to can have an effect upon their attitudes about tobacco use.

The empirical studies and surveys, expert opinion, anecdotal evidence, industry statements, and consensus report described in section VI.D.5. of this document implicate advertising as an important source of information for young people's attitudes about, and use of, tobacco products. This evidence shows that any regulation that hopes to be successful must be comprehensive and include some type of restriction upon all forms of advertising and promotions. FDA's regulation provides restrictions that will contribute directly and materially to that end but that are tailored as narrowly as possible. Except in the limited case of outdoor advertising within 1,000 feet of schools, no informational advertising will be disturbed. However, those aspects of advertising that have particular appeal to young people will be banned.

Color and Imagery—Color and imagery are necessary ingredients for advertising in conditions of ''low involvement,'' such as occurs when skimming a magazine or seeing a billboard (see sections VI.B.1.b. and VI.B.1 c. of this document).

FDA's restriction will eliminate the color and imagery but will permit information to be communicated. This requirement is as important for in-store advertising, billboards, and direct mail, as it is for traditional publications. As discussed in this section, young people get their information and product imagery from all these sources: (1) Point of sale advertising confronts young people when they go to make a purchase. The imagery is as large as life and presents the child with an enticement at the time when purchase is immediately available. It can as effectively impart information to adults with words. (2) Direct mail can frequently wind up in the hands of a young person or be addressed personally to the child or adolescent. One study found that 7.6 percent of children 12 to 17 years questioned had received mail personally addressed to them from a tobacco company (1.6 million teens).

Billboards—Billboards provide a major source of information about tobacco for young people. One study published in *Advertising Age* (April 27, 1992), found that 46 percent of children 8 to 13 years old and 34 percent of children 14 to 18 cited billboards as the predominant advertising medium for tobacco products (see section VI.E.3. of this document). The Starch Survey conducted for R.J. Reynolds found that 51 percent of children 10 to 17 who recognized Joe Camel as a tobacco mascot, reported seeing him on billboards (see section VI.D.3.d. of this document).

Cross-Country and International Studies—Studies described evidence that regulations that are stringent and comprehensive will have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones (see section VI.D.6.a. of this document). The text-only requirement, while not as stringent as a ban, will accomplish its purpose while preserving the informational function of advertising.

Finally, the regulation is narrowly tailored. It permits adult publications and adult locations to display advertising with images and colors. The agency has attempted to define these venues with as much precision as possible but recognizes that there may be some difficulties in application. It, therefore, has made it clear that it will work with the industry to try to establish as clear rules as possible. In-store, outdoor, and direct mail advertising do not lend themselves to such tailoring. Nonetheless, the agency is confident that adults seeking information about products can be adequately informed at time of purchase or by mail order catalogue using text-only.

5. Section 897.32(a)—Definition of ''Adult Publication''

The preamble to the 1995 proposed rule explained that the agency was interested in permitting advertising in publications that are read primarily by adults to continue to use imagery and color. For that reason, under proposed § 897.32(a), advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposed to define such publications as those: (1) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership, [214] or (2) that are read by fewer than 2 million people under the age of 18, whichever method ensures the fewest young readers. The agency defined the readership of a publication as the total number of people that read any given copy of that publication and stated in the preamble that it should be measured according to industry standards and, at a minimum, by asking a nationally projectable survey of people what publications they read or looked at during any given time. The preamble to the 1995 proposed rule noted that a reader is one who said that he or she read the last issue of a publication. The 1995 proposed rule provided that before disseminating advertising containing images and colors, it would be the company's obligation to establish that the publication meets the criteria for a primarily adult readership.

Numerous comments were received by the agency regarding the exception from the text-only requirement for adult publications and the definition of an adult publication. Comments from the newspaper, magazine, and advertising industries were particularly critical of the readership thresholds chosen for the definition of an adult publication and were especially concerned about whether there would be any reliable and practical way to determine readership levels for most publications. Many comments from individuals who supported the text-only requirement saw this exception as a possible loophole for the tobacco industry to escape the text-only restrictions.

In a notice published in the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period to place on the public record a memorandum that provided further explanation of the agency's proposal to exempt publications with primarily adult readership from the text-only requirement. The document provided an additional 30 days to comment on this new information. The memorandum stated that the agency had selected the 85 percent per 2-million threshold based on the public perception that certain magazines are likely to be of interest to young people under the age of 18. The agency extrapolated from the readership percentages for those publications to the proposed threshold levels. Data supporting this line had been placed in the administrative record for the proposed rule (vol. 105, document 1550) and additional readership data was

[214] This portion of the definition was edited in the final rule to make the two provisions parallel. Thus, § 897.32(a)(2)(i) now reads, ''whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence.''

provided during the comment period. The agency noted additionally that at some point the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. The agency selected 2,000,000 as that level. [215]

(57) Some comments objected to the proposed readership thresholds, calling them arbitrary and stating that FDA provided no basis, no rational justification, and no evidence for them. One tobacco industry comment stated that it used an FTC methodology based on readership and the number of pages of advertising to conclude that magazines with greater readership by minors tend to have less cigarette advertising than other publications.

Some comments also objected to the 2 million minor readers threshold because it would subject some adult-oriented magazines to the tombstone format even though their percentage of minor readers is very low. One comment cited the following examples and readership figures: *People Magazine* (3,020,000 minors: 7.8 percent of all readers) and *Better Homes and Gardens* (2,042,000 minors: 5.5 percent of all readers); *Time* (1,972,000 minors; 7.66 percent of all readers) and *Newsweek* (1,911,000 minors; 8.01 percent of all readers) are also close to the threshold. In addition, some comments suggested that FDA's explanation that 2,000,000 is a large number is not adequate basis for regulation.

Some comments stated that the proposed thresholds were unfair to the up to 85 percent, or more in some cases, of a publication's readers who were adults. ''Such a regulation is inconsistent with the principle that the government may not 'reduce the adult population * * * to reading only what is fit for children.'''

In contrast, comments supporting the proposal stated that just because the line (i.e., thresholds) could be drawn differently was not important as long as FDA can rationally explain why it drew the line where it did. One comment suggested that FDA should require the text-only format in the 10 most read magazines by young people in addition to the present proposal. Some comments recommended requiring the text-only format for advertisements in all publications.

One comment stated that no tobacco advertising, even text-only, should be allowed whatsoever in publications with youth readership, and adult publications should have text-only tobacco advertisements. This comment also said that the agency should monitor this exception to ensure that tobacco companies don't increase advertising in national adult publications that are widely read by the entire family including children and adolescents and to be wary of tobacco companies creating their own adult publications saturated with tobacco advertising.

Other comments supporting the proposal stated that some degree of overinclusiveness is acceptable and expected because of the difficulties in fine-tuning any regulation. Other comments saw any exception for any publications as a potential loophole that could be used by tobacco companies to continue using imagery in advertising. They said that experience in other countries with tobacco advertising restrictions showed that ''the tobacco industry used all of its creativity to manipulate the system to take advantage of whatever opportunities were still available to reach their target audience, particularly young, impressionable individuals.''

The comments received, especially from the magazine and newspaper industries, made clear that both defining an adult publication and determining whether a particular publication meets the definition are difficult issues. However, while these comments were helpful in pointing out the difficulty of defining an adult publication, they did not offer any realistic alternative definition in terms of a readership-by-minors threshold. Because of the concern about tobacco use by children and adolescents, which was voiced by virtually all comments pro or con, the agency believes it has sufficient evidence to justify a text-only requirement. However, the agency's concern is with advertising that affects minors and with tailoring the restrictions in this final rule to burden as little speech as possible. Therefore, FDA concludes that an exception from the text-only requirement for publications that are read primarily by adults is still reasonable and feasible.

The agency has decided to retain the exception for adult publications and to retain the readership thresholds in this final rule. The 15 percent young readers threshold is reasonable based on readership data submitted with comments. The 15 percent threshold would require text-only advertising in the following sports and racing magazines: *Sports Illustrated* (18 percent), *Car and Driver* (18.3 percent), *Motor Trend* (22.1), and *Road & Track* (20.6 percent) and in the following general circulation magazines: *Rolling Stone* (18.5 percent), *Vogue* (18 percent), *Mademoiselle* (19.7 percent), and *Glamour* (17.1 percent). [216] The agency's judgment is based on common public perception that these are the types of magazines that young people under the age of 18 will find of interest and read. Thus, based on public perceptions and inductively given the nature of the magazines involved, FDA finds a 15 percent cut-off to be appropriate.

The 2 million number is justified based upon the agency's concern for young people. The agency finds that at some point, the number of underage readers is so great that the magazine can no longer be considered to not be of interest to children and adolescents under 18 years of age. This threshold would require text-only advertising in a publication like *People*, where the percentage of readers who are minors is only 7.8 percent, but where the number of readers under 18 years of age is 3,020,000. Publications like *Time*, *Newsweek*, *Family Circle*, and *Popular Mechanics*, however, would not be subject to the text-only format under either threshold; based on how these publications are affected, FDA concludes that, on balance, the thresholds are reasonable. [217] The agency's concern is not with the ''intended'' audience of the publication because there is no magic curtain between the interests of young adults and adolescents. The agency's concern is to protect children from the appeal of advertising that they cannot avoid. Fifteen percent youth readership or 2 million young readers narrowly addresses this concern.

The agency does not agree with comments that the rule should be made more restrictive by, for example, allowing only text-only advertising in adult publications and no advertising at all in other publications. The text-only format will reduce the appeal of tobacco advertising to young people while allowing communication of important information to adults. The agency will continue to monitor the effect on young people of text-only advertising as well as the exception created for adult publications and will consider taking any additional action that is appropriate.

[215] See section XV. of this document, Analysis of Impacts, for a discussion of publications that would be affected.

[216] Barents Group, LLC, citing Publishers Information Bureau and Mediamark Research, Inc., pp. 53–54.

[217] *Id.*

Finally, the agency finds no basis to the comments' concern that the regulations will reduce the reading level of adults to those of children. The agency has crafted the exception for adult publications specifically to minimize the effect of the regulations on adults. Moreover, text-only, or the absence of color and imagery, will have significantly less impact on adults than on young people. As discussed more fully in the introduction to this section, adults generally have more capacity to engage in high involvement search than do young people. Furthermore, full information will be available to them in the text format. The First Amendment demands no more.

(58) Several comments recognized that FDA made the March 20, 1996, Federal Register document and the associated data in the record publicly available to meet its obligation under the APA to provide interested parties with an opportunity to comment meaningfully on the proposed rule. These comments stated, however, that one of the memoranda, dated March 11, 1996, placed on the public record by the Federal Register document makes clear that FDA had readership numbers in mind when it developed the proposal, but that the agency had failed to disclose those numbers to the public. The comments said that these numbers are neither reflected in the memorandum added to the record in the March 20, 1996, Federal Register document nor the administrative record that FDA has made publicly available. The comments said that the memorandum in question refers to readership numbers that were in comments submitted by the tobacco industry, and thus these numbers could not have been the numbers that FDA considered in developing its proposal. The comments said that FDA's failure to disclose this information rendered the proceeding arbitrary and capricious.

These comments are in error. FDA placed the information that it relied upon in developing the tentative 15-percent threshold on public display at approximately the time that it published the proposed rule. The data appear at pages 95T030074–75 of the administrative record (vol. 105, number 1550). (The numbers are similar but not identical to those supplied by the industry.) As one comment pointed out, in *Connecticut Light and Power Co.* v. *Nuclear Reg Com'n.*, 673 F.2d 525, 530 (D.C. Cir.), *cert. denied* 459 U.S. 835 (1982), the United States Court of Appeals for the District of Columbia Circuit stated, ''In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.'' The agency fully complied with this expectation by including the data that it had reviewed in the material that it made publicly available. Thus, the agency finds the claims in the comments summarized here to be without any basis in fact.

(59) Several comments asserted that the memorandum added to the record in the March 20, 1996, Federal Register document did not provide a reasoned explanation for the threshold that FDA had proposed. Several comments argued that there is no principle in, or discernible from, the memorandum that leads to the choice of 15 percent, as opposed to 49 percent, as the ceiling for the percentage of underage readers a publication could have and still be considered primarily adult. One comment said that FDA's reasoning was circular. Other comments said that FDA had pointed to no facts in the March 20, 1996, Federal Register document or the attendant memorandum that supports its judgment. These comments stated that FDA merely applied an arbitrarily chosen 15 percent figure to readership data and concluded that it had hit the right number. Some comments questioned why a publication with 84 percent adult readership was problematic, while a publication with 86 percent adult readership was not. Of all the comments that criticized FDA's proposed threshold, only one provided any alternative. This comment cited the tobacco industry's voluntary Cigarette Advertising and Promotion Code, Advertising 1(a), which prohibits advertising in publications directed primarily to those under 21 years of age.

In contrast to the foregoing comments, which were from the tobacco and advertising industries, a comment from a coalition of groups concerned about smoking and health stated that the agency's tentative judgment was unbiased, reasonable, and narrowly tailored to meet FDA's stated goal of limiting the specific forms of advertising that have the greatest impact on children to those publications that do not have a regular heavy readership of children.

FDA has carefully reviewed these comments. Based on this review, FDA first considered whether its March 20, 1996, Federal Register document and the memorandum added to the record under that notice had adequately explained the basis for the proposed threshold.

The legislative history of the APA states that agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or arguments thereto (S. Doc. 248, 79th Cong., 2d sess. 200 (1946)). The notice must disclose in detail the thinking that has animated the form of the proposed rule and the data on which that rule is based. (See *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9 (D.C. Cir. 1977).) In *Connecticut Light & Power* v. *Nuclear Reg. Com'n*, 673 F.2d at 530, the court held that a notice of proposed rulemaking should provide an accurate picture of the agency's reasoning, so that interested persons may comment meaningfully on the proposed rule.

The March 20, 1996, Federal Register document and the associated data in the record clearly meet this standard. As stated in this section, FDA made clear that its tentative judgment was based on a review of available data (from Simons Market Research) on the readership profiles of various publications. By dividing the publications based on whether, in the FDA employees' experience, the publications were publicly perceived as being of interest to minors or not and then examining readership information on each publication, FDA employees found that the publications that were viewed as being of interest to young people had readerships that included individuals under the age of 18 at a level of 15 percent or higher. FDA also found that the information on additional publications that it received during the comment period produced results that were consistent with the pattern that emerged from its initial review. [218]

Thus, FDA's reasoning is not circular. FDA based the threshold on its tentative finding, from the work that its employees had done, that the publications viewed as of interest to young people had readerships that were more than 15 percent under 18. Significantly, while the comments of the tobacco and advertising industry disagreed with the basis for the proposed threshold in various ways, none presented any data showing that publications with a youth readership of 15 percent or more are not viewed by consumers as of interest to young people.

It is important to keep in mind that the purpose of the threshold is to ensure

[218] See memorandum of March 11, 1996, added to the administrative record in the March 20, 1996, Federal Register.

that no more speech than necessary is burdened by FDA's restriction on advertising. Given that FDA wants to ensure that its restriction is as narrowly tailored as possible, in response to the criticisms in the comments, FDA considered whether there was a more appropriate basis on which to craft the restriction. Unfortunately, the comments criticizing the proposal were not helpful. The only suggested alternative to the proposed threshold that they put forward was the provision in the Code. This provision is inadequate on its face, however, because it is based on a minimum age of 21, rather than 18, which is the minimum provided in the laws of all the States and section 1926 of the PHS Act. Moreover, the comment that suggested this alternative gave no indication of how the age group to which a publication is primarily directed would be determined.

As a matter of common sense, FDA focused on the percentage of readers under the age of 18 in the general population and on comparing that percentage to the percentage of readers under 18 years of age for a particular publication. Certain conclusions can logically be drawn on the basis of such a comparison. If the percentage of young readers of a publication is greater than the percentage of young people in the general population, the publication can be viewed as having particular appeal to young readers. A publication with a youth readership percentage that is approximately equal to the percentage of young people in the general population can be viewed as one of general appeal, including appeal to young readers. A publication with a lower percentage of young readers than in the general population, however, would obviously be one of limited appeal to young people, and thus one that could appropriately be considered of interest primarily to adults.

Given the logic of this approach, FDA turned to the U.S. census. What the agency found is that young people between the ages of 5 and 17 constitute approximately 15 percent of the U.S. population.[219] Since this percentage is the same as the one that FDA used in developing the proposal, this approach fully supports the approach that FDA proposed. (Although 5 and 6 year olds may not be reading magazines, utilizing this age group builds in a margin for error.) It ratifies the judgments that FDA employees made in arriving at the proposed threshold.

Some may assert that it is mere coincidence that the two approaches produce the same result. FDA disagrees. The congruence of the two approaches, the FDA employee anecdotal search and the use of the census data, is attributable to the basic validity of the premise underlying FDA's initial approach. Magazines have reputations as to the audiences to which they appeal, and those reputations are generally earned based on the nature of their contents. Thus, contrary to the assertions in some of the comments, the 15 percent threshold is well-supported and appropriate.

As for the question as to why a publication with 84 percent adult readership would be problematic, while a publication with 86 percent adult readership would not, the agency turns to the case law on narrow tailoring, which is, as stated in section VI.E. of this document, what this exercise is about. In *Board of Trustees of State University of N.Y.* v. *Fox*, the Supreme Court stated:

> In sum, while we have insisted that ''the free flow of commercial information is valuable enough to justify would-be regulators the costs of distinguishing * * * the harmless from the harmful,'' * * * we have not gone so far as to impose upon them the burden of demonstrating that the distinguishment is 100% complete, or that the manner of restriction is absolutely the least severe that will achieve the desired end. What our decisions require is a ''fit between the legislature's ends and the means to accomplish those ends,'' * * *—a fit that is not necessarily perfect but reasonable * * *. (492 U.S. at 480 (citations omitted))

FDA has done its best to distinguish publications that are likely to be read by children and adolescents from those that are not. FDA finds that, if its restriction on advertising is to be meaningful, it must be based on a line that is enforceable. While only 2 percentage points separate a publication with 84 percent adult readership from one with 86 percent (although those 2 percentage points can mean a difference of tens of thousands of youngsters), the underrepresentation of underage readers in the readership of the latter publication establishes its limited appeal to young readers, and thus that it is less likely to be read by them.

For the foregoing reasons, FDA is adopting the 15-percent threshold.

(60) Comments from an association of magazine publishers and others expressed a number of concerns about the adequacy of current data for determining whether a publication met the definition of an adult publication. Some comments said that current data and methodology to determine youth readership, while adequate for marketing purposes, are totally inadequate to justify their use as measuring devices for the imposition of criminal or civil liability on the exercise of First Amendment rights. These comments noted that the vast majority of magazines do not subscribe to either adult or youth surveys. Two comments stated that only about 2 percent of all magazines participate in the two major adult audience surveys. One comment stated that participation in the youth readership surveys, Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK, is even more limited, just over one-half of one percent of all magazines.

One comment noted that to comply with the 1995 proposed rule, publications must identify readers of all ages but that current audience measurement systems do not provide this comprehensive coverage especially for readers younger than 12 years of age. Another comment noted that since the survey organizations do not survey individuals on college campuses, in the armed services, or in institutional settings, adult readership would be underestimated. Several comments noted the difficulty in determining readership data for any one issue of a magazine. Another comment noted that multi-issue advertisements would be a problem for publications right around the threshold if the publication crosses back and forth.

Several comments noted that the survey organizations would have to make substantial methodological changes to the surveys to meet the 1995 proposed rule's standard. One comment said that some problems would include adding magazines to the surveys, and dealing with unreliable results. Another comment asked who would decide the research design for the surveys since different research methodologies could be competent and reliable yet result in different conclusions. Another comment said that it could be prohibitively expensive to increase audience samples to create a legally enforceable standard, and that changes to audience measurement procedures could undermine the usefulness of the surveys for their designed marketing information purpose.

One supporting comment from an association of addiction specialists stated that ''the agency should require the industry to monitor with surveys of ad recall (correlated with tobacco use

[219] U.S. Bureau of the Census, Population Paper Listing 21, 1994.

and intention to use patterns) among the population under age 18 years to help the agency understand the extent to which image-based messages continue to reach the young.''

One comment pointed out that it would be virtually impossible to determine a legally enforceable standard for the 15 percent youth readership threshold since there is substantial variation in audience estimates between survey organizations and over time. Several comments noted that FDA's definition of a reader is not consistent with the definition used by Simmons and MRI.

Some comments suggested that a more realistic measure of who reads a publication would be who subscribes to it. Other comments opposed this alternative stating that the key criteria should be regular readership, not paid subscribers. One comment said that ''[t]his alteration of the proposed exemption would destroy the intent and purpose of the advertising limitation.''

Several comments said that the proposal would violate due process by punishing publishers or advertisers who are unable to determine whether their conduct violates the law because the survey data are not sufficiently comprehensive and reliable. Several comments, including one from an association of newspaper publishers, expressed concern about who would determine readership. One comment asked whether a newspaper would be subject to criminal liability based on readership data it supplies, and whether the responsibility for ascertaining whether a publication qualifies as an adult publication would be on those running the advertisements.

The agency recognizes the limitations of current readership data and the difficulties of using current readership surveys to meet the requirements of this rule. However, the agency concludes that the exception from the text-only format for adult publications is feasible as well as reasonable. First of all, the burden of proof for determining youth readership is placed by the rule on the tobacco company doing the advertising, not on the publication or the advertising agency. Under § 897.32(a)(2), the tobacco company will need to be able to demonstrate that a publication in which it is running an advertisement with images and colors meets the definition of an adult publication. Therefore, only the tobacco company will be subject to any penalties for improperly placing advertisements, even if it used data provided by the publication as part of its determination.

Second, either of the two methodologies can be used to measure readership. In addition, the agency has modified § 897.32(a)(1) and (a)(2) to make clear that any other competent and reliable private sector survey evidence may be used. A tobacco company may use one of the two major customary and reasonable readership surveys (such as MRI and Simmons). The agency does not believe that there is only one acceptable methodology. The agency is willing to accept the standard methodology currently used by MRI and Simmons as evidence. Moreover, the agency is willing to use the age range of 12 to 17, which appears to be the current standard for defining youth, in determining youth readership.

If a particular publication is not currently covered by one of the major surveys, it is the tobacco company's responsibility to develop the readership data necessary to justify a decision to advertise in that publication. The company could request a survey by one of the major survey firms, or it could develop an acceptable alternative. In either case, the agency will be available to work with the company. The company will always have the alternative to advertise in any publication in the text-only format.

The agency also acknowledges the difficulty in determining the youth readership for any particular issue of a publication. Thus, data from a survey for the most recent issues of a publication can serve as proof of readership for comparable upcoming issues unless a particular upcoming issue is being targeted at younger readers. The survey schedule used by the major survey organizations would be acceptable to the agency. A tobacco company could utilize a more frequent survey schedule if it believed the readership had changed in its favor. A rolling average of a certain number of issues could be used, for example, to determine youth readership. The problem of multi-issue contracts for advertising could be solved by a survey for a comparable period of time (e.g., winter months) preceding the contract.

The agency is willing to accept the definitions of a reader that are customarily used by the major survey organizations. The agency does not agree that using subscribers to a publication in lieu of readers is a better measure. Many children who read a publication will not be listed as subscribers (for example, *Sports Illustrated* has a youth readership of 18 to 20 percent but a youth subscriber rate of only 6.5 or 7 percent).[220] Also, adults are more likely to subscribe for their families, thereby creating an underestimation of youth exposure.

(61) Several comments assumed that the purpose of the March 20, 1996, Federal Register document was to justify the restriction on advertising format that the agency had proposed for other than adult-oriented publications. These comments argued that explaining how the agency arrived at the 15 percent and 2 million readership thresholds does not approach the factual justification necessary to restrict First Amendment freedoms.

Other comments asserted that FDA's assumption that certain magazines were of interest to those under 18, as the starting point in arriving at the 15 percent threshold, shows that the limits were content based. These comments argued that basing restrictions on content violated the First Amendment.

The comments misunderstood FDA's purpose in proposing, and in adopting, the 15 percent and 2 million under 18 readership thresholds and of the memoranda added to the public record in the March 20, 1996, Federal Register document that indicated how the agency tentatively arrived at those thresholds. As discussed in section VI.D. of this document, the evidence in this proceeding establishes the effect of cigarette and smokeless tobacco advertising on those under 18 years of age. This evidence fully justifies FDA's decision to restrict the advertising for these products.

However, in imposing such a restriction on commercial speech, FDA has an obligation to ensure that the restriction is no more broad than necessary to serve the agency's substantial interests (*Board of Trustees of State University of N.Y.* v. *Fox*, 492 U.S. at 476). The purpose of the memorandum was to document FDA's efforts to tailor the restriction to ensure that it did not restrict advertising in those publications that were not likely to be read by children or adolescents and thus were not likely to have an effect on the group that FDA is trying to protect. Consequently, contrary to the claims of the first group of comments, the agency's goal in the memorandum was not to justify a restriction on First Amendment freedoms but to explain how it sought to ensure, and why its tentative decision was that, the limits it proposed to place on the coverage of the

[220] Interview on ''The News Hour With Jim Lehrer,'' Public Broadcasting Systems, May 16, 1996.

restriction are reasonable (see *Id*. at 480).

On the other hand, other comments that opposed FDA's proposed restriction on format said that the threshold would have different impacts on similar publications. One comment provided the following examples of publications that would be considered ''youth oriented'' or primarily adult under the 15 percent threshold (the comment argued that the effects of the 2 million readership threshold were not relevant to the rationality of the 15 percent threshold):

Table 1b.—Examples of Publications

Youth Oriented Publications	Primarily Adult Oriented Publications
Popular Science	Popular Mechanics
Soap Opera Weekly	Soap Opera Digest
Outdoor Life	Field and Stream
Cable Guide	TV Guide
Mademoiselle	Cosmopolitan

The positions taken by these comments makes clear that the thresholds were not content based. If the thresholds were content based, then publications that have similar content would be subject to the same restriction. They are not. The reason they are not is that FDA's goal in arriving at the thresholds was to ensure that cigarette and smokeless tobacco advertisements that are likely to be seen by children and adolescents are the kinds of advertisements that are likely to appeal to them. The agency's only way of judging the likelihood that an advertisement that appears in a publication will be seen by those under the age of 18 is by considering the readership profile of that publication. Thus, the agency has tailored the threshold to either reflect the percentage of readership that are under 18 years of age or to ensure that publications with an extensive youth readership are covered.

The comments that complained about the differing impact of FDA's threshold on similar publications, given the purpose of the threshold, serve to underline its significance. The information submitted by the comments shows that there are significant differences in the readership of similar publications and thus in the likelihood that the material contained in these publications will be seen by young people. The treatment of publications under the agency's restriction reflects the latter fact, not the former.

Popular Science magazine has a readership that is 6 percent more youthful than *Popular Mechanics*; *Soap Opera Weekly* has a 3 percent more youthful readership than *Soap Opera Digest*; and there is a 9 percent bigger youth audience for *Outdoor Life* than for *Field and Stream*. These differences are not minor or meaningless and demonstrate that, although the 15 percent threshold is not perfect, it will serve, as it was designed to, protect those under 18. *TV Guide* and *Cosmopolitan* are not excluded although, as mass distribution magazines the percentage of young readers is less than 15 percent, because they attract over 2 million young readers—a number of young people too large to ignore.[221]

(62) Many comments, especially from the magazine and newspaper industries, expressed concerns about the impact of this proposal on their way of doing business. One comment stated that the proposed text-only format would provide financial disincentives for magazines and newspapers to attract young readers, especially if the publication were near the borderline of being required to use the text-only format. This comment suggested that the provision would affect editorial and content decisions regarding young readers.

Some comments noted that newspapers have been struggling to attract young readers raised on television, but that success in doing this might cause the loss of significant tobacco advertising revenue. One newspaper industry association comment stated that the rule would discourage newspaper programs promoting youth reading and literacy. Some comments stated that the loss of advertising revenue could cause publications to decrease content and increase prices. Some comments thought the result of these effects of the rule would be losses in jobs in the newspaper and magazine industries.

The agency is not sure what impact the exception for adult publications will have on incentives for magazines and newspapers to attract young readers, on editorial content, and on youth literacy programs. The comments that raised these issues mostly speculated about these effects and did not provide any data as to how many of the thousands of newspapers and magazines in the United States carry tobacco advertising, or on what portion of their total advertising revenue comes from tobacco companies. Many business factors affect a publication's decisions regarding its target audience and editorial content, and these are likely to change for a variety of reasons. Those publications affected by this regulation will have to adjust just as they would if a major advertiser reduced its advertising. Under the rule, all publications could still accept text-only advertising. The cigarette and smokeless tobacco industries are capable of designing their advertising to be attractive to adult readers (see section VI.E.4. of this document). Thus, it seems as likely that the effects of the rule in these areas will be minimal and will be far outweighed by the overall benefits of reducing youth smoking. The effect of the rule on prices and jobs in the magazine and newspaper industries is addressed in the section on the economic impact of the rule.

(63) Several comments argued that FDA's restrictions on the format of advertising, and the standard that it proposed for deciding whether a publication has a predominantly adult readership, interfere with the rights of newspapers and magazines to decide what to print. One comment said that some publications will not want to give up revenue from tobacco advertising. Therefore, the comment continued, these publications will base decisions about editorial content on how appealing a particular story would be to readers under the age of 18. Because of the impact of the restrictions on editorial content, the comment concluded, they should be subject to strict scrutiny rather than the more limited scrutiny given to commercial speech.

FDA finds no merit to this argument. A similar argument was made in *Pittsburgh Press Co*. v. *Pittsburgh Com'n on Human Relations*, 413 U.S. 376 (1973). The newspaper company in that case, which involved a First Amendment challenge to a municipal ordinance that prohibited a newspaper from carrying gender-designated advertising for nonexempt job opportunities, argued that the focus of the case must be on the exercise of editorial judgment by the newspaper rather than on the commercial nature of the ads in question.

The Supreme Court rejected this argument. The Court said that under some circumstances, at least, a newspaper's editorial judgments in connection with an advertisement take on the character of the advertisement. In those cases, ''[t]he scope of the newspaper's First Amendment protection may be affected by the content of the advertisement''

[221] Barents Group, LLC, citing Publishing Information Bureau and Mediamark Research, Inc., pp. 53–54.

(*Pittsburgh Press Co*., 413 U.S. at 386). The Court said that, at least under some circumstances, a commercial advertisement remains commercial in the hands of the media (*Id*. at 387). The Court found that nothing about the decision to accept a commercial advertisement for placement in a gender-designated column lifts the newspaper's actions from the category of commercial speech. The Court said that the ad was in practical effect a commercial statement (*Id*. at 387–88; see also *United States* v. *Hunter*, 459 F.2d 205, 212 (4th Cir. 1972) (''But it has been held that a newspaper will not be insulated from the otherwise valid regulation of economic activity merely because it also engages in constitutionally protected dissemination of ideas'')).

Here, the question that is raised is whether or not a publication will decide to put itself in a position of being able to accept an advertisement that is particularly appealing to individuals under 18 years of age or not. Nothing about this judgment distinguishes it from the commercial speech itself. Because nothing about FDA's restrictions would prevent the publication from carrying a cigarette or smokeless tobacco advertisement no matter what judgment the publication makes, essentially the editorial judgment comes down to the question of what will be the format of the advertisement that it will carry. This judgment clearly comes within the category of commercial speech, and FDA has fully justified its regulation of commercial speech under the *Central Hudson* test.

6. Advertising—§ 897.32 Requirements for Disclosure of Important Information

a. *Established name and intended use—§ 897.32(c).* Proposed § 897.32(b) (now renumbered as § 897.32(c)) provided that each manufacturer, distributor, and retailer (of tobacco and smokeless tobacco) advertising or causing to be advertised, disseminating or causing to be disseminated, advertising, but not labeling, permitted under § 897.30(a), shall include, as provided in section 502(r) of the act, the product's established name and a statement of its intended use as follows: ''Tobacco—A Nicotine Delivery Device,'' ''Cigarette Tobacco—A Nicotine-Delivery Device,'' or ''Loose Leaf Chewing Tobacco,'' ''Plug Chewing Tobacco,'' ''Twist Chewing Tobacco,'' ''Moist Snuff'' or ''Dry Snuff,'' whichever is appropriate for the product, followed by the words ''A Nicotine-Delivery Device.''

The preamble to the 1995 proposed rule explained that section 502(r)(1) of the act requires, for any restricted device, that all advertising or other descriptive printed material contain a true statement of the device's established name. Under section 502(r)(2) of the act, a restricted device is misbranded unless all advertising contains ''a brief statement of the intended uses of the device.'' The agency explained in the preamble to the 1995 proposed rule that it is necessary to require that the product's established name and intended uses be placed on all advertising, under section 520(e) of the act, as a measure that affirmatively identifies the products to persons reading the advertising (the other brief statement requirements under section 502(r)(2) of the act are discussed in section IV.E.6.b. of this document).

The agency did not receive any comments on the ''established name'' provision and has thus codified the provision in the final rule as § 897.32(c). The agency has modified the ''intended use'' provision in this final rule to require that cigarette and smokeless tobacco advertising contain the statement ''A Nicotine-Delivery Device for Persons 18 or Older.'' For clarity, the agency has referenced subpart D generally rather than § 897.30(a) specifically. As stated in the 1995 proposed rule, the established name requirement applies to both tobacco and smokeless tobacco.

(64) Several comments opposed the proposed ''intended use'' provision. One tobacco industry comment stated that FDA's proposal is not authorized under section 502(r) of the act because: (1) The ''intended use'' of tobacco products is for smoking taste and pleasure, not a ''nicotine delivery device;'' (2) the ''intended use'' provision of the act does not require that manufacturers list all information related to all purposes for which a drug is intended; and (3) FDA is not free to prescribe an ''intended use'' of its own invention. The comment also argued that FDA's statement, which communicates only that a cigarette yields nicotine, is not a statement of ''intended use'' and is of no value to consumers who obtain more complete nicotine information that cigarette manufacturers already provide in advertising.

The agency disagrees with the comments stating that it is not free to prescribe an intended use. As discussed in this section, the agency is required by section 502(r)(2) of the act to require a brief statement of intended use for all restricted devices.

Additionally, it is within FDA's primary jurisdiction and expertise to determine a device's intended use. FDA has decades of experience evaluating the intended uses of FDA-regulated products, including restricted devices, prescription and over-the-counter drugs, biological products, and dietary supplements through its review and approval process for those products.

As described in the 1996 Jurisdictional Determination annexed hereto, the available evidence demonstrates that manufacturers intend to affect the structure and function of the body by delivering pharmacologically active doses of nicotine to the consumer. Although the agency proposed that the intended use include the language ''Nicotine Delivery Device,'' the agency has determined, based on the comments received, that a more accurate statement of the intended use would provide more value to consumers. Because cigarettes and smokeless tobacco products can legally be sold only to those persons 18 years of age and older, the agency believes the intended use statement should reflect the target population for which the product is intended. Often, the intended use statement for a drug or device includes the patient population by whom the product may be used. Accordingly, the intended use statement has been revised to require the following language on all advertisements for cigarette and smokeless tobacco: ''A Nicotine-Delivery Device For Persons 18 or Older.''

b. *Section 897.32(d) Brief statement.* Proposed § 897.32(c) and (d) would have required that each manufacturer, distributor, and retailer of cigarettes include in all advertising, but not labeling, a brief statement, printed in black text on a white background that was readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning. Because the Smokeless Act preempts other statements about tobacco use and health in advertising, the 1995 proposed rule stated that the provision only applied to cigarettes (and not smokeless tobacco). The 1995 proposed rule provided one brief statement as an example (''ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING'') (60 FR 41314 at 41338). The agency requested comment on what other information should be included in the brief statements concerning relevant

warnings, precautions, side effects, and contraindications and on how best to ensure that the statement will be clear, conspicuous, and prominently displayed. The agency also requested comment on whether it should require a listing of the component parts or ingredients of these restricted devices.

The preamble to the 1995 proposed rule explained that the agency was proposing to require this brief statement under section 502(r)(2) of the act. The preamble stated that the act specifically excludes labeling from the requirements in section 502(r) of the act. The 1995 proposed rule stated that the agency would specify the design, content, and format of the brief statements, in part based on focus groups with young people, to ensure that the information would be communicated effectively to young people.

The agency received numerous comments on this brief statement, and about half of the comments supported the provision and half opposed it. Most of the comments that supported the brief statement requirement recommended other information to be included in the brief statement, and offered suggestions on how best to ensure that the statement will be clear, conspicuous, and prominently displayed.

During the comment period, FDA performed extensive focus group testing on the brief statement to evaluate the content and various formats for the brief statement to determine if the information would be communicated effectively to young people. Those results were placed on the public record and made available for comment, 1 month prior to the close of the comment period. FDA received a few comments on the focus group results from the tobacco industry and concerned individuals.

The final rule does not specify a particular statement to be placed in all cigarette advertisements, as proposed in § 897.32(c), nor does it require the brief statement to be targeted to young people. Rather, the agency has concluded that the current Surgeon General's warnings contain important health information, concerning the risks related to the use of cigarettes, of the sort required under section 502(r) of the act and, consequently, has decided not to require a specific, different statement. Specifically, the Surgeon General's warnings currently required to be included in cigarette advertisements and on cigarette packages contain the following information: Cigarettes cause lung cancer, heart disease and emphysema, may complicate pregnancies, and contain carbon monoxide; smoking by pregnant women may result in fetal injury, premature birth and low birth weight; and quitting reduces serious risks.

The agency has also considered the fact that there is a heightened public awareness by adults of the addictiveness of cigarettes, as well as the serious health effects that can result from their use. Much of this awareness stems from: (1) The publicity of the numerous Surgeon General's reports that have issued in the last few decades, (2) the campaigns supported by health groups and State and local governments, as well as (3) the attention generated by the agency's investigation of these products.

Under the current circumstances, the agency has determined that the current Surgeon General's warnings, which must be in virtually all advertisements, contain the type of important health information required under section 502(r) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings meet section 502(r) of the act.

Finally, because the agency has determined that the Surgeon General's warnings are adequate, and those warnings must be displayed in a format prescribed by law, there is no longer any need for proposed § 897.32(d), which required that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning.

(65) One comment argued that the proposed warning requirement for tobacco is not a warning, nor is it part of a brief statement, as those terms are used in section 502(r) of the act. The comment stated that because FDA proposes to allow tobacco to be marketed as devices subject only to general controls, one of which is the brief statement provision, then the ''brief statement'' must be capable of providing, with other general controls, ''reasonable assurance of the safety and effectiveness'' of tobacco under the act. The comment argued that because FDA regards tobacco as having ''dangerous health consequences'' (60 FR 41314 at 41349), and does not believe that tobacco can be ''safe and effective'' for anyone, then FDA's proposed ''brief statement'' provision is not within the scope of the act. The comment stated that the only warning that is consistent with FDA's view would be one that warned against anyone using the device at all.

The comment miscomprehends the purpose of the brief statement, which is to provide information about the risks and benefits regarding the product. This provision is not intended to serve, on its own, as a mechanism to provide reasonable assurance of safety for these products.

(66) One comment argued that even if FDA could validly require a brief statement for tobacco as an exercise of its statutory authority, the imposition of a warning requirement as part of the brief statement is invalid because advertisements for tobacco are already required to bear the Surgeon General's warning under 15 U.S.C. 1333(a)(2) and (a)(3). In addition, the comment stated that FDA is not authorized to require that the information be presented ''in a lurid fashion to achieve an ulterior purpose'' or as ''a threat intended to scare people,'' and that the warning information is meant only for the purposes of enabling the physician or patient to make a rational risk/benefit judgment.

Another comment argued that the contention that the Surgeon General's warning is ''ineffective'' is without merit. The agency agrees that the current Surgeon General's warnings contain the type of important health information that advertisements must contain under section 502(r)(2) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings sufficiently meet the brief statement requirement of the act.

(67) One comment stated that the brief statement provision would ''cause so much visual clutter in tobacco advertising as to render effective communication nearly impossible.''

Another comment stated that FDA will be unable to justify the economic burdens on communication with adults that are created by the brief statement requirement because, in order to include all the mandated statements, advertisers would be required to purchase additional space and thus would have to reduce, because of budgetary pressures, the number of advertisements they could place.

Because the agency has determined that the current Surgeon General's warnings will be sufficient as a brief statement, the issue raised by these comments is no longer pertinent.

(68) Several comments which supported the 1995 proposed rule suggested alternative statements and submitted recommended language for the brief statement. Many comments suggested specific types of information

for inclusion in the brief statement. Several comments provided recommendations on how the statement could be ''clear and conspicuous.'' One comment stated that messages must be carefully pretested on members of the target audience to ensure that labels: (1) Attract attention; (2) are personally relevant; and (3) do not elicit psychological reactance, i.e., behaviors directly counter to those desired due to irritation, rebellion, or misinterpretation. The comment recommended that messages be varied periodically to ensure that they remain attention-getting and pertinent.

Several comments recommended that the rule be more specific in what is meant by ''readable, clear, conspicuous, prominent'' by giving either a detailed set of format specifications of the lettering and background or by giving a set of performance criteria. One comment enclosed an unpublished review on warnings, which recommended that warnings should attract attention of the target audience by using high contrast and color; separating warnings from other information; considering size (relative to other information in the display) and location (since people tend to scan left to right and top to bottom warnings should be located near the top or to the left, depending on the overall design of the display); and by using signal words to capture attention, such as ''CAUTION,'' OR ''WARNING,'' pictorials, rotational warnings to avoid habituation, and auditory warnings. In addition, the review stated that warnings should describe the hazard, without ''overwarning,'' and describe the nature of the injury, illness or property damage that could result from the hazard. The review recommended that written warnings should be organized with an attention getting icon and signal word at the top, then hazard information, then instructions. Finally, the review recommended that warnings should instruct about appropriate and inappropriate behaviors, motivate people to comply, be as brief as possible, and should last and be available as long as needed.

One comment recommended that the relevant warnings, precautions, side effects, and contraindications be in a language understandable and appealing to even the youngest potential tobacco user. Several comments recommended that a minimum size should be required, expressed as a percentage of the advertisement (e.g., 25 percent of the advertisement). Several comments recommended that a border be placed around the brief statement and suggested other graphic enhancements to make the information in the brief statement more noticeable.

The agency recognizes that there are several ways to communicate the requirement for ''relevant warnings, precautions, side effects, and contraindications'' set forth in section 502(r) of the act. In this case, however, the agency has determined that the current Surgeon General's warnings are sufficient as at least one way of complying with section 502(r) of the act. In addition, the agency appreciates the numerous suggestions on how to make the brief statement readable, clear, conspicuous, and prominent. However, since no additional information will be required at this time, and the format for the Surgeon General's warnings is determined by law, the agency has deleted proposed § 897.32(d).

(69) One comment stated that FDA's attempt to gather information through the focus group studies about adolescents' perceptions of the adequacy of the Surgeon General's warnings for use in designing its own additional warning underscores the direct conflict between the Cigarette Act and the proposed regulation.

This comment has misinterpreted the purpose and the results of the focus group testing. FDA's focus groups were intended to explore how adolescents perceive various messages. The Surgeon General's warnings, as well as other warnings, were tested with the focus groups merely to serve as a basis for reactions to messages that currently exist in the public domain.

(70) FDA received few comments concerning the focus group results. In general, these comments questioned the validity and usefulness of focus groups. Further, some comments asserted that the warnings preferred by the young people in the focus groups may have unintended consequences.

As discussed in this section, the focus groups tested a variety of specific brief statements that were intended to be directed towards young people. However, the agency has decided that the final rule will not specify a particular brief statement, but will accept the current Surgeon General's warnings as sufficient. Moreover, section 502(r) of the act does not require that the brief statement be directed to young people, but rather that it provide ''a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.'' This function is adequately filled by the intended use statements required by § 897.32(c) and the Surgeon General's warnings. Thus, because the final rule is not based on the focus group results, the agency need not address the previous comments concerning the focus group results.

7. Section 897.34(a) and (b)—Promotions, Nontobacco Items, and Contests and Games of Chance

The agency proposed in § 897.34(a) to prohibit the sale or distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. FDA stated in the 1995 proposal that this requirement is intended to reach such items as tee shirts, caps, and sporting goods and other items bearing tobacco brand names or other indicia of product identification (60 FR 41314 at 41336).

As discussed in the preamble to the 1995 proposed rule (60 FR 41314 at 41336), a Gallup survey found that about one-half of adolescent smokers, and one-quarter of all nonsmokers, own at least one promotional item. The IOM found that this form of advertising is particularly effective with young people. Young people have relatively little disposable income, so promotions are appealing because they represent a means of ''getting something for nothing.'' In many cases, the items—tee shirts, caps, and sporting goods—are particularly attractive to young people. Some items, when used or worn by young people, also create a new advertising medium—the ''walking billboard''—which can come into schools or other locations where advertising is usually prohibited (60 FR 41314 at 41336). Moreover, this form of advertising has grown in importance over the last 20 years. The portion of annual expenditures of the cigarette industry devoted to these promotions rose from 2.1 percent in 1975 to 8.5 percent in 1980. [222]

On the basis of the evidence before it, the agency tentatively concluded that the ban on nontobacco items was necessary to eliminate the something-for-nothing appeal of these items, as well as to prevent wearers or users of these items from becoming image-laden walking advertisements.

FDA proposed in § 897.34(b) to prohibit all proof of purchase transactions of nontobacco items as well as all lotteries, contests, and games of chance associated with a tobacco purchase. The agency stated that, because contests and lotteries are

[222] IOM Report, p. 109.

usually conducted through the mail, it was not able to devise regulations that would reduce a young person's access to contests or lotteries.

(71) FDA received a substantial number of comments concerning the 1995 proposed rule to prohibit these promotional activities. Comments opposing these provisions argued that tobacco companies should be allowed to advertise in a fair manner however they wish. Many comments from individuals stated that they like the ''freebies.'' They contended that the agency does not have authority to regulate the clothes people wear or to ban contests and promotional activities that are only available to adults. A number of comments from individuals stated that what they did with their lives was their business.

Comments also objected to the agency's proposed ban on contests and games of chance. These comments stated that existing laws and regulations already provide a sufficient regulatory framework.

The majority of comments, however, supported these provisions and stated that children and adolescents should not be ''walking billboards.'' Moreover, these comments argued that even though young people cannot participate in the contests, they can easily get caught up in the excitement of promotional activities. Comments declared that prohibiting tobacco product-related gifts, items, contests, and games of chance will break the enticing connection between sports and tobacco use.

The agency agrees with the comments that said that existing laws and regulations of lotteries, contests, and games of chance are sufficient. First, there appears to be little evidence about these practices and young people's participation in them. Secondly, current laws prohibit all games of chance and the like that are advertised on a product label or that are conditioned on the sale of the product. Therefore, participation, if any, by minors is not necessarily related to a purchase. Third, any promotional material associated with the advertising of the games, which is of primary concern, will be required to appear in text-only format. Therefore, the agency has modified this section to delete the ban on these practices. In addition, the agency has modified § 897.34(a) to clarify that responsibility for complying with this provision rests with the manufacturer and the distributor of imported tobacco, but not other distributors or retailers.

(72) Comments differed on whether proposed § 897.34(a) is beyond FDA's authority under the act. The comments addressed a number and variety of legal issues. One comment stated that FDA has no authority to ban the items and services covered by § 897.34(a). It stated that items and services (e.g., travel agencies) bearing indicia of tobacco product identification are not foods, drugs, cosmetics, or devices as defined in the act and, therefore, are outside the agency's jurisdiction.

Another comment stated that nontobacco items cannot be regulated as advertising in the way FDA proposes because: (a) The 1995 proposed rule extends to goods and services provided to product users in connection with cigarette purchases, most of which are not displayed or disseminated to the general public, and thus do not constitute advertising (see *Marcyan* v. *Nissen Corp.*, 578 F. Supp. 485, 507 (N.D. Ind. 1982), *aff'd sub nom. Marcyan* v. *Marcy Gymnasium Equip. Co.*, 725 F.2d 687 (7th Cir. 1983)); and (b) many of the types of items covered by § 897.34(a) are promotional items but not advertising (e.g., a logo-bearing mug given away or sold by a manufacturer is not an advertisement).

One comment, which favored the provision, provided support for the classification of promotional items as advertising. The comment referenced *Public Citizen* v. *FTC*, 869 F.2d 1541 at 1556 (D.C. Cir. 1989), in which the U.S. Court of Appeals for the D.C. Circuit held that the Smokeless Act requirement that ''advertisements'' carry health warnings ''plainly covers utilitarian items [nontobacco items] that are distributed for promotional purposes.'' FTC defined utilitarian objects as items that are sold or given or caused to be sold or given by any manufacturer, packager, or importer to consumers for their personal use and that display the brand name, logo, or selling message of any tobacco product (16 CFR 307.3n). FDA's interpretation of what is covered by § 897.34(a) and (b) is consistent with this definition. The comment also stated that as a result of that court case, FTC's smokeless tobacco rules now require that utilitarian items promoting smokeless tobacco bear specific health warnings required of all smokeless tobacco advertising (16 CFR 307.9). [223]

Another comment pointed out that the *Public Citizen* case provides ample legal precedent not only for the conclusion that promotional materials are advertising, but also that they have a direct impact on a minor's tobacco use. The court, relying on evidence compiled by the FTC, found that ''in the case of adolescents, utilitarian items might be among the most effective forms of promotion'' (869 F.2d at 1549 n. 15). In addition, the lower court provided an additional rationale for restriction based upon the items' longevity and durability.

> [P]rinted advertising is customarily quickly read (if at all) and discarded (as, of course, are product packages) by typical consumers. ''Utilitarian objects,'' on the other hand * * * are retained, precisely because they continue to have utility. They are also likely to be made of durable substances: fabric, plastic, glass, or metal. They may be around for years. And each use of them brings a new reminder of the sponsor and his product * * *
>
> (688 F. Supp. 667, 680 (D.D.C. 1988), *aff'd*, 869 F.2d 1541 (D.C. Cir. 1989))

The agency finds that the reasoning in the *Public Citizen* case is persuasive and compels the conclusion that branded nontobacco items are advertising. It also finds that young people acquire and use these products.

Moreover, the agency finds nothing in the *Marcyan* v. *Nissan Corp.* case is to the contrary. In relevant parts, that case involved an endorsement that appeared in the front of a users' manual. The court held that this endorsement did not constitute ''advertising'' because it is not ''distributed to the general public for the purpose of promoting plaintiffs' products: it is a user's manual and is provided to a purchaser of the defendants' equipment together with the equipment in order to describe its proper use'' (578 F.2d at 507). Promotional items are distributed or sold to the general public. They are festooned with the product's brand name or identification, and they are intended to remind the user and others who see the item about the product. As the court in *Public Citizen* found, ''each use of them brings a new reminder of the sponsor and his product'' (688 F. Supp. at 670). Therefore, the comments' suggestion that these advertising items are beyond FDA's jurisdiction is plainly wrong.

(73) One comment, which had argued that promotional items were not drugs or devices nor were they advertising, objected as well to FDA's alternative

[223] The FTC comment also indicated that although nontobacco items are ''advertising'' under the Smokeless Act, a different legislative history exempts these items from the Cigarette Act. The comment stated that the definition of advertising under the Cigarette Act is understood to exempt utilitarian items because of legislative history expressly stating Congress's intent to preserve the arrangement under consent agreements entered into by the tobacco industry in 1972 and 1981 (*Public Citizen*, 869 F.2d at 1555).

categorization of these items as labeling. The comment stated that nontobacco items could constitute ''labeling'' only if there were a ''textual relationship'' between them and the product (*Kordel* v. *United States*, 335 U.S. 345, 350 (1948)). The comment argued further that items that provide no more substantive information than a brand name, logo, or recognizable color or pattern of colors simply do not explain the use of the product, and therefore do not constitute labeling. The comment concluded that if the items are not advertising or labeling, FDA would not have authority to take the actions required by this provision.

The agency agrees that these promotional items are neither devices nor drugs; however, this fact is not relevant to the agency's authority to proscribe their use. As explained earlier in this document, FDA has authority to impose restrictions on the access to and promotion of devices under section 520(e) of the act, and this authority provides the basis for restrictions on advertising, including those that FDA is imposing on promotional items. FDA also derives authority for these restrictions from section 502 of the act. Likewise, it is not relevant in this instance whether the items are described as advertising or labeling. The agency has the authority to restrict them because they promote the use of restricted devices, cigarettes and smokeless tobacco, by young people and thus undercut the restrictions on access to these products that FDA has imposed. Therefore, FDA has authority to regulate how these promotional items are used by manufacturers, distributors, and retailers of the restricted devices.

(74) Many comments challenged FDA's evidentiary basis for this provision. Those opposing the provision made the point that promotional items do not cause young people to use tobacco, and that banning them will not reduce tobacco use. These comments fall into two categories: Those that rely on theoretical or policy arguments and those that provide or criticize studies or other evidence.

a. *Theoretical or policy considerations.* Several comments argued generally that it is well-documented that the significant factors associated with regular underage tobacco use are peer pressure and smoking by friends, older siblings and parents. They noted that FDA cited no evidence that the use of a tobacco trademark on a nontobacco product, such as a lighter or jacket, has any impact on underage tobacco consumption, or that its removal will reduce youth tobacco use. Consequently, they argue, banning the use of tobacco brand names on nontobacco products will fail to achieve FDA's goal of curbing teen smoking.

One comment maintained that people, including those under age 18, do not wear these items in order to advertise anything or to be ''walking billboards.'' Rather, according to this comment, they wear them to make a public statement, because they find the items aesthetically pleasing, or for other reasons. Moreover, the comment argued, FDA has no authority to regulate the attire of adults, school students, or anyone else.

In addition, the comment argued, the goal of these programs is to reinforce brand loyalty among existing customers. Their purpose is to expand market share among existing smokers, not to induce nonsmokers to start smoking. These programs are, by their very nature, aimed at people who already are smokers, that is, the merchandise is provided only to consumers who have accumulated and submitted significant numbers of proofs of purchase. No one would be persuaded to start smoking by a cents-off coupon or by the offer of a free cigarette lighter, but a smoker might be tempted by the offer. The comment argued that in the hard fought battles for market share among cigarette companies, discounts and premiums represent a way to promote and retain brand loyalty and to weaken loyalty to competitors' brands.

Some comments bolstered their arguments with a citation to the decision of the Supreme Court of Canada, which, they claimed, invalidated a similar ban. The Canadian court concluded that there was no direct or indirect evidence of any causal connection between the objective of decreasing tobacco consumption and the absolute prohibition on the use of a tobacco trademark on articles other than tobacco products. These comments argued that FDA should follow the Canadian judgment (see section VI.D.3.f. of this document for a complete discussion of this case).

On the other hand, one comment stated that U.S. and international experience provide substantial support for a ban. It stated that in the United States, nontobacco items were heavily used by RJR to market its Camel tobacco to young people.

In addition, one comment that supported FDA's action stated that young people participate to a marked extent in tobacco company promotions. It noted that these promotions all use attractive imagery and prizes that are intrinsically interesting to adolescents. Other comments stated that these promotions are particularly effective with young people, who have less disposable income. The items are a way for young people to get something for nothing and provide added incentive for young people to purchase tobacco products. One comment that supported this provision stated that these items can become ''walking billboards,'' that can come into schools and other places where tobacco advertising is generally prohibited.

Another comment stated that the ban serves as an important corollary to the advertising restrictions, specifically, it argued that the impact of removing tobacco product advertisements from minors' magazines would surely be reduced if minors themselves continued wearing the advertisements on their heads and bodies. The comment asserted that there is a correlation between participation in a promotion and susceptibility to tobacco use.

b. *Studies and evidence.* One comment referenced a new study [224] that found that participation in tobacco company promotions by 12 to 17 year olds is more predictive of susceptibility to use tobacco products than smoking by those close to the individual. The measure of ''participation'' was the possession of a catalog, the ownership of any promotional item, or the saving of coupons that could be redeemed for promotional items. The study found that catalog ownership was the most common form of participation in tobacco company promotions.

A comment that opposed this provision argued that FDA had cited no credible studies that demonstrate either that these items are especially appealing to young people, or that possessing these items causes young people to start smoking or to smoke more. It stated that although FDA relied on a study by Dr. John Slade [225] that reported that there is an association between participating in promotions and a person's susceptibility to tobacco use, FDA did not describe the study thoroughly. The comment stated that the notion of susceptibility is itself problematic. It stated that even if this study is taken at face value, it does not support FDA's conclusions. While the study reported that 83.5 percent of

[224] Evans, N., et al., ''Influence of Tobacco Marketing and Exposure to Smokers on Adolescent Susceptibility to Smoking,'' *Journal of the National Cancer Institute*, vol. 87, pp. 1538–1545, 1995.

[225] Slade, J., et al., ''Teenagers Participate in Tobacco Promotions,'' presented at the 9th World Conference on Tobacco and Health, October 10–14, 1994.

respondents age 12 to 17 were aware of at least one tobacco company promotion, it also reported that only 10.6 percent of respondents owned a nontobacco promotional item. These numbers, the comment asserted, do not support the theory that nontobacco items are appealing to youth or have a discernible impact on youth smoking rates.

Moreover, the comment took exception with Dr. Slade's finding that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash or Marlboro miles. The comment stated:

> the reason for these apparently high percentages is clear from the most cursory analysis of the data * * * [I]n this supposedly random survey, fully 45.7 percent of the households of 12–13 year olds interviewed had someone at home who smoked (37.9 percent in households of 16–17 year olds), and yet, in reality only 25 percent of the American public—half the rate of the population relied upon by Dr. Slade—smoke. [Thus], the unrepresentative sample population Dr. Slade employed created a significant bias, which distorts the results of this survey and renders them entirely unreliable.

Finally, one comment stated that the primary basis for the provision appeared to be data [226] that allegedly show that 44 percent of teenage smokers and 27 percent of teenage nonsmokers have received nontobacco promotional items. The comment stated that the study is irrelevant because it drew no conclusion as to the significance of the number, nor did it indicate how the teenagers received the items.

In response, the agency concludes that the evidence presents a compelling case to prohibit the sale and distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. The evidence establishes that these nontobacco items are readily available to young people and are attractive and appealing to them with as many as 40 to 50 percent of young smokers having at least one item (60 FR 41314 at 41336). The imagery and the item itself create a badge product for the young person and permit him/her the means to portray identification.

FDA has shown that tobacco advertising plays out over many media, and that any media can effectively carry the advertising message. Moreover, the agency recognizes that the tobacco industry has exploited loopholes in partial bans of advertising to move its imagery to different media. When advertising has been banned or severely restricted, the attractive imagery can be and has been replicated on nontobacco items that go anywhere, are seen everywhere, and are permanent, durable, and unavoidable. By transferring the imagery to nontobacco items, the companies have ''thwarted'' the attempts to reduce the appeal of tobacco products to children.

In addition, items, unlike advertisements in publications and on billboards, have little informational value. They exist solely to entertain, and to provide a badge that, as the Tobacco Institute asserted, allows the wearer to make a statement about his ''social group'' for all to see. But because tobacco is not a normal consumer product, it should not be treated like a frivolity. Advertising that seeks to increase a person's identification with and enjoyment of an addictive deadly habit has the ability, particularly among young people, to undermine the restriction on access that FDA is imposing. For these reasons, the agency continues to find sufficient evidence to support a ban on these items.

Finally, regarding the unpublished paper by Dr. Slade, the comment has confused the household smoking rate with the overall population smoking rate. The smoking rate per household can be as high as twice the overall adult smoking rate. For example, if the smoking rate for adults were 25 percent and assuming two adults per household and only one of the pair smokes, then the household smoking rate could be as high as double that of the individual rate. Therefore the range of possible household smoking rates would be 25 percent to 50 percent, with 44 percent being quite plausible.

Lastly, the comments that state that peer pressure and smoking by friends and family are significant factors in influencing a young person's tobacco use, rather than promotional items, fail to recognize that if a young person is influenced by what a peer says about tobacco use, he or she will also likely be influenced by that same peer wearing a tobacco promotional item.

(75) One comment from a small smokeless tobacco company expressed concern because much of the packaging used for its products also bears its corporate logo. Moreover, several of its brand names include words in its corporate logo. Thus, the comment argues that FDA might find that its corporate logo is an ''indicium of product identification'' covered by the restrictions in § 897.34. The comment stated that promotional items are a small but important part of its advertising and promotional activity, and these items allow its customers to feel like a part of an extended family. It would be unfair, the comment argued, as well as harmful to the company, if FDA were to determine that a corporate logo may not be used on promotional items.

One comment stated that the total merchandising and ban in § 897.34(a) is unreasonably broad in scope. It stated that it virtually limits all merchandising, because all colors or patterns of colors are associated with some brand or another of tobacco product. The comment stated that the proposed regulation is so confusingly vague that one could argue that a ''distributor'' would be prohibited from using the color red in any event for any product category, brand, or corporation because Marlboro brand tobacco products utilize the color red.

Another comment stated that because the definitions of ''cigarette'' and ''smokeless tobacco product'' are limited to tobacco products with nicotine, the agency should consider the possibility that a tobacco company could market a nicotine-free brand extension of a cigarette or a smokeless tobacco product and advertise this product free of restrictions. The comment stated that the advertising for such a product could have carryover value for the nicotine containing versions of the product thereby undermining the intent of the regulations.

The agency agrees that it needs to clarify the scope of § 897.34(a). The regulation covers any item with indicia of the brand identity. If the corporate logo is not an indicium of a brand identity, its use would not be prohibited in nontobacco labeling or advertising. On the other hand, if a corporate logo includes an identifiable brand name or image, it must comply with the restrictions. Any other position would permit a company to evade the intent of this regulation by using a corporate logo to continue to display brand imagery. For example, RJR may continue to sell or distribute hats and tee shirts with the name ''R. J. Reynolds'' on them, but not the name ''Camel.'' Nor can it put the Camel inside the Reynolds logo. The agency, therefore, has amended § 897.34(a) to state that the indicia of product identification cannot be identical or similar to, or identifiable

[226] ''Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings,'' the George H. Gallup International Institute, Princeton, NJ, p. 59, September 1992.

with those used ''for any brand of ciagarettes or smokeless tobacco''.

In addition, it is not the agency's intention to ban the use of registered or recognizable colors for all advertising. Only the owner or user of the brand identification is prohibited from using that color or pattern of colors in a manner so as to advertise tobacco or smokeless tobacco. For example, Philip Morris would be prohibited from using the distinctive red, black, and white pattern of colors which identify Marlboro, but neither RJR nor Joe's Garage would be prohibited by the regulations from using those colors.

Finally, in response to the last comment, the agency has restricted the coverage of this regulation to promotions of cigarettes and smokeless tobacco products containing nicotine. It has no evidence justifying a broader coverage of the regulation to nicotine-free products at this time. However, a company could not give a nontobacco product (a nicotine free product) a tobacco brand name. This is exactly what this section of the final rule forbids.

(76) Several comments argued that § 897.34(a) constituted a restriction on symbolic expression that cannot be characterized as commercial speech. The comments argued that these items do not propose a commercial transaction. One comment argued that in *Cohen* v. *California*, 403 U.S. 15 (1971), the Supreme Court recognized that otherwise objectionable words worn on a jacket are fully protected speech.

FDA finds no merit to these comments. Section 897.34(a) on its face is limited only to manufacturers and to distributors of imported cigarettes or smokeless tobacco. It does not limit the rights of individuals to express themselves by wearing an article of clothing that bears a picture of a cigarette or a logo.[227] What it does limit is the ability of manufacturers and some distributors of tobacco and smokeless tobacco to do what is the essence of commercial speech—to take actions to call public attention to the products whose logo the items bear, so as to arouse a desire to buy those products. (See *Public Citizen* v. *FTC*, 869 F.2d at 1554.) Because this is what the nontobacco items that are the subject of § 897.34(a) are designed to do, they share all the characteristics of the pamphlets that the Supreme Court in *Bolger* v. *Youngs Drug Products Corp*., 463 U.S. 60, 66–67 (1983), found to be commercial speech. Consequently, FDA may regulate the nontobacco items as commercial speech, as long as its regulation passes muster under the *Central Hudson* test (see 463 U.S. at 68).

(77) Some comments challenged the constitutionality of the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco products under the *Central Hudson* test. The comments argued that the prohibition does not directly advance FDA's interest because the prohibition is unrelated to the goal of protecting children. The comments also argued that the prohibition is not narrowly tailored because it is not limited to children and not limited to products that are particularly attractive to children.

Several comments disagreed and argued that the prohibition is a constitutionally permissible restriction on speech. One of these comments pointed to the finding in the IOM's Report *Growing Up Tobacco Free* of the effectiveness of this type of advertising with young people. The comment said that FDA would therefore be justified in prohibiting its use.

FDA has carefully considered these comments. The agency concludes that the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco items is a permissible restriction under the First Amendment.

First, this restriction will directly advance FDA's interest in protecting the health of people under 18 years of age. In *Public Citizen* v. *FTC*, 869 F.2d at 1549 n. 15, the Court of Appeals for the D.C. Circuit recognized that the nontobacco ''utilitarian items might be among the most effective forms of promotion with respect to adolescents.'' This judgment is consistent with much of the other evidence in the administrative record. A 1992 Gallup survey found that 44 percent of all adolescent smokers and 27 percent of adolescent nonsmokers owned at least one promotional item from a tobacco company.[228] Testing by RJR in 1988 found that nontobacco items performed best among young adults.[229]

The IOM Report pointed out that the ubiquity of nontobacco items conveys the impression that tobacco use is the norm.[230] As stated in section VI.D.3.c. of this document, this impression, that tobacco use is widespread and accepted, fosters experimentation with tobacco and smokeless tobacco by young people. This fact led the IOM to recommend that the use of tobacco product logos on nontobacco items be prohibited.[231] The IOM said that this and several other related steps (including requiring the use of the text-only format) were necessary to eliminate those features of advertising that tend to encourage tobacco use by children and youths.

Thus, the prohibition on the use of these logos will directly advance FDA's interest. The IOM's recommendation provides significant evidence of this fact.

Second, even though FDA is prohibiting the use of brand logos on nontobacco items, this restriction meets the requirement of narrow tailoring. The Supreme Court has held that a ban may satisfy this requirement if the agency's judgment is that it is ''perhaps the only effective approach'' (*Board of Trustees of the State of N.Y.* v. *Fox*, 492 U.S. at 479). In this case, FDA has determined that a ban of these items is necessary for several reasons. The appeal of something for nothing items for youngsters is great, and the extent of the appeal makes it virtually impossible to distinguish among items, as suggested by one comment. As the IOM pointed out, these items, when worn or used by children, are capable of penetrating areas of a child's world that might be off-limits to other forms of advertising.[232] Because they penetrate the young persons' world, they are very effective in creating the sense that tobacco use is widely accepted, which, as stated in section VI.D.3.c. of this document, is extremely important to children and adolescents. These items act like a badge that marks an individual as a member of a group, another attribute that makes them particularly attractive for young people. There is no way to limit the distribution of these items to adults only. The industry claims that it already is taking sufficient action to ensure that only adults get these items[233] but as the evidence

[227] The fact that individuals would be free to make their own articles of clothing with brand names of tobacco products on them does not make the regulations fatally underinclusive. (See *U.S.* v. *Edge Broadcasting Co.*, 509 U.S. 434 (''Accordingly, the Government may be said to advance its purpose by substantially reducing lottery advertising, even where it is not wholly eradicated.'').)

[228] ''Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings,'' The George H. Gallup International Institute, Princeton, NJ, pp. 17, 59, September 1992.

[229] Bolger, M. R., *Marketing Research Report, entitled Camel ''Big Idea'' Focus Groups-Round II*, September 21, 1988.

[230] IOM Report, p. 110.

[231] *Id.*, p. 133.

[232] *Id.*, p. 110.

[233] The Cigarette Advertising and Promotion Code, subscribed to by the major cigarette manufacturers, contains three provisions that

Continued

indicates, a substantial number of young people have them. As noted in this section, almost one-half of young smokers and one-quarter of nonsmokers have one or more items. Moreover, even were items to be distributed to adults only, this would not prevent the wearers from becoming walking advertisements that would continue to display the attractive imagery.

For all these reasons, FDA finds that all nontobacco items that bear cigarette or smokeless tobacco brand logos are capable of playing a significant role in a young person's decision to engage in tobacco use. Because no distinction among these products is apparent, and no way of limiting their availability to adults is possible, FDA finds that the most direct and effective means of controlling their appeal to adolescents and children under the age of 18 is to prohibit manufacturers, distributors, and retailers of tobacco products from distributing or selling them.

(78) One comment opposed § 897.34(a) because the comment argued that the provision would impose restrictions on an otherwise lawful use of trademarks. It stated that § 897.34(a) would prohibit the right of any trademark owner to use a trademark for the sole reason that the trademark is used by another party on tobacco products. The comment stated that § 897.34(a) also would prevent large distributors and retailers, who handle a wide variety of both tobacco and nontobacco products, from distributing or selling any product which happened to bear the same or similar mark as that used on a tobacco product. The comment stated that, for example, grocery markets could not stock or sell Beechnut baby food or chewing gum because Beechnut also is used as a trademark for chewing tobacco even though the manufacturers are two different companies with the same name. It stated that the Lanham Act (15 U.S.C. 1051 (1996)) would, and in fact does, permit such identically branded products to coexist in the marketplace because of the absence of any likelihood that these products would be associated or confused with each other.

FDA recognizes that § 897.34(a) as proposed created unintended confusion and therefore will amend the provision to clarify the agency's meaning. Changes have been made that are intended to clarify § 897.34(a) so that retailers and distributors of domestic tobacco products are not included, thus avoiding the problem identified with the comment and making it possible for grocers to sell Beechnut baby food and Beechnut tobacco products.

(79) Several comments stated that § 897.34(a) would unlawfully constrain the separate and distinct activity of trademark diversification in connection with products that are unrelated to the marketing of tobacco products by cigarette manufacturers. One comment contended that general bans on the licensing of brand logos pertaining to tobacco products are incompatible with long-established principles of international trademark law. The comment asserted that the use of such trademarks in a nontobacco context is not an indirect means of advertising or promoting tobacco products. The comment stated further that it is an increasingly common practice in many industries to ''spin off'' new products by marketing them under a trademark that has acquired some cachet or represents quality. It stated that such licensed products are not marketed in an effort to sell the ''root'' product, rather, the trademark has some ''detachable'' qualities that help build demand for the licensed goods. It stated that the same is true of marketing a nontobacco product under the trademark of a tobacco product.

FDA cannot agree with the comments' claims. While the agency recognizes that the use of these trademarks on hats and tee shirts promotes the underlying tobacco product by continuing the extensive imaging in these venues. Moreover, as the court in *Public Citizen*, 869 F.2d at 1549, n. 15, recognized, branded nontobacco items might be the most effective type of promotion to young people. Therefore, failure to include this form of advertising and promotion in the regulation, would weaken considerably FDA's efforts to reduce the appeal of these products to young people under 18, and would undermine the agency's access restrictions.

The agency also disagrees with the comment's suggestion that § 897.34(a) effects a taking (or deprivation of a property right) by prohibiting the use of tobacco trademarks to market nontobacco products. Section 897.34(a) clearly relates to commercial speech and the comment is merely attempting to cloak commercial messages with the issues of registrability and value of well-known trademarks. As discussed in section XI. of this document, the agency has determined that this regulation does not effect a taking compensable under the Fifth Amendment.

One comment that supported FDA's proposal stated that smokeless tobacco makers circumvent the FTC regulation that covers the use of brand names of smokeless tobacco products on promotional items such as caps and tee-shirts. For instance, rather than stop making such items, U.S. Tobacco has registered Skoal Bandit Racing, Skoal—Copenhagen Pro Rodeo, and Skoal Music as service marks and places these names on many of the items it offers the public, thereby evading FTC's regulation. The comment stated that this experience demonstrates the need for regulations of this sort to be comprehensive.

The comment stated further that there may be other relatively easy ways around § 897.34(a). It stated that if the rights to a brand name were transferred to an entity that was not a manufacturer, distributor, or retailer that this separate entity could then license back the use of the brand name to the tobacco company and proceed to market, license, distribute, or sell other goods and services using that same brand name. The comment stated that one way to close this loophole would be to require manufacturers to own the trademarks and the rights to all associated symbols for each brand they produce.

FDA disagrees with these comments and believes that the concerns expressed are misplaced. Section 897.34(a) prohibits all use of the Skoal brand name on nontobacco items, whether used alone, i.e., ''SKOAL,'' or with other words, such as ''Skoal Racing Bandit.'' In addition, the provision forbids not just the use of the brand name, logo, etc. by the manufacturer but also the marketing, licensing, distributing, selling of them, or the causing of any of those activities; thus, effectively preventing the type of license-transfer arrangement described in the comment.

(80) Several comments stated that FDA cannot ban contests and lotteries under section 520(e) of the act, because they are not devices. Moreover, the comments stated that existing laws and regulations provide adequate protection and to the extent that the participation of minors in these activities is a problem the States already have ample power to regulate them.

In addition, a comment stated that FDA offered no evidence, or citation to studies, that contests, lotteries, or games involving tobacco products have particular appeal to adolescents. Moreover, the comment stated, that any inability to quantify participation by youth does not mean that the agency

address the necessity of preventing anyone under the age of 21 from getting promotional items.

can ban an entire form of promotion to adults.

One comment pointed out that, by law, customers wishing to participate in games of chance or similar promotional activities must be adults. The comment stated that banning such activity bears no relationship to achieving FDA's stated purpose. The sole effect of FDA's ban would be to unjustly impair the relationship between tobacco manufacturers, retailers, and their adult customers.

One comment stated that the agency should not prohibit all use of contests or games of chance by the tobacco industry because regulations already exist and are enforced by the Bureau of Alcohol, Tobacco, and Firearms (BATF).

Another comment stated that the proposed rule misunderstands the nature of such activities, misrepresents the appeal of promotions, and assumes without proof that promotions induce young people to smoke. It stated that promotional activities are not undertaken to encourage people, young or old, to smoke, but rather to introduce existing smokers to the brand being promoted and to provide them with incentives to choose that brand over others. Moreover, participation in such games is expressly limited to smokers who are 21 years of age or older.

Conversely, one comment provided support for the 1995 proposed rule. It stated that, while it is unlikely that anyone under 18 years of age actually has ever received any of the major prizes or offers from the give-aways, the award of prizes is not the point of these marketing tools. It stated that the consumer's participation in the fantasy of the prize in association with the brand being promoted is the reason these contests are used.

FDA has been persuaded by the comments to modify § 897.34(b) regarding lotteries and games of chance in connection with nontobacco items. Federal law already prohibits ''any certificate, coupon, or other device purporting to be or to represent a ticket, chance, share, or an interest in, or dependent on, the event of a lottery to be contained in, attached to, or stamped, marked, written, or printed on any package of tobacco products'' (26 U.S.C. 5723(C)). BATF has issued regulations enforcing this provision (27 CFR 270.311).

In addition, although no Federal agency has issued specific restrictions on games of chance and lotteries in connection with advertising of tobacco products, Federal and State law prohibit games, contests, and lotteries if based on product purchase (18 U.S.C. 1302–1307, 1341 (1995)). Given these existing Federal requirements, the agency has concluded that there is no need to add FDA regulations. Therefore, § 897.34(b) has been modified to delete the provision concerning lotteries and games of chance but to continue to the prohibition of gifts and proof of purchase acquisitions.

It must be understood, however, that advertising for games, lotteries, or contests may not contain any indicia of product identification other than black text on a white background, since the advertisement for a contest in the name of a tobacco brand, or identifiable as a tobacco brand, is restricted to text-only format as required in § 897.32(a). The agency points out that, as part of the review of the regulation that it plans to undertake in 2 years, FDA intends to consider the effect of games of chance and lotteries on young people and determine whether additional regulations are necessary.

Based on the evidence amassed during its investigation, and the surveys described in the preamble to the 1995 proposed rule (60 FR 41314 at 41336) and submitted during the comment period, FDA has concluded that nontobacco items (identified with a tobacco brand), either sold, given away, or provided for proof of purchase are an instrumental form of advertising in affecting young people's attitudes towards and use of tobacco. Moreover, banning this form of advertising is essential to reduce tobacco consumption by young people. This form of advertising has grown in importance over the last 20 years. As discussed in this section, expenditures rose from 2.1 percent in 1975 to 8.5 percent in 1980 (60 FR 41314).

Studies—A Gallup survey found that about one-half of young smokers and one quarter of all non-smokers, own at least one promotional item (60 FR 41314 at 41336). Another study, detailed more fully in this section, found that participation in tobacco company promotions (owning an item, collecting coupons for gifts, or having a catalogue) by 12 to 17 year olds is more predictive of susceptibility to use of tobacco products than smoking by those close to the individual. Another study, by Slade, found that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash and Marlboro miles (60 FR 41314 at 41336).

Evidence Provided by Industry Members—Two separate studies done for R.J. Reynolds, and described in this section, found that tee shirts were a significant source of information about tobacco for some young people and that these items performed best among young people.

A ban on this type of advertising will prevent the ''something for nothing appeal'' of give aways and proofs of purchase and will eliminate the walking billboard, who can enter schools and other locations where advertising is inappropriate. Thus, FDA concludes that the restriction it is adopting on this type of promotional material will directly advance FDA's efforts to substantially reduce consumption of tobacco products by children and adolescents under 18.

8. Section 897.34(c)—Sponsorship of Events

Proposed § 897.34(c) provided that ''no manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event, in the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products.'' Proposed § 897.34(c) would have permitted a manufacturer, distributor, or retailer to sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation that manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence before January 1, 1995.

The preamble to the 1995 proposed rule explained that sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events such as car racing and rodeos, and provides an opportunity for ''embedded advertising'' that actively creates a ''friendly familiarity'' between tobacco and sports enthusiasts, many of whom are children and adolescents. The preamble to the 1995 proposed rule cited several studies that demonstrate the impact of sponsorship on consumer attitudes (60 FR 41314 at 41337 through 41338). The proposed restriction was intended to break the link between tobacco company-sponsored events and use of tobacco and reduce the ''friendly familiarity'' that sponsorship generates for a brand.

(81) FDA received a substantial number of comments concerning the agency's 1995 proposal on sponsorship, including comments submitted by the

tobacco industry, motorsport industry, advertising agencies, adult smokers, medical professionals, public interest groups, and racecar drivers. Approximately 300,000 individuals submitted a form letter that was produced by 1 tobacco manufacturer. The form letter inaccurately referred to the 1995 proposal as a ''ban on tobacco sponsorship of events including concerts, State fairs and consumer promotions'' whereas the agency proposed to permit tobacco company sponsorship of all events to continue as long as they are in the corporate name. Other comments submitted by the tobacco industry, adult smokers, and motorsport industry strongly objected to the provision. In contrast, those comments submitted by public interest groups, medical professionals, and some racecar drivers strongly supported the provision.

In response to comments, the agency has modified this provision to prohibit all sponsored entries and teams using the brand name in addition to the prohibitions that were proposed. Moreover, the final rule clarifies that the corporate entity that can sponsor events, teams and entries must not only be registered but that the registration must be in active use in the United States, and the corporate name cannot include any indicia of product identification ''that are identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.''

(82) Several comments addressed the issue of whether young people attend, or even see, sponsorship events. Some comments opposed the provision, arguing that sponsored events (such as motorsport events and seniors golf tournaments) are created for and attended by adult smokers, and that there is no credible evidence that these events are targeted at, created for, attended by, or even seen by significant numbers of children and adolescents. One comment stated that ''contrary to FDA's assertions,'' the industry takes special steps to ensure that material distributed at events is not attractive to minors. One comment stated that ''[r]ecent industry studies demonstrate that the overwhelming majority of fans at motorsports events are adults,'' and that ''for example, 97 percent of NASCAR Winston Cup Series race attendees are 18 years of age and older [and] [m]ore than 90 percent of NHRA Winston Drag Racing Series attendees are 21 years old and older.'' The underlying studies were not, however, cited or attached to the comment.

One comment added that motorsport events are not seen by ''significant'' numbers of children under the print media standard proposed by FDA (i.e., the ''15 percent/2 million benchmark''). The comment argued that:

> [o]n the one hand, the agency concedes that image advertising is permissible in publications with a primarily adult readership because ''the effect of such advertising on young people would be nominal,'' but on the other hand, it attempts to measure the impact of cigarette brand sponsorships * * * by using statistics on the viewing audience of sponsored motorsport events without recognizing that these figures demonstrate the fact that the vast majority of viewers of such events are adults.

The comment stated that:

> [I]n fact, the 64.05 million underage viewers of the 354 motorsport broadcasts studied represents only 7 percent of the total viewing audience of these broadcasts. This averages out to 180,806 underage viewers per event. These figures are far below the 15 percent and two million readership benchmarks that are permitted for image advertising in print media.

* * *

The comment also stated that FDA made no attempt to measure the percentage of adolescents in the live gate of sponsored events, and that industry estimates indicate that the overwhelming percentage of fans attending motorsport events are adults.

One comment stated that the price of a typical ticket to a stock car race event is expensive enough to preclude adults from taking their children to events and to preclude children themselves from attending these events.

Other comments supported the provision, stating that tennis tournaments, sports car, motorcycle and powerboat racing, and rodeos all are aimed at sports enthusiasts, many of whom are children or teenagers, and that rock concerts and country music festivals are ''magnets'' for adolescents.

One comment stated that:

> [it] is also no coincidence that when the tobacco industry sponsors events where the audience is almost entirely educated adults, the sponsorship is in the name of the corporation (i.e., art exhibits, modern dance companies), but when the event fits the psychological image the tobacco industry needs to attract adolescents, the sponsorship is in the name of the brand most likely to appeal to those children (Virginia Slims, Marlboro, Winston, Skoal Bandit).

The agency, which acknowledges the comments' reports on the number of young people at events, did not receive any data to support or refute these numbers. However, recent reports in the press indicate that the number of young people attending these events may be growing.

> In NASCAR we found a great kids' business. I was astounded by their information, statistics and demographics regarding kids. [Fred Siebert, president of Hanna-Barbera, Inc., explaining why the company is sponsoring a cartoon race car to appear in NASCAR races emblazoned with Fred Flintstone and other cartoons on the hood.] After reviewing the 1995 NASCAR season, we concluded that a sizable number of attendees at NASCAR events were families with kids ages 6–11. Yet we felt NASCAR was not specifically serving that audience. [Gary Bechtel, owner Diamond Ridge Motorsports, who will field a NASCAR car and team named Cartoon Network Wacky Racing.] [234]
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> * * * * *
>
> We looked at NASCAR and saw how quickly it was growing nationally and the fact that so many families go to the races it seemed like a natural fit. [235]

Moreover, the agency finds that 64.05 million underage viewers (or 180,806 underage viewers per event) is clearly not ''insignificant.'' As discussed in the preamble to the 1995 proposed rule, the ''Sponsor's Report,'' which estimated the value of all product exposure for most U.S. automobile races, found that 354 motorsport broadcasts ''had a total viewing audience of 915 million people, of whom 64 million were children and adolescents.'' The preamble to the 1995 proposed rule stated: ''the impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television'' (60 FR 41314 at 41337). In addition, recent news accounts indicate that televising of races has increased both in volume and diversity. For example, television can often support three major races in 1 day. The two cable ESPN channels had 150 hours of auto racing programming in May, 1996, including 95 hours of live races, time trials, qualifying and practice laps. [236]

The effect of sponsored events on the young people who attend or see these events is enormous. Advertising affects young people's opinion of tobacco products, first, by creating attractive and exciting images that can serve as a ''badge'' or identification, second, by utilizing multiple and prolonged exposure in a variety of media, thereby

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[234] ''Diamond Ridge Motorsports and Hanna-Barbera, Inc., to form Wacky Racing Team Changing Face of NASCAR; Deal Launches Cartoon Network Consumer Branding Initiative,'' *Business Wire*, November 10, 1995.

[235] ''Automobile Racing's Widening Appeal Gets the Flintstones in Sponsor Table,'' *The Times Union*, p. B11, March 30, 1996.

[236] Moore, S., ''Ladies and Gentlemen, Start Your Televisions,'' *Washington Post*, May 26, 1996.

creating an impression of prevalence and normalcy about tobacco use, and finally, by associating the product with varied positive events and images. The sponsorship of events by tobacco companies uniquely achieves all three objectives. Sponsorship creates an association between the exciting, glamorous or fun event with the sponsoring entity. Whether at the live gate, or on television, young people will repeatedly see and begin to associate the event, which they are enjoying, with the imagery and appeal of the product. All of the attendant concerns of hero worship of the sports figures and glamorization of the product by identification with the event are present, whether there are thousands or hundreds of thousands of young people in attendance. Race car drivers are extremely popular with young people and often are looked up to as heroes. According to one promoter of NASCAR properties, ''We've found that boys look to NASCAR drivers the same way they do to heroes, such as firemen, policemen, professional fighters, or astronauts.'' [237]

Furthermore, sponsorship events present a prolonged period of time in which to expose the audience, including young people, to the imagery. Sponsorship events do not provide people with a momentary glimpse at the imagery, but from 1 to 2 or 3 hours of constant attractive imagery. The audience has more than enough time to associate the images of the sporting event or the concert with the product.

The agency agrees that there may be some events (such as seniors golf tournaments) that are primarily attended by adult audiences. The agency also does not claim that *all* sponsorship events are *attended* primarily by young people, but that the *exposure* (which includes television broadcasts) of young people to sponsored events is substantial. Even if a small percentage of young people attend certain sponsorship events, the amount of television exposure that young people receive is substantial.

In addition, the agency recognizes that numbers or percentages of the audience less than 18 may be lower than the threshold established for ''adult'' publications. However, the type of exposure in these two media are dramatically different. Young people reading or flipping through a magazine may momentarily glance at advertisements if they are interesting or eye-catching, and as a result, the exposure, if any, to one particular advertisement may be brief (the average time spent viewing an advertisement is about 9 seconds [238]). However, young people who attend sponsorship events or view them on television are unavoidably bombarded with posters, signs, hats, t-shirts, cars, and the like, linked with a fun, exciting, or glamorous event that they enjoy for a prolonged period of time. Often, celebrities participating in these events are wearing clothes and hats bearing the brand name and attractive imagery, and young people come to associate athletes who they admire with tobacco products. The amount of time viewed and the positive association with the event are incalculable as persuasive messages. Thus, the agency rejects the idea of setting a minimum attendance threshold for brand name advertising.

(83) FDA received many comments addressing its use of the concept of ''friendly familiarity'' in connection with tobacco sponsorship of events. Several comments stated that FDA misunderstood the theory, [239] arguing that sponsorships and promotions do not cause young people to smoke, and that FDA has failed to meet its burden of demonstrating that a ban of such activities will result in any decrease in underage smoking. In fact, according to this comment, the studies demonstrate that young people are most familiar with the brands of tobacco that are most heavily advertised.

One comment asserted that since motorsport advertising and promotion comprises a small percentage of overall tobacco advertising (on the order of 4 or 5 percent of total tobacco advertising), there is little support for the conclusion that tobacco sponsorship of motorsports has any significant effect on the rate of youth smoking.

One comment from a 26-year old ex-smoker (who began smoking at age 10, and smoked for 13 years) and NASCAR racing fan stated:

[M]y favorite driver is sponsored by a beer company. I don't drink and I'm not going to start because my favorite driver has that sponsor. However- if I DID drink already, I may switch brands to support my driver. All the advertising in the world will not sway me (or most-intelligent people) to do something I wouldn't do anyway.

In contrast, several comments labeled the 1995 proposed rule a ''reasonable measure'' and stated that ''the evidence cited by FDA in support of this proposal is substantial and entirely consistent with the best available evidence.'' One comment supported FDA's sponsorship restrictions because sponsorship heightens product visibility, molds consumer attitudes, links the product with a particular lifestyle, and thus increases sales.

One comment commended FDA for drawing a ''reasonable line—one that allows tobacco companies to continue to sponsor events and therefore to reap the corporate good will that flows from sponsorship, but compels the companies to jettison the hard-sell message that now typifies these events.''

Several comments stated that the events sponsored by tobacco companies have a direct and powerful impact on young people because they are fun, exciting, and glamorous, and events such as tennis tournaments (Virginia Slims), sports car (NASCAR), motorcycles and powerboat racing, rodeos, rock concerts, and country music festivals are aimed at sports and music enthusiasts, including children or teenagers. The comment stated that when minors view these events, either in-person or on the television, they are: ''inundated with images of the brandname or product logo (which are pasted on uniforms, vehicles, signs and virtually every surface imaginable), creating a direct and compelling association between the product and an enjoyable event.''

The comment stated that children and young adults are particularly vulnerable to this sort of product advertising, because adolescence is the time of life during which identities are shaped. The comment further stated that there is ample evidence that demonstrates that the sponsorship of events leads to strong associations between the event and the brandname, that in turn influences the purchasing decisions of minors.

One comment stated that Virginia Slims' sponsorship of tennis was vital to the image advertising Philip Morris used to sell Virginia Slims tobacco to adolescent girls, and that Marlboro sponsorship of racing events is no less effective with adolescent boys. The comment stated that sports sponsorship has a secondary impact because ''[the athletes who participate in the sponsored event, whether they be race

[237] Williams, S., ''NASCAR Races into Kid's Licensing, National Association for Stockcar Auto Racing Seeking Promotional Appeal and Other Products,'' *Children's Business*, vol. 9, No. 7, p. 28, July 1, 1994.

[238] Fischer, P., J. Richards, and E. Berman, ''Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements,'' *JAMA*, vol. 261, pp. 84–89, 1989.

[239] The comment stated that ''[t]he need to establish a 'friendly familiarity' with a brand name is not about deciding to smoke * * * nor about deciding to use a commodity at all—the decision to make a category purchase within a mature product category is ALREADY made before advertising affects the brand choice within the category.''

car drivers or tennis players, become walking advertisements and role models.'' The comment stated that ''[a]s reflected by the Industry's own Code, everyone agrees that athletes should not endorse tobacco products because of her potential impact on children, but being a spokesperson for the Virginia Slims Tennis Tournament, NASCAR racing, etcetera is no less effective.''

The agency finds that the evidence regarding the effect of advertising and sponsorship on children's smoking behavior is persuasive and more than sufficient to justify this regulation. The preamble to the 1995 proposed rule described the available evidence and explained why the agency is regulating sponsored events. The evidence demonstrates that sponsorship of sporting events by tobacco companies can lead young people to associate brand names with certain life styles or activities and can affect their purchasing decisions (60 FR 41314 at 41336 through 41338). The industry, in its comments, has questioned the relevance of the evidence but has failed to demonstrate that FDA's tentative views were wrong (the industry's criticisms of the individual studies are described below).

Sponsorship events actively create an association between tobacco and event enthusiasts. People under the age of 18 are still forming attitudes and beliefs about tobacco use, see smoking and smokeless tobacco use as a coping mechanism, a gauge of maturity, a way to enter a new peer group, or as a means to display independence (60 FR 41314 at 41329). This final rule is intended to break the link between tobacco brand-sponsored events and images and use of tobacco by young people. In addition, the tobacco industry itself has recognized the vulnerability of young people to advertising featuring sports heroes and other celebrities. In its 1994 Code, the cigarette industry promised that ''No sports or celebrity testimonials shall be used or those of others who would have special appeal to persons under 21 years of age.'' [240] The impact of tobacco's association with the race driver, the car, or the event is no less powerful and no less persuasive.

Finally, although motorsport advertising comprises only a small percent of overall tobacco advertising, its effect, like that of magazines, or hats and tee shirts, is cumulative. Each separate advertising venue, in and of itself, does not produce the entire effect. However, taken together, the effect of each advertising exposure is magnified beyond each discrete exposure, to create the impression that cigarette and smokeless tobacco use is widespread and widely accepted. These impressions, as stated in section IV.D.3.c. of this document, are very influential to children and adolescents.

(84) Several comments criticized in detail the studies relied on by FDA to show the effect that sponsorship has on young people.

One comment stated that the studies relied on by FDA (40 FR 41331 and 41332) do not provide scientifically valid support for the conclusion that there is a causal relationship between the promotional and sponsorship activities banned under § 897.34(c) and the problem of underage smoking.

The agency proposed to regulate sponsored events based upon its tentative finding that the best evidence supported such regulation. Although the comments argued that the studies are inadequate, the comments offered no new evidence to suggest that the conclusions are invalid.

(85) One comment argued that although the conclusion reached by an unpublished paper by John Slade [241] is that 7 percent of the viewing audiences for NASCAR races are youths, the NASCAR Demographics brochure states that ''NASCAR records of the age of persons who attend motorsport events show that only 3 percent are youths.'' The comment stated that this does not constitute a principled basis for outlawing tobacco company sponsorship of these races even if every other assumption FDA makes about the impact of event sponsorship were true.

The agency disagrees with the comments on the paper by Dr. Slade. Slade's paper established that these events are attended by and seen by a large number of young people. The study measured its stated objective, it establishes the important fact that children are being unavoidably exposed over and over again to attractive and appealing images associated with tobacco products at NASCAR events. The study establishes that young people are present at events where a popular sport is associated with tobacco on signs, cars, people, etc.

The agency also disagrees with the comment that suggested that the price of tickets to motorsport events was sufficiently high to preclude adults from taking their children to see them. In fact, some motorsport events allow children to attend free of charge or offer discount tickets for children. [242]

(86) One comment stated that the study performed by Aitken, et al. [243] (the Aitken study) did not attempt to gauge whether exposure to tobacco-sponsored events or teams engendered favorable feelings for tobacco products in the surveyed young people and stated that the study only addressed the effect of factors such as sex, age, and socioeconomic status on awareness of cigarette sponsorships. The comment also stated that the Aitken study did not test the effect of sponsorship activities in this country, and that FDA ignores the fact that tobacco companies sponsor a wider variety of more popular sports in the United Kingdom, such as ''snooker, cricket and darts.'' Finally, the comment accused FDA of ''selective reading,'' citing FDA's omission of a statement made by the authors when discussing past studies that even though minors may be aware of the sponsorships, ''[t]his of course does not mean that cigarette advertising plays a part in inducing children to start smoking.'' The comment also criticized the author of the study for stating that even though very few of the primary schoolchildren named John Player Special or Marlboro as being associated with racing, ''[t]his suggests that linkages or associations between brand names (or their visual cues) and exciting sports are often unconscious, or at the very least, not readily retrieved by consciousness (Aitken et al., p. 209).'' The comment claims ''[t]hat astonishingly biased hypothesis was not tested by any questions that attempted to probe the ''unconscious'' or the ''consciousness'' of the interviewees.''

The agency disagrees with the comment's criticism of the Aitken study. This study conducted in the United Kingdom demonstrated that primary schoolchildren who said that they intended to smoke when they were older tended to be more favorably disposed to cigarette advertising. Moreover, Aitken's comment that this

[240] Cigarette Advertising and Promotion Code, 1990.

[241] 60 FR 41314 at 41337, n. 225; citing Slade, J., ''Tobacco Product Advertising During Motorsports Broadcasts: A Quantitative Assessment,'' presentation at the 9th World Conference on Tobacco and Health, October 10–14, 1994.

[242] See, e.g., Rosewater, A., ''Retirement is no Drag for Prudhomme,'' *Plain Dealer*, p. 7D, June 4, 1996; ''Fun Book 96/ This Spectator Sport: Easy Over,'' *Newsday*, p. 80, May 19, 1996; Schmiedel, M., ''Motor Sports World Motorcycle Trials in Exeter Next Weekend,'' *The Providence Journal-Bulletin*, p. 13D, May 19, 1996.

[243] 60 FR 41314 at 41337, n. 226; citing Aitken, P. P., D. S. Leathar, and S. I. Squair, ''Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the UK,'' *Health Education Research, Theory and Practice*, vol. 1, pp. 203–211, 1986.

study did not mean that advertising plays a part in inducing children to start smoking'' is an accurate statement of the study. The purpose of the study was to examine the effect of sponsorship on children's awareness of tobacco sponsorship and brand name identification with that sport, not on their smoking behavior. This fact is not a flaw but a description of the study design and the study's limitations. The study, however, is quite useful in showing the effect of sponsored events on young people's awareness of brands.

In addition, the comment selectively quoted a portion of the Aitken study (regarding linkages), while ignoring the reason the statement was made. The author of the study made this statement in the context of the finding that whereas only 9 percent of the primary schoolchildren named John Player Special or Marlboro as sponsoring or being associated with racing cars, 47 percent of primary schoolchildren chose John Player Special or Marlboro as being liked by ''someone who likes excitement and fast racing cars.'' The authors also found that linkages or associations between cigarette brand names (or their visual cues) and exciting sponsored sports can be elicited by simple advertisements, even among children who do not have a critical awareness of the purpose of commercial sponsorship. This type of linkage is the primary issue, rather than whether such information is ''conscious'' or ''unconscious'' in nature.

(87) One comment stated that the study performed by Ledworth [244] (the Ledworth study), which found that even a fairly brief exposure to tobacco sponsored sporting events on television may increase children's brand awareness, failed to control for other sources of information that could result in brand awareness (i.e., if a family member smokes), and that even the author of the study stated that further investigation needed to be done to determine whether tobacco sports sponsorship persuades children to smoke. The comment also stated that FDA cannot extrapolate the study results to the United States because the study was based on foreign sponsorship and viewership practices, which differ significantly from those in this country. The comment stated that the differences are highlighted by the fact that 74 percent of the surveyed children watched at least part of the snooker match, and that the child viewership of NASCAR is ''* * * significantly more limited, at most, even by Slade's number, to 7 percent.''

The agency disagrees with the comment's criticism of the Ledworth study. The Ledworth study demonstrates the power of association between an event and brand awareness among young people. The study is evidence of the important link formed by that association.

(88) One comment stated that the study performed by Hock et al. [245] (the Hock study), which showed that nonsmoking boys who saw a tobacco sponsorship advertisement had a diminished concern that tobacco hurt sports performance, ''has no real relevance to the issue of event sponsorship and suffers from obvious, significant methodological flaws.'' The comment explained that the video viewed by one of the groups contained an advertisement promoting a cigarette company's sponsorship of a sporting event and thus reports the effect of a particular advertisement, not the effects of the types of sponsorships at issue here. The comment also stated that American tobacco companies are not permitted to advertise sponsorships in this fashion under 15 U.S.C. 1335 (the television advertising ban). The comment argued that the portion of the conclusion quoted by FDA overstates the results of the flawed research because the authors themselves emphasized that ''nonsmokers''' general attitudes to smoking were not significantly affected by exposure to sponsorship events. Finally, the comment argued that, among the group of smokers, the authors reported that exposure to the sponsorship advertisement did not affect the smokers' brand choices, and that the authors cautioned that ''these findings do not, in themselves, constitute a case for legislation.''

The agency disagrees with the comment's criticism of the Hock study. Although the advertisement used in the Hock study may have been different than advertisements that appear in the United States, and only a single advertisement was tested, these factors alone do not render the author's conclusions invalid. Again, most importantly, the study provides evidence that brand sponsorship produces awareness of the product and the brand in young viewers. The agency also disagrees with the comment's assertion that FDA overstated the findings of the study. The agency specifically acknowledged in the preamble to the 1995 proposed rule that exposure to the particular advertisement did not affect overall attitudes toward smoking (60 FR 41314 at 41338).

Moreover, the agency disagrees with the comment regarding brand preferences of smokers. As the study authors noted, the study primarily focused on nonsmokers. Thus, the fact that there were few smokers in the study makes it more difficult to find significant effects on smokers. In addition, the authors note more than once that the effects of sponsorship appear to be primarily on nonsmokers.

The important point of this study and the others cited by the agency is that sponsorship of events helps create a positive association between the event and the tobacco company. The child relates the event to the product and this contributes to the perception that tobacco use is acceptable and not dangerous. This attitude helps an environment that fosters experimentation with tobacco products.

Finally, the comment asserted that FDA's reliance on the two-page memorandum from Nigel Gray [246] is ''not only disingenuous, but demonstrates that FDA has not evaluated the data on which it purports to rely.'' The comment stated that ''the statistics cited in this study lack any explanation or support.'' The comment also states that ''[the conclusions stated in the memorandum are at odds with those in the studies by Aitken and Hock cited by FDA.'' The comment stated that the author cited a ''Western Australian survey'' that found that 65 percent of 10 to 11 year olds surveyed believed that tobacco sponsorship of sports is advertising for tobacco, whereas the Aitken study ''found that only 4 percent of 10 to 11 year olds identified advertising as a component of sports sponsorships by tobacco companies.'' The comment also argued that the study by Hock found no effect of the sponsorship advertisement on brand choice, whereas the memorandum by Gray revealed that sponsorship did effect brand choice.

The agency recognizes that there are problems with the two-page memorandum from Nigel Gray because the data on which it was based have not been made available. Therefore, the

[244] 60 FR 41314 at 41338, n. 227; citing Ledworth, F., ''Does Tobacco Sports Sponsorship on Television Act as Advertising to Children,'' *Health Education Journal*, vol. 43, no. 4, 1984.

[245] Hock, J., P. Gendall, and M. Stockdale, ''Some Effects of Tobacco Sponsorship Advertisements on Young Males,'' *International Journal of Advertising*, vol. 12, pp. 25–35, January 1993.

[246] 60 FR 41314 at 41338, n. 228; citing memorandum from Gray, N., (Anti-Cancer Council of Victoria), to all members of the Federal Parliament, December 15, 1989.

agency has placed no weight on its findings and does not rely on it in the final rule.

On the other hand, the memorandum cannot be used to diminish the usefulness of the other studies that have been cited. A careful reading of the data presented by the Aitken study reveals that indeed 17 percent of 10 to 11 year olds identified advertising as a component of sports sponsorship by tobacco companies. While it is true, as the comment indicated, that 4 percent mentioned only the advertising component, the comment has overlooked the fact that an additional 13 percent of 10 to 11 year olds mentioned both advertising and economic components.

In summary, these studies provide ample support that brand name sports sponsorship produces, for young people, memorable associations between the sport and the tobacco product and brand name. As shown in section VI.B.1. of this document, young people pay attention to and rely on peripheral cues such as the color and the imagery of advertising for some of their information about products. Tobacco sponsorship creates powerful images of fun and excitement to add to that ''information'' mix.

(89) FDA had proposed that entries, such as racing cars, or events or teams that participate in events be permitted to display a brand name in a black and white text only format. Thus, although the Skoal 500 would be prohibited, the Skoal Bandit racing car could participate in a race event.

Several comments supported the provision's requirement for teams and entries but recommended that the agency go further to restrict labeling on entries and teams in sponsored events. One comment, which was submitted by a ''participant in motorsport events,'' stated that ''even when the Marlboro name, for example, is removed from a racing car body, the distinctive color scheme still sends the Marlboro message, loud and clear.''

One comment stated that ''under the rationale applied to the regulation on event sponsorship, * * * FDA would be justified in restricting tobacco companies from entry and team sponsorship.'' The comment recommended that FDA ''limit the scope of the terms 'entries' and 'sponsored events,' for the breadth of possible entries and possible events is enormous.'' The comment stated that for instance, professional sporting events such as football, basketball, baseball, and hockey games, should be excluded from 'sponsored events,' so that tobacco product brand names cannot be used as the name of a professional sports team.'' The comment stated that the term ''entries'' is ambiguous because, for example, a race car competing in a sponsored race would qualify as an ''entry'' under the proposed rule, ''but would the Company X Choir be considered an 'entry' when it appears in a sponsored concert?''

The agency has carefully considered the comments and has decided to delete ''entries and teams in sponsored events'' from the list of permissible advertising media in § 897.30(a) and to specifically include teams and entries within the scope of the ban on sponsored events. The agency is persuaded that sponsored teams and entries, such as cars: (1) Create the same associations with sports figures and other ''heroes,'' (2) create a linkage between a tobacco product and an enjoyable and exciting event when they appear as part of an event, (3) are displayed for a significant period of time. They have the same potential to create images and influence children and adolescents as does sponsorship of events, and (4) are able to leave the event and be seen at fairs and malls and other places frequented by young people.

The agency appreciates the comment's suggestions that color and imagery are as problematic as the brand name but advises that the comment has misinterpreted the 1995 proposed rule. Proposed § 897.34(c) stated that sponsorship would be prohibited in ''the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products.'' Thus, a car sponsored by Philip Morris may not be named after the Marlboro brand nor be painted in the distinctive tri-color pattern.

(90) Some comments addressed the issue of whether sponsorship is advertising. One comment argued that the International Events Group's (IEG) ''IEG Complete Guide to Sponsorship'' states that sponsorship is not advertising, and that the guide explains that advertising involves the delivery of messages about specific product attributes, while sponsorship merely shapes the consumer's image of the brand. Moreover, to the extent the IEG is identifying sponsorship as advertising, the comment asserted that the IEG guide is a publication by an organization that depends on sponsored events for its existence, and is not in the business of conducting objective, statistically sound studies on the effects of sponsorship. Thus, the comment asserted, FDA has not cited any scientific study supporting the theory that sponsorship is advertising.

The comment argued that the position that sponsorship and advertising are one and the same is inconsistent with pronouncements from Congress and from the FTC. The comment argued that both Congress and the FTC have recognized that advertising includes messages about product attributes or appealing visual imagery, and the use of a brand name to identify an event includes neither. The comment asserted that ''nothing in the [FTC]'s findings suggests a rationale that would apply to the mere display of a logo, trademark, or other product identifier when divorced from a selling message.'' The comment asserted that Congress has never classified sponsorship of events using brand names as advertising, and that the few times it has addressed this issue, Congress has issued laws that distinguish advertising from other forms of promotion that do not have the same impact as advertising.

The comment referred to an FTC order *In the Matter of Lorillard Tobacco*, 80 FTC 455, 457 (1972), which the comment argues defines ''advertising'' to include only those practices that typically contain a selling message; and *United States* v. *R.J. Reynolds Tobacco Company*, No. 76-Civ-814 (JMC) (SDNY 1981), which the comment argued confirms the Government's view that the selling message in advertising, not the mere display of a logo, was the focus of its concern.

In addition, the comment argued that another Federal agency agrees with this interpretation. The comment stated that the FCC, expressly permits ''logos or logograms'' as long as such announcements do not contain ''comparative or qualitative descriptions, price information, calls to action, or inducements to buy, sell, rent or lease.''

In contrast, some comments supported the assertion that sponsorship is very effective advertising. One comment included in its appendices the transcript of an ABC News Day One story broadcast August 10, 1995, that reported on the commercial value of sponsorship. The comment also included a recent story in Winston Cup Scene (October 19, 1995) which describes the advertising value that sponsors expect to receive from their sponsorships.

Contrary to the comments cited, the FTC asserted, in its comment, that sponsorship is advertising, citing its 1992 consent order involving the Pinkerton Tobacco Co., (Consent Order) C–3364 (1992).

The comment also stated that in 1995, the Department of Justice announced consent decrees resolving allegations that Philip Morris, Inc., and the owners of Madison Square Garden in New York City violated the Cigarette Act's ban prohibiting advertising for tobacco on television and other media regulated by FCC through the display of cigarette brand names and logos at live sporting events that were broadcast on television (*United States* v. *Madison Square Garden, L. P.*, No. 95–2228 (S.D.N.Y., April 7, 1995); *United States* v. *Philip Morris, Inc*., No. 95–1077 (D.D.C. June 6, 1995)). The consent decrees prohibit Philip Morris and Madison Square Garden from placing cigarette advertising in places regularly in the camera's focus where they might be seen on television.

The agency finds that sponsorship is advertising within the scope of this regulation. The claim by the comments that the *Lorillard* and *Reynolds Tobacco* consent orders demonstrate that the FTC does not find sponsorship to be advertising is incorrect. The two cited cases are consent orders that did not provide a definition of advertising but limited the coverage of the consent order to the specific types of advertising mentioned in the order. The two orders clearly excluded categories of obvious advertising from the coverage of the order (see, e.g., point of sale advertisements less than 36 square inches).

Although the agency acknowledges that the ''IEG Complete Guide to Sponsorship'' (IEG guide) states that sponsorship is not advertising, IEG is creating a semantical distinction between one form of advertising (traditional media advertising) from other types of advertising (e.g., promotional items, sponsorship). The IEG guide states that ''[w]hat sponsorship generally accomplishes *better* [emphasis added] than advertising is establishing qualitative attributes, such as shaping consumers' image of a brand, increasing favorability ratings, and generating awareness.'' In addition, the IEG guide states that sponsorship is more effective than advertising in increasing ''propensity to purchase.'' This latter description of sponsorship falls within the courts definition of advertising in *Public Citizen* v. *FTC,* 869 F.2d at 1554, as ''any action to call attention to a product so as to arouse a desire to buy.''

The agency finds for all these reasons that sponsorship can be regulated as advertising under the act.

(91) Several comments argued that FDA does not have the authority to restrict sponsorship events. One comment stated that FDA has no authority to regulate cigarette advertising to ''break the link'' between sponsored events and use of tobacco, and reduce the ''friendly familiarity'' that sponsorships generate among young people. The comment stated that FDA can prohibit only false or misleading restricted device advertising and cannot prohibit advertising that simply links a name to a product. One comment stated that it is difficult to understand how the sponsorship of the IndyCar Marlboro 500 or the National Hot Rod Association Winston Drag Racing Series, promotional activities that would be prohibited under the 1995 proposed rule, involve the ''misbranding'' of tobacco products.

Several comments addressed the issue of whether FDA's proposed ban on brand name sponsorship violates the First Amendment. Several comments argued that the proposed restrictions on advertising and promotional activities are overly broad and violate the First Amendment because the 1995 proposed rule would prohibit virtually all forms of tobacco sponsorship and advertising at motorsport events, and FDA made no attempt to limit the restrictions to advertisements directed at minors. One comment argued that the provision would not directly and materially advance the government's interest, because there is no reasonable basis for asserting that sponsorship causes youth tobacco use. The comment stated that FDA did not attempt to differentiate between those events that attract children and adolescents and those that attract adults. Thus, according to the comment, a ban on tobacco sponsorship of an event that few or no children or adolescents attend will not directly and materially advance a reduction in underage tobacco use.

In contrast, one comment which supported the provision stated that sponsored events have a direct and powerful impact on young people, and thus there is a ''reasonable fit'' under the final two prongs of the *Central Hudson* test. The comment argued that the 1995 proposed rule is narrowly tailored because ''FDA has selected the approach that best effectuates its goal of reducing tobacco consumption by minors, without needlessly restricting the industry's ability to sponsor events and garner the good will that flows from such sponsorship.''

FDA concludes that sponsorship of events and sponsored teams and events is an advertising medium that is effective in influencing young people's decision to engage in smoking behavior and tobacco use.

As explained in this section, the agency has authority to restrict advertising of restricted devices like tobacco and smokeless tobacco under sections 520(e) and 502(q) of the act. As the studies described in this section [247] demonstrate, sponsorship associates the advertised brand with the event and thus shapes the image of the brand and the individual's image of tobacco use. Sponsorship of rodeos and car racing, for example, associates the product with events where risks are high but socially approved and are taken by individuals who brave the odds. [248] This type of situation fits in very well with the image concerns of adolescent males described in section VI.D.4.a. of this document.

Youths who attend the sponsored event are directly and unavoidably confronted with messages for the sponsoring product. This exposure creates a sense of familiarity and acceptance similar to that created by billboards near schools and playgrounds.

In addition, the sponsored events are televised. As a result of this fact, through mention of the sponsor and camera shots that pan the place where the event is held, awareness of the brand is created, along with the associations described above.

Given these factors, a restriction on sponsorship will be effective in limiting the influences on children and adolescents to use tobacco products and thus in protecting their health. Moreover, there is a reasonable fit between the restriction and FDA's interest. The restriction focuses on the use of the brand because of the association between the brand and tobacco use. [249] By building associations with the brand, sponsorship and the advertising displayed at the event creates a desirable image for young people that contributes to a positive feeling about the product that sponsors

[247] See e.g., Aitken, P. P., D. S. Leathar, and S. I. Squair, ''Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the U.K.,'' *Health Education Research*, vol. 1, pp. 203–211, 1986.

[248] IOM Report, p. 112.

[249] Hock, J., P. Gendall, and M. Stockdale, ''Some Effects of Tobacco Sponsorship Advertisements on Young Males,'' *International Journal of Advertising*, vol. 12, No. 1, January 1993.

the event. This positive image not only provides a brand that the young person might select but also adds to the young person's positive feelings about using the product. It is the creation of this association that FDA will prevent by restricting sponsorship.

FDA is not aware of any way to limit the restriction to events that are attended by young people. However, FDA has no desire to restrict manufacturers' abilities to contribute to the community by sponsoring athletic, cultural, or other events. Thus, the agency has narrowly tailored the restriction on sponsorship to use of brand identification because it presents the harm that FDA is trying to eliminate. For these reasons, FDA concludes that its restrictions on sponsorship are consistent with its legal authority and with the First Amendment.

(92) Several comments (including one from a participant in motorsport events) argued that allowing tobacco companies to place brand names and logos at highly visible locations during broadcast sporting events has afforded tobacco companies the opportunity to circumvent the Cigarette Act, which prohibited broadcast advertising of cigarettes. One comment stated that tobacco companies receive millions of dollars of free brand name television and radio exposure during these events and use messages in these advertisements that are particularly effective with children. One comment stated that ''the degree to which sponsoring events gives tobacco companies television time is staggering,'' and ''[j]ust in the televising of the Indiana 500 [sic], Marlboro received almost 3½ hours of television exposure and 146 mentions of its brand name.'' The comment cited cases where Congress and the courts have already recognized and upheld the importance and the constitutionality of keeping tobacco advertising off the airwaves (*Capital Broadcasting Co.* v. *Mitchell*, 333 F. Supp. 582 (D.D.C. 1971), aff'd sub nom. *Capital Broadcasting Co.* v. *Acting Attorney General*, 405 U.S. 1000 (1972)), and concluded that a reviewing court would likely sustain the provision regarding event sponsorship simply because it has become a pervasive tool used by the tobacco industry to evade the restriction on television advertising.

The agency finds that there is adequate support for its ban on brand name sponsorship of events. As stated in the preamble to the 1995 proposed rule and in response to an earlier comment, ''[t]he amount and financial value of television exposure gained by a firm can be substantial.'' The preamble to the 1995 proposed rule cited two studies which discussed the impact of sponsoring televised events and concluded that:

> [t]he impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television.

(60 FR 41314 at 41337)

By restricting brand name sponsorship of events, the final rule will eliminate those brand name sponsored events that continue to permit tobacco product brand names to appear on television.

(93) Several comments expressed concern that the 1995 proposed rule was not sufficiently inclusive; specifically, it did not prohibit the incorporation of an event in a brand name by someone other than the tobacco company and did not explicitly ban the use of the name of a foreign tobacco company in U.S. sport events. Some comments stated that restricting sponsorship of entertainment and sporting events to corporate name only for corporate sponsors that had been in existence prior to January 1, 1995, ''leaves open many shadow entities incorporated under tobacco brand names because tobacco transnationals have been creating these front groups for years to escape promotion restrictions in other countries.''

One comment stated that Canada, after it had banned brand name sponsorship, found that industry used new ''corporations'' such as Camel Racing PLC to continue sponsoring in a brand name. Thus, the comments recommended that the regulation ensure that corporate sponsorship of events be allowed only if the corporate name is the name of the manufacturing entity and that the name has no similarity to a brand name of any of that manufacturer's tobacco products.

Several comments expressed concern about a recent trend among U.S. manufacturers to develop brands that are made by a corporate entity. For example, one comment stated that RJR has developed a series of brands with an art deco style of pack design and is selling them through a wholly owned subsidiary named Moonlight Tobacco.

Another comment stated that Philip Morris has been test marketing a brand called ''Dave's,'' which it produces through a boutique company named ''Dave's Tobacco Company.'' These comments stated that the agency should amend the 1995 proposed rule to prohibit any corporate name or logo that had a brand name or product identification within it.

Finally, a comment stated that there are many other existing brand names that are also corporate names, such as ''Rothmans'' and ''Sampoerna'' (a brand of clove cigarette (Kretek) imported from Indonesia) that are manufactured overseas. This comment argued that non-U.S. corporate names must also be included in the final rules proscription.

The agency recognizes the concern expressed by the comments. As stated in the preamble to the 1995 proposed rule, the requirement that the corporation be in existence on January 1, 1995, is intended to prevent manufacturers from circumventing this restriction by incorporating separately each brand that they manufacture for use in sponsorship (60 FR 41314 at 41336). The comments have suggested that manufacturers may circumvent this restriction by the use of shadow entities, many of which have already been incorporated under tobacco brand names in other countries (or have been incorporated as events). The agency agrees that the proposed restrictions do not prevent this type of circumvention.

Thus, in response to the comments' suggestions, the agency has modified the proposed regulations to reflect that the registered corporate name and corporation must have been in existence and registered in the United States and have been in active use in this country before January 1, 1995. Thus, FDA has modified § 897.34(c) to state: ''Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered, and in use in the United States prior to January 1, 1995, * * *.'' This provision makes clear that manufacturers are free to sponsor events in their corporate name but contains language that will prevent the type of circumvention of the restriction that was posited by the comments.

The agency also agrees with the comments that suggest that manufacturers may also attempt to circumvent this restriction by placing within the corporate name or logo elements of brand identification such as names (Smokin' Joe), colors (the tricolor decoration), etc. Tobacco products can be promoted using more than just the brand name. In fact, the name may be less important than the attractive

imagery, recognizable colors and patterns of colors (Marlboro), characters and heroes (Joe Camel racecar drivers) all of which provide the user with a desired image. A yellow motorcross bike with a head of a Camel conveys the image of Joe Camel without the name of the product. Therefore, it is necessary in order to break the link between the event and the product to restrict the images in addition to the name. Thus, FDA has modified § 897.34(c) so that it concludes with the following statement:

''* * * and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco products.

The agency also recognizes that at some time in the future, corporate entities may be formed to sell tobacco products, which are new to the tobacco business and in no way associated with current manufacturers. Should those entities desire to sponsor events, they would be precluded by the language of § 897.34(c) from doing so. The agency envisions that such entities could petition the agency, under 21 CFR part 10, for an exemption from this provision.

(94) One comment stated that FDA's proposed ban on brand-name sponsorship is an unjustified limitation on the right of private individuals to select their own sponsors.

This comment has misinterpreted the 1995 proposed rule. The rule does not limit the ''right'' of private individuals to select sponsors. Individuals are free to select any sponsor they choose. The rule, however, prohibits the event from including any brand name, logo, symbols, motto, selling message, or any other indicia of product identification similar or identical to those used for any brand of cigarette or smokeless tobacco. However, the final rule does not prevent corporate sponsors that were in existence and registered in the United States before January 1, 1995, from advertising in their registered corporate names.

(95) Several comments stated that sponsorship restrictions would have a negative impact on sports events. Approximately 300,000 copies of one form letter were submitted as comments. All included the statement: ''I am 21 years of age or older and oppose the new regulations proposed by the Food and Drug Administration (Docket No. 95N–0253) that would prohibit tobacco company sponsorship of entertainment and sporting events.'' The form letter also stated that ''If FDA gets control of tobacco and bans tobacco sponsorships, ticket prices could rise as well. And there might be fewer events. All this adds up to consumers being the big losers.''

One comment stated ''I oppose any attempt by President or FDA to deny RJR the right to sponsor the Winston Cup Racing Series!'' One comment stated ''[b]y banning the sponsorship of NASCAR, the races won't get any money, and if they have to stop racing, that will make me mad, and I am too old to be getting mad—75 years [old].''

One comment stated that because of the potential loss of economic support, many events will not be viable if cigarette company sponsorship is no longer available. Several comments argued that FDA's proposed ban on sponsorship, promotional programs, and contests would eliminate events enjoyed primarily by adults. One comment stated that ''[w]e believe that we and millions of other middle class fans like us, will no longer be able to afford the NASCAR we love.'' One comment stated that the provision ''will adversely affect the economy of the tobacco industry and that affects many people in many States, not just the racing industry and communities.''

One comment stated that the loss of sponsorship revenue to race track owners, operators, and promoters would negatively affect the motorsports industry because racing fans will suffer in the form of increased ticket prices or decreased services at motorsports events, and increased ticket prices will decrease attendance at race events, forcing racetrack operators to cut jobs and other employee benefits, further depressing the economies of hundreds of communities around the nation. The comment also stated that since motorsports injects hundreds of millions of dollars into local and regional economies, particularly in rural and suburban communities that have been the hardest hit by recession and job losses, FDA's proposed regulation would have a substantial impact on local and regional economies across the country and hurt the future of motorsports.

In contrast, one comment that supported the proposal was from a ''dedicated car racer,'' and stated that ''the truth is that car racing will do just fine without tying its wonderful image to the interest of the cancer promoters.'' The comment stated that:

in Europe where racing cars run without any cigarette advertising whatsoever, people camp out for days trying to get into the events, and that the recent Formula One European Grand Prix was run in cold miserable, weather with packed stands and not a single cigarette logo in sight.

The comment stated that ''I hope [FDA] will look out for the rest of us and stand firm in favor of a ban on tobacco advertising at all sporting events.''

One comment stated that ''many of the millions of dollars spent on these promotions are available to the cigarette industry only because 3,000 children start smoking each day,'' and ''[t]his situation can be viewed as an industry demanding a bounty of 3,000 lives per day in exchange for its financial support of the sports, music, and other entertainment appealing to children and youth.''

One comment stated that:

the abundance of other sponsors indicates that auto racing would not fail if tobacco products are not allowed to be event sponsors and if teams sponsored by tobacco products are restricted to black and white uniform and car designs. Similar fears were expressed when cigarette commercials were banned from electronic media, but they proved groundless.

The comment stated that sponsors do not make a sport such as auto racing or rodeo popular because auto racing and rodeo are ''compelling, popular spectator sports in their own right.'' The comment stated that ''popular sports attract sponsors who want to advertise.'' The comment stated that ''[t]he Olympics would remain a premier sporting event without Coca-Cola or Kodak'' and ''NASCAR stock car racing is among the most popular spectator sports to thrive.'' The comment stated that ''the audience is not there because of tobacco: tobacco is there because of the audience.''

The agency advises that the concerns expressed by some of these comments have misinterpreted the rule. The rule does not ''prohibit tobacco company sponsorship of entertainment and sporting events'' or ''ban tobacco sponsorships, promotional programs, and contests.'' The rule prohibits a sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other cigarette or smokeless tobacco brand identifying characteristic. All athletic, musical, artistic, or other social or cultural events would be permitted to be sponsored in the name of the tobacco company as long as the other conditions in § 897.34(c) are met.

In addition, the tobacco industry accounts for only 4 percent of all sponsored events. This rule does not prohibit the other 96 percent of

nontobacco forms of sponsorship (60 FR 41314 at 41337). Thus, even if the restriction on sponsorship of tobacco products resulted in a decrease of tobacco company sponsored events, the events will still exist through the support of the nontobacco forms of sponsorship. The agency agrees with the comment that ''auto racing would not fail if tobacco products are not allowed to be event sponsors.'' Thus, restricting tobacco product brand name sponsorship clearly will not ''ban all sponsorship events.''

Finally, recent news stories quote persons knowledgeable about car racing saying racing would survive without tobacco sponsorship, for example, one quote: ''If this happened 10 years ago, it would have been crushing to the racing industry. Now people are lining up to take Winston's place.'' [250]

In conclusion, FDA finds that sponsorship of events (such as car races, tennis matches, and rodeos) and entries in those events (race cars and drivers, tennis players) can have a profound effect on young people's attitude about and use of tobacco by providing multiple and prolonged exposure to the brand name and logo in a variety of media, thereby creating an impression of prevalence and normalcy about tobacco use (see section VI.D.3.c. of this document), by associating the product with varied positive events, images, and heroes, and by creating attractive and exciting images that can serve as a ''badge'' or an identification (see section VI.D.4.a. of this document). The industry itself recognizes the concern that sports figures as endorsers can create problems of hero worship and emulation; its Code promises not to employ sports or celebrity testimonials or those of others ''who would have special appeal to persons under 21 years of age.'' Sponsorship creates no less of an association than an endorsement. Moreover, FDA finds that restrictions on sponsorship identified with a tobacco brand are necessary to reduce tobacco use by young people. These findings are based on studies and recent reports that the number of young people who attend these events or see them on television is significant and growing.

Studies—Four different studies, one each by Slade, Aitken, Ledworth, and Hock (60 FR 41314 at 41337 and 41338) and described further in this section, provide evidence that sponsored events of all types are attended, and seen on television, by a substantial number of young people, and that the effect of the exposure is to increase brand awareness and association between the brand and the event. This attitude contributes to a sense of friendly familiarity about tobacco use and a perception that tobacco use is acceptable and common place.

Surveys on attendance and TV audience, described further in this section, establish that attendance by children at events and viewership by children and adolescents on television are significant. The preamble to the proposed rule used the number 64 million as an annual approximation of underage viewers of motorsport events in addition to those at the event (60 FR 41314 at 41337). In addition, newspaper articles detailed in this section describe the increasing importance of young people to sponsored events as a growing part of the live audience. Moreover, although less data is available on other types of sponsored events, comments received by the agency in response to the proposed rule, and described further in this section, state that many children and teenagers watch tennis, motorcycle and powerboat racing, and rodeos on television and attend and watch on television rock concerts and country music festivals.

Finally, the agency has tailored the restriction narrowly. The agency recognizes the importance of corporate sponsorship in engendering goodwill for a company with its customers and in providing support to sports, the arts, and music. Therefore, the agency has crafted the regulation to not interfere with this aspect of sponsorship but has merely denied the companies the right to use brand and product identification, which are most appealing to young people.

9. Proposed § 897.36—False or Misleading Statements

The agency proposed in § 897.36 that labeling or advertising of any cigarette or smokeless tobacco product:

> is false or misleading if the labeling or advertising contains any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made of the product.

This provision would have explicitly implemented sections 201(n), 501(a) (21 U.S.C. 351), and 502(q)(1) of the act. Section 897.36 was meant to be illustrative rather than exhaustive.

The agency stated in the 1995 proposed rule that its regulations concerning prescription drug advertising provide great specificity as to what constitutes violative advertising (part 202 (21 CFR part 202)) but that this same degree of specificity is not practical in the case of a widely used consumer product like tobacco because the advertising for it contains an unlimited variety of claims that make categorization difficult. Therefore, the agency tentatively concluded that it would provide general guidance for the types of advertising claims that will be considered violative, rather than to attempt to identify every possible type of false and misleading claim (60 FR 41314 at 41339 and 41340).

(96) Several comments objected to various portions of the definition, for example the phrases ''omits important information'' and ''lacks fair balance.'' They asserted that the phrases expand the definition of what constitutes ''misleading'' advertising, are subjective, and make compliance burdensome because the phrases are not defined. Moreover, the comment complained that neither ''fair balance'' nor ''substantial evidence'' were appropriately included in the definition of false and misleading.

Additionally, the comments argued that laws regarding false and misleading advertising are well established, and that false and misleading advertising is subject to the jurisdiction of the FTC. The comment stated that it was, therefore, inappropriate for FDA to establish vague and overreaching parameters of ''unfair and deceptive'' advertising.

One comment stated that what ''information'' is important is undefined. It stated that there is always information that someone may consider ''important'' (e.g., price, availability, freshness, taste research), and that it would be unreasonable to allow FDA, or any regulatory organization or entity, to review tobacco advertising in the capacity of determining information that should have been included. This comment argued that the legal precedent defining deceptive advertising is already established and should not be changed by FDA.

One comment stated that by introducing the word ''important'' into the proposed standard for misbranding of tobacco, FDA has impermissibly gone beyond the ''materiality'' test for misbranding set forth by Congress in section 201(n) of the act, acted arbitrarily and capriciously, and proposed a new standard that is unconstitutionally vague.

[250] Quoting Ardy Arani, a director of the Atlanta-based Championship Group, a sports marketing agency in Jacobsen, G., ''Mass Merchandisers Jostle With Tobacco Companies to Cash in on the Auto Racing Craze,'' *The New York Times*, p. D71, February 21, 1996.

One comment stated that FDA also proposes that labeling or advertising would be false or misleading if it ''lacks fair balance.'' It stated that FDA has obviously borrowed this concept from the prescription drug regulations (§ 202.1(e)(5)(ii)), but it is inapplicable to tobacco. The comment stated that, first, the ''fair balance'' requirement for drugs is based not on the section 502 ''false or misleading'' prohibition but rather on section 502(n)(3), which requires that prescription drug advertising contain a ''true statement'' relating to ''side effects, contraindications, and effectiveness.''

The comment stated that, second, as the drug regulation makes clear, the ''fair balance'' required is between information about a product's therapeutic benefits and information about its adverse effects when used. It stated that because no therapeutic claims are made for tobacco, the ''fair balance'' concept is simply inapplicable.

One comment, however, stated that, under this regulation, advertising for cigarettes and smokeless tobacco will be considered false or misleading if it ''omits important information.'' It stated that this is a reasonable rule, and that it should be part of the final rule, but it is one that may be difficult for manufacturers to comply with absent guidance from FDA.

FDA has been persuaded that the proposed general guidance in proposed § 897.36 on what might constitute false and misleading advertising has created unintended confusion. Under section 502(a) and (q)(1) of the act, any restricted device is misbranded if its advertising or labeling is false or misleading in any particular. Section 201(n) of the act states that:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

After review of the applicable provisions of the act concerning labeling and advertising, the agency has determined that those provisions are adequate and that the definition in proposed § 897.36 is unnecessary. Because cigarette and smokeless tobacco advertising remains subject to regulatory action if it is false or misleading in any particular, FDA has decided to delete § 897.36 from the final rule.

(97) Some comments supporting proposed § 897.36 recommended that specific restrictions be placed on advertising that emphasizes tar and nicotine levels and implies a weight benefit to tobacco products.

Other comments suggested requiring the disclosure of ingredients. These comments argued that consumers do not know the ingredients of these products or the functions that these ingredients serve. It added that consumers do not know the doses of nicotine and other critical materials that they ingest with these products. The comment stated that terms such as ''light'' and ''low tar'' have little meaning in view of the tendency of consumers to smoke cigarettes differently depending upon the way nicotine delivery has been engineered. A comment from a tobacco company opposed disclosure of ingredients fearing loss of valuable trade secret information.

The agency has decided that these comments fall outside the scope of this rulemaking. The agency did not propose labeling or advertising restrictions concerning the levels of tar, nicotine, or other components of cigarettes or smokeless tobacco, or perceived benefits of tobacco products, only that labeling or advertising not be false or misleading. It did not receive comments sufficient to warrant restrictions addressing these issues. Consequently, advertising and labeling claims will be evaluated on a case by case basis for compliance with sections 201(n), 502(a), (q), and (r), 510(j) (21 U.S.C. 360(j)), and 520(e) of the act. Therefore, FDA is not modifying part 897 to address these concerns at this time.

F. Additional First Amendment Issues

Finally, several general issues were raised by commenters concerning the nature of the protection afforded commercial speech by the First Amendment.

(98) One comment argued that the original understanding of the First Amendment was that truthful commercial messages are fully protected.

In response to this comment, FDA points out that the Supreme Court took the position that the First Amendment does not protect commercial speech (see *Valentine* v. *Chrestensen*, 316 U.S. 52 (1942)), until it repudiated that position in *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). Since 1976, the Court has decided numerous cases, most recently *Rubin* v. *Coors*, *Florida Bar* v. *Went For It, Inc.*, and *44 Liquormart Inc.* v. *Rhode Island*, that address the level of protection afforded commercial speech by the First Amendment. FDA has followed that case law in its development of this final rule. Therefore, FDA has developed this final rule in accordance with the applicable law.

(99) A comment filed by an association of advertising agencies warned that the proposed regulations ''establish a dangerous precedent that could open the floodgates to dramatic government intrusion into the process of communication * * * and [are] a dangerous blueprint for government censorship of other kinds of advertising.'' The comment expressed concern that regulations of advertising for tobacco products will permit, in fact will encourage, the future regulation of other ''controversial products.''

Tobacco products are not ''controversial'' products as these comments contend. They represent the single most preventable cause of death in the United States (1989 Report to the Surgeon General at p. i). Not only is the harm caused by tobacco use real (the comment refers to ''imagined harm''), but the product that produces the disease and death is addictive. Moreover, tobacco use begins among young people, who may be able to describe the risks of tobacco use, but who do not personalize that risk to themselves. These young people begin to use tobacco before they can adequately weigh the consequences of use and thus, become addicted and subject to the real long term harms caused by tobacco use. That is why all 50 States and the District of Columbia outlaw the sale of tobacco products to those under 18 years of age. Finally, as discussed in section VI.D. of this document, advertising does affect young people's decision to use tobacco products in a significant and material way. This is not an ''assertion'' made out of whole cloth but a reality. Thus, regulation of tobacco advertising may set a precedent for future government action, but it sets a high threshold for such regulation.

The Supreme Court has granted ample protection to commercial speech, but the Court has also stressed, nothing in the First Amendment prevents the Government from ensuring ''that the stream of commercial information flows cleanly as well as freely.'' (See *Edenfield*

v. *Fane*, 506 U.S. 761, 768.) One comment noted: ''This concern takes on special force where, as here, crucial public health concerns are implicated, and where a particularly powerful seller * * * has used its virtually limitless resources to saturate the marketplace with its promotional messages.''

The Government's interest in protecting the health of children and teenagers through measures designed to prevent them from beginning a lifetime of addiction and disease is of the highest order and is sufficient justification for the restrictions finalized here.

VII. Education Campaign

In the Federal Register of August 11, 1995 (60 FR 41314), the Food and Drug Administration (FDA) proposed to require that tobacco companies establish a national education program, using television as its predominant medium, to discourage children and adolescents from using cigarettes and smokeless tobacco (the 1995 proposed rule). The agency received more than 1,500 comments concerning the program, nearly three-quarters of which favored going forward with it. The comments raised many issues concerning the program as proposed, including whether the proposed funding would be either equitable or sufficient, whether industry's level of involvement would jeopardize its effectiveness, whether current industry educational programs are sufficient, about the design of the educational programs, the manufacturer's obligations to carry them out, the agency's statutory authority to require an education campaign under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360j(e)), and the constitutionality of the campaign as proposed.

The agency has reexamined its statutory authority for requiring an education campaign and believes that section 518(a) of the act (21 U.S.C. 360h(a)) is more appropriate and practicable than the restricted device authority in section 520(e) of the act under which FDA had proposed the education campaign. Under section 518(a) of the act, if the agency finds that a device presents an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act, then, after consultation with device manufacturers, the agency may issue a notification order that requires them to notify the appropriate persons in a form appropriate to eliminate the risk. The agency has used section 518(a)'s separate, affirmative grant of statutory authority on a number of occasions to compel medical device manufacturers to provide notice to users or potential users of their products about risks presented by their use or misuse.

The agency believes that, with respect to cigarettes and smokeless tobacco, it could make the findings required by section 518(a) of the act and so could order tobacco manufacturers to notify young people about the substantial health risks that tobacco products present in a form appropriate to eliminate the risk. That is, the agency believes that it could find that cigarettes and smokeless tobacco present an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act.

The agency has concluded, therefore, that it will not require an education campaign as part of this tobacco rule. The agency intends, however, to send letters that indicate that the agency believes that it could make the statutory findings necessary to issue notification orders under section 518(a) of the act to cigarette and smokeless tobacco manufacturers. As section 518(a) of the act requires, these consultation letters will offer tobacco companies an opportunity to consult with the agency about the necessity for, and specific requirements of, any notification orders before the agency issues any orders to the companies.

Because the education campaign will not be a requirement of this final rule, the agency need not respond to the many comments that it received concerning the proposed campaign. Nevertheless, because the agency intends to pursue implementation of an education campaign using the notification provision of section 518(a) of the act, the agency will respond briefly to comments that questioned the effectiveness and design of the proposed education campaign.

(1) The agency received comments questioning the effectiveness of other educational campaigns and the agency's use of these campaigns to support the position that a national educational campaign would be effective in helping reduce tobacco use among young people. Comments from the tobacco industry argued that studies cited by FDA are scientifically flawed and therefore that the agency overstated the likely effects of the provision. One industry comment argued that FDA misinterpreted a study by Simonich [251] (the Simonich study), cited in the preamble to the 1995 proposed rule to demonstrate that the media campaign conducted under the Fairness Doctrine (FD) reduced cigarette consumption by 6.2 percent (60 FR 41314 at 41327). The comment concluded that the data from the Simonich study indicated that the overall effect of the Fairness Doctrine was merely a 0.4 percent decline in per capita consumption.

FDA disagrees with the industry's interpretation of the Simonich study. The agency believes that the Simonich study results, correctly interpreted, indicate that the FD education campaign reduced per capita cigarette consumption an average of 4.5 percent, [252] that is, a 4.5 percent reduction in consumption over the period of time over which the FD was in effect for entire quarters. Thus, the FD education campaign did play an important role in reducing per capita cigarette consumption.

(2) Comments also questioned the effectiveness of education programs cited by the agency. The tobacco industry's comment argued that California's $26 million multi-year media campaign actually confirmed that televised education campaigns do not influence youth smoking. Further, the comment stated that it was not possible to say what impact, if any, a national media campaign's introduction or termination had on consumption in Greece because Greece's educational television and radio advertising campaign was only one element of an overall education campaign.

With regard to the California media campaign, FDA notes that this campaign was directed to adults, not young people. Moreover, the media campaign was countered by increased per capita spending by the tobacco industry in the types of imagery-based advertising that influences children and adolescents. Therefore, the agency would have expected the media campaign to have had a greater negative impact on tobacco use by adults than by children and

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[251] Simonich, W. L., ''Government Antismoking Policies,'' Peter Lang Publishing, Inc., 1991.

[252] Simonich modeled the effect of the FD as: $\% \Delta \text{ Consumption} = -0.063(X_t + .46416X_{t-1} + .46416^2X_{t-2} + .46416^3X_{t-3})$ where X_t represents antismoking advertising expenditures in quarter t and -0.063 is the coefficient for the FD stock variable obtained from the analysis (*Id*., p. 153). FDA used Simonich's model and his ''Estimated Fairness Doctrine Real Advertising Expenditure per Capita 14+'' data series (*Id*., pp. 250, and 259-260) to calculate the quarterly percent reduction in per capita cigarette consumption from March 1967 through April 1970. The average percent reduction in consumption for this period was 4.5 percent.

adolescents. FDA continues to believe that California's efforts indicate that education campaigns, over time, can counter and reduce the impact of prosmoking efforts.

Further, while the comment correctly notes that Greece's national effort to reduce smoking included posters, booklets, and similar educational materials distributed through schools, health centers, and other channels, the primary and most significant element of its program consisted of antismoking messages broadcast on television and radio. FDA continues to believe the Greek experience indicates, as stated in the preamble to the 1995 proposed rule, that intensive education and media messages about the health risks associated with tobacco use can be effective.

(3) Many comments from the tobacco and media industries and from adult smokers argued that an education campaign is unnecessary because cigarette manufacturers, individually and through the Tobacco Institute, have undertaken voluntarily a variety of educational programs aimed at discouraging underage smoking, and because antismoking lessons are taught in schools.

By contrast, other comments questioned industry's commitment to reduce underage use of tobacco products. For example, several comments emphasized that a voluntary program run by industry in the mid 1980's failed to acknowledge that tobacco is addictive or causes disease.

FDA agrees with comments that the tobacco industry has failed to include in its voluntary youth educational programs important information, such as the addictive nature of tobacco and the association between tobacco use and disease. FDA further agrees that this lack of complete information about tobacco products makes it necessary to require that messages about the risks of tobacco use be directed to children and adolescents. The recently observed decline in the proportion of youth who see smoking as dangerous, despite the widespread dissemination through schools of information about the health hazards associated with tobacco use, supports the need for an immediate response to this problem. Moreover, recent evidence suggests that school-based education programs most effectively reduce underage smoking when used in conjunction with media messages.

VIII. Additional Regulatory Requirements

Subpart E of part 897 in the Food and Drug Administration's (FDA's) August 11, 1995, proposed rule (60 FR 41314) would have consisted of three provisions: § 897.40 would have required manufacturers to submit certain reports and would have required manufacturers, distributors, and retailers to make records available to FDA upon inspection; § 897.42 would have instructed manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco and would have notified State and local governments how to request an advisory opinion concerning the preemptive effect of part 897 on any particular State or local requirement; and § 897.44 would have required the agency to take additional regulatory measures if, 7 years after the date of publication of the final rule, the percentage of people under age 18 who smoke cigarettes had not decreased by 50 percent since 1994 and/or the percentage of males under 18 who use smokeless tobacco had not decreased by 50 percent since 1994.

Proposed § 897.40 Records and Reports, would have implemented sections 510(j) and 704(a) of the act (21 U.S.C. 360(j) and 374(a)) with respect to cigarettes and smokeless tobacco. Section 510(j) of the act requires the submission of labels, labeling, and a representative sampling of advertising to FDA, and section 704(a) of the act gives the agency inspection authority, which also includes the authority to examine records, files, papers, processes, controls, and facilities:

> bearing on whether * * * restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act.

Proposed § 897.42 Preemption of State and Local Requirements and Requests for Advisory Opinions, was intended to reflect the preemption provision in section 521(a) of the act (21 U.S.C. 360k(a)); that section states, in relevant part, that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Proposed § 897.42 was also intended to recognize that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco and to encourage further activity in these areas (60 FR 41314 at 41340).

In proposed § 897.44 Additional Regulatory Measures, FDA recognized that many different factors influence a young person's decision to start smoking or to use smokeless tobacco and that the affected industries have historically shown their ability to find new ways of promoting their products whenever restrictions were imposed (60 FR 41314 at 41341). Consequently, to guard against the possibility that its comprehensive regulations might be circumvented and to give firms an incentive to take appropriate actions to discourage cigarette and smokeless tobacco sales to people under 18, the agency proposed to require additional regulatory measures if the outcome-based objectives specified in proposed § 897.44 were not met.

In response to comments and upon further examination of existing statutory and regulatory requirements, the agency has deleted §§ 897.40, 897.42, and 897.44 from the final rule.

§ 897.40—Records and Reports

Proposed § 897.40(a) would have required each manufacturer to submit, on an annual basis, copies of all labels (or a representative sample of labels if the labels would be similar for multiple products), copies of all labeling, and a representative sample of advertising. Proposed § 897.40(b) would have provided an address for such materials.

(1) The agency received a number of comments from distributors, wholesalers, and retailers stating that it would be too costly and time-consuming, and thus too burdensome for small businesses to submit the information required by proposed § 897.40(a) and further, that the information collected would not be useful in prohibiting young people from using tobacco products.

These comments misread proposed § 897.40(a) by interpreting the section to apply to distributors of tobacco products. By its terms, this provision only applied to manufacturers of cigarettes and smokeless tobacco. FDA agrees with the comments that it is unnecessary for the agency to receive labels, labeling, and a representative

sampling of advertising for cigarettes and smokeless tobacco handled by distributors. In order to clarify this point further, FDA has deleted proposed § 897.40(a) and (b), and is explicitly exempting distributors of cigarettes and smokeless tobacco from the registration requirement in section 510 of the act. Exempting distributors from the registration requirement results in their exemption from the record submission requirements in section 510(j) of the act. The agency has amended the existing device registration and listing regulations in part 807 by adding a new provision, at § 807.65(j), to reflect this exemption.

FDA is authorized, under section 510(g)(4) of the act, to exempt persons from the requirement of registering under section 510 of the act. The agency agrees with the comments discussed above that stated that reporting by distributors would be too burdensome and would not result in any useful information. FDA believes that it will receive all the information it needs from manufacturers, who are required to list information with FDA under section 510 of the act. Further, there was virtually no public comment supporting a registration and listing requirement for distributors. Based on these considerations, FDA finds that it is appropriate to exempt distributors of cigarettes and smokeless tobacco, as defined in § 897.3(c), from the registration requirement in section 510 of the act as originally proposed because compliance with section 510 of the act by distributors ''is not necessary for the protection of the public health.''

A comment from the cigarette industry argued that § 897.40(a) was inconsistent with the recordkeeping requirements in part 807 (21 CFR part 807) (the device registration and listing regulations) by requiring annual submissions. A comment from a public health organization supported proposed § 897.40, and stated that the reporting requirements were the same as those faced by other manufacturers of drug delivery devices.

Cigarette and smokeless tobacco manufacturers are required to register and list under section 510 of the act. Upon consideration of the industry comment, the agency believes it is more appropriate for manufacturers to comply with the existing device registration and listing requirements in part 807 than to create new requirements in this regulation. Therefore, as stated earlier, FDA has deleted proposed § 897.40(a) and (b) from the rule.

(2) A comment from the country's largest association of health professionals supported proposed § 897.40, but suggested that FDA expand the reporting requirements to have each manufacturer monitor brand-specific uptake by children and adolescents. The comment suggested that these data could be used to supplement information from the Monitoring the Future project and other surveys that do not currently contain brand-specific data. The comment also stated that cigar and loose-leaf tobacco manufacturers should be required to monitor and report on use of their products by people under 18.

The agency declines to accept the comment's suggestions. FDA believes it is not necessary to obtain such data at this time. Rather, it is more appropriate to allow the provisions of the final rule to become effective and to monitor the effectiveness of the program before considering the addition of new requirements. FDA also notes that it is not asserting jurisdiction over cigars; cigar manufacturers are not subject to the requirements of this rule.

Proposed § 897.40(c) would have required manufacturers, distributors, and retailers to make records and other information available to FDA inspectors for purposes of inspection, review, copying, or any other use related to the enforcement of the act.

(3) An industry comment argued that proposed § 897.40(c)—which required manufacturers, distributors, and retailers to ''make all records and other information collected under this part and all records and other information related to the events and persons identified in such records'' available to FDA officials—so exceeds FDA's authority that it fails the test set out in *United States* v. *Morton Salt Co.*, 338 U.S. 632, 652 (1950), and, therefore, violates the Fourth and Fifth Amendments to the Constitution. The comment argued that § 897.40(c) may require the release, for example, of marketing strategies, sales figures, profits, personnel data, and proprietary information.

FDA disagrees with this comment, but nevertheless, the agency has deleted § 897.40(c). Part 897 does not add records requirements beyond those applicable to devices generally under existing regulations, e.g., part 803 (21 CFR part 803) (medical device reporting), part 804 (21 CFR part 804) (medical device distributor reporting), part 807 (registration and listing), and part 820 (21 CFR part 820) (good manufacturing practice). Section 897.40(c), as proposed, is therefore unnecessary, since FDA retains the records, reports, and inspection authority with respect to cigarettes and smokeless tobacco that it has with respect to other restricted devices. This authority is found, for example, in sections 510, 519, 702, 703, and 704 of the act (21 U.S.C. 360, 360i, 372, 373, and 374). In particular, section 704 of the act explicitly authorizes the agency to inspect records regarding restricted devices, including records and reports (and the related research) required under section 519 of the act, shipment data, and data as to the qualifications of technical and professional personnel performing functions subject to the act, except that such inspections may not extend to financial, sales, pricing, or other personnel and research data.

Warrantless inspections of drug and device manufacturers authorized by section 704 of the act are ''reasonable'' and therefore consistent with the Fourth Amendment, in part because section 704 delineates the scope of inspections with respect to prescription drugs and restricted devices. (See *United States* v. *Jamieson-McKames Pharmaceuticals*, 651 F.2d 532, 538 and n.9 (8th Cir.), *cert. denied*, 455 U.S. 1016 (1981).)

In particular, section 704 of the act meets the test established by the Supreme Court, and cited in the comment, that is applied to scrutinize administrative subpoenas under the Fourth Amendment's proscription of unreasonable searches and seizures and the Fifth Amendment's Due Process Clause: ''the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant'' (*Morton Salt*, 338 U.S. at 652 (regarding order requiring report about compliance with earlier agency order); see also *EEOC* v. *Shell Oil Co.*, 466 U.S. 54, 72 n.26 (1984) (citing *Morton Salt* regarding administrative subpeona); *Reich* v. *Montana Sulphur and Chem. Co.*, 32 F.3d 440, 448 (9th Cir. 1994) (same), *cert. denied*, 115 S.Ct 1355 (1995); *Resolution Trust Corp*. v. *Walde*, 18 F.3d 943, 946 (D.C. Cir. 1994) (same)).

The comment stressed that § 897.40(c) as proposed failed to satisfy the first part of the *Morton Salt* test because the act does not grant FDA authority to regulate tobacco products and because Congress has repeatedly refused to give FDA such authority. As discussed in detail in the 1996 Jurisdictional Determination annexed hereto, FDA is extending jurisdiction over tobacco products by a lawful application of the act. Moreover, the records, reports, and

inspection provisions in sections 510, 519, 702, 703, and, in particular, section 704 of the act, clearly specify the agency's authority to inspect regarding restricted devices, including records and reports required pursuant to section 519 of the act. An inspection of records from manufacturers, distributors, or retailers regarding tobacco products—which are restricted devices and which pursuant to this rule are subject to the reporting requirements of parts 803 and 804—is therefore ''within the authority of the agency'' as required by the Supreme Court in *Morton Salt* (338 U.S. at 652). Moreover, because sections 704 and 519 of the act define the scope of such requests, by their terms, such requests would meet the second and third parts of the *Morton Salt* test, since they would not be ''too indefinite and the information sought [would be] reasonably relevant'' to enforcement of the provisions of part 897 (*Id*.).

Even in the absence of proposed § 897.40(c), manufacturers, distributors, and retailers of cigarettes and smokeless tobacco are subject to the same records access and inspection requirements as are any manufacturers, distributors, and retailers of restricted medical devices. As discussed in this section, these requirements are fully consistent with the Fourth and Fifth Amendments.

(4) Several comments from distributors and retailers asserted that the recordkeeping requirements in proposed § 897.40(c) would be expensive and especially hard on small businesses. A few comments also claimed that proposed § 897.40(c) would not affect sales to children and adolescents, but would instead result in lost business as distributors or retailers would have to take the time to prepare and to maintain records. A small number of comments simply opposed proposed § 897.40(c) without providing any reason or said it was ''offensive,'' ''intrusive,'' or would not produce any useful information during an inspection.

As stated previously in this section, FDA has revised the rule to delete § 897.40(c) entirely. The agency believes that the existing reporting requirements in other regulations (such as part 803 for medical device reporting (as amended by this rule), part 804 for medical device distributor reporting (as amended by this rule), part 807 for registration and listing (as amended, to exclude distributors of cigarettes and smokeless tobacco), and part 820 for good manufacturing practices) make proposed § 897.40(c) unnecessary. The agency has also amended the rule to exempt distributors of cigarettes and smokeless tobacco from part 807. Thus, distributors are only expected to comply with the medical device distributor reporting requirements in part 804.

Retailers have no recordkeeping or reporting requirements under part 897.

Notwithstanding these changes to the rule, FDA believes that the comments misunderstand the purpose of recordkeeping and reporting. The records and reports that were described in the 1995 proposed rule were never intended to have a direct role in reducing illegal sales to children and adolescents. Neither were they intended to divert distributor or retailer staff to ministerial functions or to intrude into business activities. To the contrary, records and reports can help firms and FDA ensure compliance with the regulations. For manufacturers, distributors, and retailers, records and reports demonstrate whether they have complied with a particular requirement. Records are especially valuable in this respect because FDA's enforcement strategy relies heavily on site inspections to determine whether a party has complied with a statutory or regulatory requirement, and records can show or help an agency inspector determine whether a firm has a good compliance history. Firms that have good compliance histories usually are inspected less frequently than others, whereas firms with poor compliance histories may be inspected more frequently or more rigorously.

Inspections have other important benefits for firms. Inspections can reveal areas where firms can improve their operations. Inspections also apply to firms equally, regardless of their size, so firms that manufacture, distribute, or sell the same or similar products meet the same conditions or requirements. Furthermore, inspections, and FDA enforcement generally, give consumers greater assurance in the products they purchase because those products are held to the same standards or requirements.

For FDA, records and reports can provide information on current industry practices and trends, help identify potential problems in a regulatory program or in a firm's or industry's practice, and even conserve agency resources by letting the agency concentrate its inspection efforts on firms with poor compliance histories.

Thus, for these reasons, FDA disagrees with those comments suggesting that recordkeeping and reporting requirements or FDA inspections will have no useful purpose.

§ 897.42—Preemption of State and Local Requirements and Requests for Advisory Opinions

(5) FDA received several comments that opposed proposed § 897.42, claiming that it was inconsistent with the process for requesting exemptions from the preemption requirement in section 521 of the act. The agency also received some comments supporting proposed § 897.42 precisely because it would have recognized and would have preserved more stringent State and local requirements.

After careful consideration and closer review of the act, the agency has deleted proposed § 897.42 from the rule. This issue is addressed in greater detail in section X. of this document.

Under § 897.44 of the 1995 proposed rule, FDA would have established goals of a 50-percent reduction in cigarette use by individuals under the age of 18 years; a 50-percent reduction in smokeless tobacco use by males under the age of 18 years; and no increase in smokeless tobacco use by females under the age of 18 years. The agency stated it would take additional regulatory measures if these goals were not met 7 years after the publication date of the final rule.

FDA derived its outcome-based goals from the ''Healthy People 2000'' objectives. ''Healthy People 2000'' sets national health promotion and disease prevention objectives for Americans. The report was a joint effort by the U.S. Public Health Service (PHS), the Institute of Medicine (IOM) at the National Academy of Sciences (NAS), almost 300 national membership organizations such as the American Medical Association (AMA), the American Academy of Pediatrics (AAP), and the Blue Cross and Blue Shield Association, and all State health departments. ''Healthy People 2000'' established a basic goal to reduce by half the initiation of cigarette smoking by children and youth by the year 2000.

The agency proposed measuring progress toward the stated goals by use of an objective, scientifically valid, and generally accepted survey, such as the Monitoring the Future Project (MTFP). MTFP, funded by the National Institute on Drug Abuse (NIDA) and administered by the Institute for Social Research at the University of Michigan, has collected data on daily smoking by 12th graders every year since 1976 and on smokeless tobacco use by 12th graders for the years 1986 to 1989 and 1992 to 1995.

The agency did not include any specific additional requirements in the

1995 proposed rule, but stated that FDA would propose specific additional measures when it publishes a final rule and invited public comment on what additional requirements should be considered.

The agency received a number of comments arguing that the agency should wait until it knows specifically what progress has been made toward the goals before proposing additional regulatory measures. This approach would allow the agency to identify specific barriers to achieving the goals and to tailor any additional requirements to these barriers. Other comments argued that FDA must provide the public an opportunity to comment on specific additional regulatory measures before they would take effect. FDA has decided that there is merit to these comments. At this time, therefore, the agency is not proposing additional regulatory measures beyond the restrictions in this regulation and the requirements under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h). The agency instead plans to monitor industry compliance with the agency's requirements as well as the progress made toward meeting the stated goals of reducing the use of tobacco products by individuals under the age of 18 within 7 years. In the event that additional measures are necessary to achieve the goals, the agency retains the authority to propose and issue additional regulatory requirements in a future rulemaking proceeding.

FDA received approximately 60 individual comments related to this provision, about evenly divided in support and opposition. Opposition came primarily from the tobacco manufacturing and advertising industries and from tobacco retailers. Comments from several State legislators also opposed additional measures, as did one from a State department of agriculture. Some comments maintained the provision was invalid and unconstitutional; others objected that ''when regulations fail, the answer is not more regulations.''

Support for the measure came from national health organizations, State health departments, and individuals who identified themselves as parents, public health professionals, educators, and former smokers. Supporters stressed the importance of effective measures to improve the health of current and future generations.

(6) One comment opposing the proposed provision contended that imposing additional regulatory measures at the time that the final rule is published would be unreasonable because it would not permit a flexible response to future circumstances. It argued, for example, that the same additional regulatory measures ''apparently would be triggered at the specified date regardless of whether the reduction in the next 7 years is 49.8 percent or 2 percent.''

Several comments in support of the provision also advocated greater flexibility, but for different reasons. Because of the serious adverse health effects linked to the use of tobacco products, these comments urged the agency not to wait 7 years to evaluate progress and institute corrective measures. Instead, they recommended interim or ongoing review of compliance with the regulations and progress toward achieving the goals.

FDA agrees it is useful to put in place a system that will allow flexibility in responding to future circumstances. Therefore, the agency has decided to review on an ongoing basis the effectiveness of specific provisions. It will rely on data from the MTFP and other surveys recognized as using sound methodology to help measure compliance with the provisions, detect loopholes, and evaluate progress in achieving the goals. This will permit FDA to identify problem areas in a timely manner and seek public comment on whether additional measures should be considered.

(7) Some comments objected to any further restrictions. Others argued specifically against further advertising restrictions, saying it is illogical to impose such additional measures without first considering and attacking other causes for continued smoking among youth. A few comments were concerned that the proposed provision would inevitably result in a complete ban of all tobacco products, with a few of those charging that this was FDA's true intent.

One comment objected to the agency announcing as part of a final rule specific measures it will impose, rather than simply propose, some time in the future, maintaining that '' * * * the agency will have failed to provide meaningful notice and opportunity to comment.''

Many comments supported additional regulatory measures, if needed, to achieve the desired reductions in tobacco use by young people. Some advocated further restrictions on advertising, including: (1) Eliminating all tobacco product advertising except for point-of-purchase announcements of product availability limited to black and white text only; (2) prohibiting all point of purchase advertising; (3) eliminating direct mail marketing for cigarettes and smokeless tobacco; (4) prohibiting all outdoor advertising; (5) prohibiting advertising in publications marketed to youths, and possibly revising the definition of ''adult publications''; and (6) outlawing all marketing of cigarettes and smokeless tobacco. One comment recommended plain packaging of cigarettes, and one suggested broadening the proposed education program.

Comments also proposed additional sales restrictions on tobacco products, including stringent licensing requirements, increasing the age of sale to 19, and selling cigarettes in cartons only.

FDA rejects the comments suggesting that the agency intends to eventually ban all tobacco products, as the agency has repeatedly stated that such an outcome is not the appropriate public health response under the act. FDA is not proposing the additional restrictions on advertising or access suggested in the comments because FDA does not anticipate at this time that these additional measures will be required.

IX. Implementation Dates

The Food and Drug Administration (FDA) has concluded that the provisions of this rule should become effective 1 year after its date of publication in the Federal Register, with three exceptions. A 6-month effective date is established for the requirements in § 897.14(a) and (b) prohibiting retailers from selling cigarettes or smokeless tobacco to persons under age 18 and requiring retailers to check photographic identification of young purchasers for proof of age. The requirement in § 897.34(c) prohibiting sponsorships using cigarette or smokeless tobacco brand names or other indicia of product identification will be effective 2 years from the date of publication of this final rule. Finally, manufacturers will be required to comply with the registration and listing requirements in part 807, and the good manufacturing practice requirements in part 820, 2 years from the date of publication of this final rule.

Although the agency specifically requested comment on when the various provisions in the proposed rule should become effective, FDA received relatively few comments on this subject.

(1) One comment that opposed the rule argued that FDA should give industry an opportunity in a hearing to challenge the ''factual underpinnings''

of the rule before proceeding to implementation. In contrast, a supporting comment strongly favored immediate action to implement the rule, and a second comment stated that postponing implementation by even a year ''means that another 500,000 young people will become regular users of tobacco products.'' Another supporting comment recommended that the effective date for provisions that prohibit sales to persons under 18 be no more than 90 days from the date the final regulations are issued, and that the effective date for provisions affecting advertising and labeling be 6 months from the date the final regulations are issued.

FDA is not persuaded that a hearing is needed on the ''factual underpinnings'' of the rule. In the preamble to the 1995 proposed rule, the agency provided its rationale and evidentiary basis for each provision of the regulation; interested persons have had a full opportunity to submit their comments and any factual supporting data for the agency to consider. Informal notice and comment rulemaking does not require more. Moreover, the agency believes that there would be little to gain from holding such a hearing, and that this step would needlessly delay implementation of the final rule. Full responses to the challenges made by this and other comments on the factual bases for the rule are provided in this document.

Because FDA has found that thousands of children purchase cigarettes every day, the agency agrees with the supporting comments that restrictions on such sales should be put into effect as soon as possible. FDA recognizes, however, that the States also have laws restricting youth access to tobacco products, some of which may be preempted under section 521 of the act by this final regulation. The agency intends to allow sufficient time for applications for exemption from preemption to be requested, considered by the agency, and acted upon. Therefore, FDA has determined that § 897.14(a) and (b), which prohibit the sale of tobacco products to individuals under the age of 18 and require retailers to examine a photographic identification to ensure that the purchaser is at least 18 years of age, and is basic to the goals of this final rule, will become effective 6 months from the date of publication of this final rule in the Federal Register. This should allow adequate time for the agency to process the applications for exemption from preemption while not unduly delaying the implementation of a very important part of the regulation.

(2) As for the recommendation by one comment that the advertising and labeling provisions of the rule become effective 6 months after the final rule is issued, FDA believes that this period of time is not consistent with the agency's policy of allowing sufficient time for affected entities to learn about and comply with new regulatory requirements. Instead, based on its own experience and that of other Government agencies in regulating product advertising and labeling, FDA has arrived at a period of 1 year from the date of publication of this final rule in the Federal Register for manufacturers, distributors, and retailers to meet most of the requirements of the rule. In reaching this conclusion, FDA has taken into consideration the time needed to comply with all the requirements of the rule, including time for designing new labeling and advertising, for printing or filming these new materials, for affixing new product labels and disseminating new advertising materials, and for using up existing inventories of products, supplies of promotional materials, and coupons that do not comply with the new requirements.

Examples of activities that will become violative and must cease 1 year from the date of publication of this rule in the Federal Register include vending machine sales of cigarettes and smokeless tobacco and sales from self-service displays (except in the narrowly-defined locations that are exempted), sales of single cigarettes from opened packages (''loosies''), sales of packages with fewer than 20 cigarettes, mail-order redemption of coupons for tobacco products, distribution of free tobacco samples, and the sale or distribution of nontobacco items showing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern or colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Examples of additional requirements that must be met 1 year from the date of publication include all advertising requirements (except as noted below), and the requirement that manufacturers not use a trade or brand name of a nontobacco product on a cigarette or smokeless tobacco product except as specified in § 897.16(a).

The agency is excepting from the 1-year implementation period the requirement that manufacturers comply with the existing registration and listing requirements, found in part 807. The agency recognizes that manufacturers are not accustomed to complying with these recordkeeping and reporting requirements and will require additional time in which to develop appropriate compliance procedures. Therefore, FDA is granting manufacturers 2 years from the date of publication of this final rule to begin complying with the requirements under part 807. The same reasoning has led the agency to allow manufacturers the same 2-year-period to prepare before they are required to comply with the good manufacturing practice requirements in part 820.

Finally, the agency is also excepting from the 1-year implementation period the prohibitions in § 897.34 (c) of sponsorship using cigarette or smokeless tobacco brand names or other indicia of product identification. The agency recognizes that sponsorship of events is often arranged well in advance and that some event promoters may be disadvantaged if they are not allowed adequate time to replace tobacco sponsors who elect to cease sponsoring the event, rather than switch to their corporate name. Accordingly, this final rule provides that § 897.34(c) will become effective 2 years from the date of publication of this final rule.

X. Relationship Between the Rule and Other Federal and State Laws

This section of the document discusses issues concerning the relationship between this rule and other Federal and State laws. More specifically, sections X.A. and X.B. of this document analyze comments that addressed the potential effect upon this rule of other Federal statutes that contain express provisions that restrict some areas of Federal regulation of tobacco products. Section X.C. of this document analyzes comments that raised the issue of whether this rule conflicts with the congressional purpose behind the current regulatory scheme for tobacco products. Section X.D. of this document analyzes comments that addressed the issue of whether Congress intended for the current regulatory scheme for tobacco products to be exclusive, such that this rule might be foreclosed. Finally, sections X.E. and X.F. of this document analyze comments that addressed the preemptive effect under the Federal Food, Drug, and Cosmetic Act (the act) that the Food and Drug Administration's (FDA's) regulation of tobacco products as drug delivery devices will have upon

State and local requirements and upon State product liability claims.

A. The Federal Cigarette Labeling and Advertising Act

(1) A number of comments argued that FDA's August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) is precluded by section 5 of the Federal Cigarette Labeling and Advertising Act (the Cigarette Act (15 U.S.C. 1334)). Other comments expressed the opposite view, stating that 15 U.S.C. 1334 did not preclude the 1995 proposed rule. Some of the comments that found no preclusion noted that the scope of 15 U.S.C. 1334 is narrow, and applies only to cigarette packages, thereby allowing for regulation of cigarette advertising and promotion as contemplated by the 1995 proposed rule. After considering all of the comments, FDA has concluded that none of the rule's provisions, as embodied in the final rule, is expressly precluded by the Cigarette Act. The following analysis explains this conclusion.

The Cigarette Act contains the following provisions pertaining to regulation of cigarettes:

(a) No *statement relating to smoking and health*, other than the statement required by [15 U.S.C. 1333], shall be required on any *cigarette package*.

(b) No requirement or prohibition based on smoking and health shall be *imposed under State law* with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

(15 U.S.C. 1334 (emphasis added))

15 U.S.C. 1334(b) is expressly limited to requirements or prohibitions imposed under State law, that relate to advertising or promotion of cigarettes. Thus, 15 U.S.C. 1334(b) is inapplicable to FDA's regulation under part 897 and does not foreclose FDA from regulating cigarette advertising or promotion.

15 U.S.C. 1334(a), which applies to statements on the cigarette package, extends to both Federal and State regulation. However, the scope of 15 U.S.C. 1334(a) is narrow, precluding Federal and State regulation of cigarettes only to the extent that such regulation would require any statement (other than the statement required by 15 U.S.C. 1333) ''relating to smoking and health'' to appear on the cigarette package.

There are two types of information that the final rule requires on cigarette packages. The first is the ''established name,'' such as ''Cigarettes,'' which is required by section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), and which the agency is implementing under § 897.24. The established name requirement is applicable to all devices regulated under the act, and it serves merely to aid consumers in the identification of the product.

The second type of information that the final rule requires on cigarette packages is the statement of intended use and age restriction required under § 897.25. This statement informs consumers about the products' intended uses and that the products may not be sold to persons under the age of 18.

Neither the established name nor the statement of intended use and age restriction is ''relat[ed] to smoking and health.'' Any indirect relationship these requirements might have to smoking and health is incidental and would be too ''tenuous, remote, or peripheral'' to trigger preclusion under 15 U.S.C. 1334(a). (See *District of Columbia* v. *Greater Washington Bd. of Trade*, 113 S. Ct. 580, 583 n.1 (1992) (''Pre-emption does not occur * * * if the [law at issue] has only a 'tenuous, remote, or peripheral' connection with [the subject to which preemption is applicable], as is the case with many laws of general applicability'') (citations omitted).) To find otherwise could render the limiting language of 15 U.S.C. 1334(a) meaningless. (See *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995) (finding that overly broad construction of the phrase ''relate to'' ''would * * * read Congress's words of limitation as mere sham, and [would] read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality'').)

The agency notes that the established name requirement under § 897.24 is analogous to requirements imposed by the Bureau of Alcohol, Tobacco and Firearms (BATF) on cigarette packages. Under 26 U.S.C. 5723(b), ''[e]very package of tobacco products * * * shall * * * bear the marks, labels, and notices, if any, that the Secretary by regulation prescribes.'' Under this statutory provision, BATF has issued regulations requiring, for instance, that ''[e]very package of cigarettes shall * * * have adequately imprinted thereon, or on a label securely affixed thereto, the designation 'cigarettes', the quantity of such product contained therein, and the classification for tax purposes, i.e., for small cigarettes, either 'small' or 'Class A', and for large cigarettes, either 'large' or 'Class B'.'' (See 27 CFR 270.215.) In the same way that the requirement under 27 CFR 270.215 does not run afoul of 15 U.S.C. 1334 because it does not relate to smoking and health, the established name requirement under § 897.24 is also not precluded.

Further guidance on the scope of preclusion under the Cigarette Act can be found in the legislative history and purpose behind the Cigarette Act. The history and purpose make clear that Congress intended 15 U.S.C. 1334 to preclude only those ''statements'' that constituted warning or cautionary statements on cigarette packages. (See *Cipollone* v. *Liggett Group, Inc.*, 112 S. Ct. 2608, 2618–19 (1992) (finding that ''no statement relating to smoking and health'' language in 1965 version of the Cigarette Act referred to the sort of warning provided for in section 4 of that statute).)[253] (See also H. Rept. 449, 89th Cong., 1st sess. (1965), reprinted in 1965 U.S. Code Cong. & Admin. News 2350, 2350 (the Cigarette Act prohibits ''the requirement of any other caution statement on the labeling of cigarettes under laws administered by any Federal, State, or local authority'').)

Clearly, neither § 897.24 nor § 897.25 is a warning or cautionary statement of the type Congress intended to preclude under 15 U.S.C. 1334. Accordingly, the requirements under these sections of the final rule are not foreclosed by the Cigarette Act.

B. The Comprehensive Smokeless Tobacco Health Education Act

(2) Several comments noted that the 1995 proposed rule would prohibit advertisements for smokeless tobacco from appearing in certain locations and media. One comment stated that any prohibition on advertising under the 1995 proposed rule amounts to a ''compelled absence of advertising,'' and is as much a ''statement relating to the use of smokeless tobacco and health'' as is an explicit message requirement. Thus, the comment asserted that such restrictions are expressly precluded by the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act).

[253] Some of the comments take issue with FDA's application of Federal-State preemption law, pointing out that the Supremacy Clause and Tenth Amendment upon which this law is based have no application in determining the relationship between different Federal statutes. FDA is fully aware that Federal-State preemption law, as well as those cases such as *Cipollone* that apply it, do not directly govern the present situation concerning preclusion of Federal regulations by Federal law. However, the principles contained in Federal-State preemption law provide some general guidance for determining the scope of preclusion intended by Congress, regardless of whether that preclusion is directed at State or Federal law.

Another comment stated that FDA's proposed restrictions on the advertising of smokeless tobacco are foreclosed because they directly affect such advertising in a manner that is ''so nearly identical'' ''in purpose and effect'' to the advertising requirements mandated by the Smokeless Act that they fall within that statute's express prohibition of any other Federal ''statement'' related to smoking and health. In contrast, some comments stated the position that the 1995 proposed rule is not expressly precluded by the Smokeless Act.

After considering all comments, FDA has concluded that none of the 1995 proposed rule's provisions, with one exception, is expressly precluded by the Smokeless Act. The following analysis explains this conclusion.

The Smokeless Act contains the following provision pertaining to regulation of smokeless tobacco:

> No *statement relating to the use of smokeless tobacco and health*, other than the statements required by [15 U.S.C. 4402], shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(15 U.S.C. 4406(a) (emphasis added))

15 U.S.C. 4406(a) precludes only ''statement[s].'' Most requirements under the final rule, such as those that limit the locations or media in which smokeless tobacco may be advertised, do not constitute ''statements'' within the meaning of 15 U.S.C. 4406(a). (See *Banzhaf* v. *Federal Communications Commission*, 405 F.2d 1082 (D.C. Cir. 1968) (holding that the FCC ruling was not precluded by the Cigarette Act because the ruling did not require inclusion of any ''statement * * * in the advertising of any cigarettes''), *cert. denied*, 396 U.S. 842 (1969).) Thus, those sections of the final rule that limit the location or media in which smokeless tobacco may be advertised, as well as other requirements in the final rule that do not actually mandate an affirmative statement, are not expressly precluded by the Smokeless Act.

Only three sections of the final rule actually require inclusion of a ''statement'' on the packaging or in the advertising of smokeless tobacco. These sections are §§ 897.24, 897.25, and 897.32(c). In addition, proposed § 897.36, which is being omitted from the final rule for reasons discussed later in this section, would have required such a statement.

As with cigarettes, § 897.24 requires that packages of smokeless tobacco bear the products' established names. Section 897.25 mandates, in part, that packages of smokeless tobacco bear a statement of the products' intended uses and age restriction. Section 897.32(c) requires that advertising for smokeless tobacco include the products' established names and statements of their intended uses. (See section 502(r)(1) and (r)(2) of the act.)

For reasons similar to those discussed with regard to the Cigarette Act, none of the statements required under §§ 897.24, 897.25, and 897.32(c) are precluded under 15 U.S.C. 4406(a). (See section X.A. of this document.) First, the required statements do not directly ''relat[e] to the use of smokeless tobacco and health.'' Second, the required statements are not ''statements'' of the sort precluded by 15 U.S.C. 4406(a) because they do not convey any type of cautionary message or warning of the sort Congress intended to foreclose. Accordingly, the statements are not precluded by 15 U.S.C. 4406(a).

Proposed § 897.36 would have declared the labeling or advertising of cigarettes and smokeless tobacco to be false or misleading if it contained ''any express or implied false, deceptive, or misleading statement, omit[ted] important information, lack[ed] fair balance, or lack[ed] substantial evidence to support any claims made for the product.'' Upon review of the comments and reconsideration of this provision, FDA believes that, in some instances, manufacturers of smokeless tobacco might have been required under FDA's proposed rule to incorporate a statement relating to the use of smokeless tobacco and health on the package or in the advertising of a smokeless tobacco product in order to correct an omission of important information or a lack of fair balance. Similarly, cigarette manufacturers might have been required to include a statement relating to smoking and health on the cigarette package. Such requirements would be precluded under the Smokeless Act or the Cigarette Act. Thus, FDA has omitted § 897.36 from the final rule.

The agency notes, however, that tobacco products, like other products regulated under the act, are still subject to section 502(a) of the act, which provides, in part, that a device shall be deemed to be misbranded ''[i]f its labeling is false or misleading in any particular.'' Any requirement imposed under section 502(a) of the act upon tobacco products is limited, however, to the extent that it is precluded by the Smokeless Act or the Cigarette Act.

C. Conflict With Congressional Purpose Behind Current Regulatory Scheme For Tobacco Products

A number of comments asserted that the 1995 proposed rule conflicts with other Federal statutes that regulate tobacco products. These comments focused on three specific statutes: The Cigarette Act, the Smokeless Act, and the Public Health Service Act (the PHS Act)

1. The Cigarette Act and The Smokeless Act

(3) A number of comments argued that the 1995 proposed rule would conflict with, and would nullify, some of the congressional objectives behind the Cigarette Act and the Smokeless Act. Based on the alleged conflict, some of the comments asserted that the general provisions of the act must give way to the specific provisions of the Cigarette Act and the Smokeless Act.

FDA disagrees. As explained in sections X.A. and X.B. of this document, FDA regulation of tobacco products under the authority of the act does not conflict with the Cigarette Act or the Smokeless Act, and thus such regulation is clearly capable of coexisting with these statutes. (See *Connecticut National Bank* v. *Germain*, 112 S. Ct. 1146, 1149 (1992) (''so long as there is no 'positive repugnancy' between two laws, a court must give effect to both'') (citation omitted); *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974) (''The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective'').)

The comments asserted a number of areas in which the 1995 proposed rule would allegedly conflict with Federal law and congressional intent:

(4) Numerous comments argued that the 1995 proposed rule is precluded because Congress, through enactment of the Cigarette Act and the Smokeless Act, intended to foreclose all Federal agencies other than the Federal Trade Commission (FTC) and the Federal Communications Commission (FCC) from regulating the labeling and advertising of tobacco products. Some of the comments criticized the 1995 proposed rule, asserting that it would cause tobacco product manufacturers to be held to separate and conflicting standards of conduct by different agencies, thus conflicting with congressional intent to prevent ''diverse, nonuniform, and confusing cigarette

labeling and advertising regulations.'' As a specific example of potential separate and conflicting Federal standards, some of the comments noted that proposed § 897.34 would completely prohibit the use of some promotional items that are exempted by FTC from the congressionally mandated warning under the Cigarette Act.

FDA disagrees with these comments. When Congress enacted the Cigarette Act and the Smokeless Act, it very carefully considered the proper scope of preclusion applicable to Federal agencies in the regulation of tobacco products. The express terms of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a) clearly reflect the full scope of preclusion of Federal agencies intended by Congress.

Had Congress believed more preclusion to be necessary, it could have easily expanded the express scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a). (See *Banzhaf*, 405 F.2d at 1089 (Had Congress intended to foreclose other types of Federal regulation, ''it might reasonably be expected to have said so directly—especially where it was careful to include a section entitled 'Preemption' specifically forbidding designated types of regulatory action''); *Central Bank of Denver* v. *First Interstate Bank*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).) Indeed, Congress took this very approach with respect to the scope of preemption applicable to States under the Cigarette Act when it drafted 15 U.S.C. 1334(b) in a broad manner to encompass ''requirement[s]'' and ''prohibition[s].''

The discrepancy in Congress' choice of words with regard to the scope of 15 U.S.C. 1334(a) and (b) is significant in its implications. By not including ''requirement or prohibition'' in 15 U.S.C. 1334(a) and expressly foreclosing only ''statements'' relating to smoking and health, Congress clearly intended to narrowly limit the scope of foreclosure of regulation applicable to Federal agencies. (See *Brown* v. *Gardner*, 115 S. Ct. 552, 556 (1994) (''[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion'') (citation omitted).) In a similar fashion, Congress demonstrated an intent to restrict the scope of Federal preclusion under 15 U.S.C. 4406(a) by narrowly tailoring the language of that subsection.

Thus, given the narrow scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), the Cigarette Act and the Smokeless Act do not foreclose ''separate'' Federal requirements, other than cautionary health-based statements as discussed in sections X.A. and X.B. of this document. Although the final rule imposes requirements on tobacco product manufacturers, these requirements do not conflict with the Cigarette Act or the Smokeless Act and, consequently, are not precluded by those statutes. Moreover, that FTC might allow certain actions under its statutory mandate does not preclude FDA from prohibiting such actions under a different statutory mandate. (See *New York Shipping Ass'n* v. *Federal Maritime Comm'n*, 854 F.2d 1338, 1367 (D.C. Cir. 1988) (''there is no anomaly if conduct privileged under one statute is nonetheless condemned by another''), *cert. denied*, 488 U.S. 1041 (1989).)

(5) Some of the comments asserted that Congress intended that the sole health-based restraints that were to be imposed on the commerce of tobacco products were to be those provided in the Cigarette Act and the Smokeless Act.

FDA disagrees with this assertion. First, FDA clearly may exercise legal authority to regulate tobacco products when the evidence establishes that the products have intended uses that fall within the act's definition of a ''drug.'' Indeed, the agency has done so in several instances. (See, e.g., *United States* v. *354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States* v. *46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338–39 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease).) Moreover, the comments' assertion that health-based constraints can be imposed upon tobacco products only under the Cigarette Act and the Smokeless Act necessarily leads to the erroneous conclusion that much Federal and State regulation, such as health-based workplace smoking restrictions and health-based age limits on access, is foreclosed. As other comments recognized, Congress obviously did not intend for such broad preclusion to be the case. (See *Banzhaf*, 405 F.2d at 1089 (finding that ''[n]othing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation'').)

(6) Some comments asserted that FDA's proposed restrictions on certain advertising for tobacco products are at odds with congressional intent to allow the continued use of advertising for these products in conjunction with the statutorily required warnings.

FDA disagrees. As discussed in sections X.A. and X.B. of this document, preclusion of Federal regulation of advertising for tobacco products is very narrow in scope and does not encompass FDA's final rule. Moreover, as one court has noted:

> [T]here is no anomaly if conduct privileged under one statute is nonetheless condemned by another; we expect persons in a complex regulatory state to conform their behavior to the dictates of many laws, each serving its own special purpose.

(New York Shipping Ass'n, 854 F.2d at 1367)

Thus, the mere fact that certain advertising for tobacco products is permitted under the current regulatory scheme for those products does not preclude FDA from placing restrictions on such advertising.

(7) Some comments alleged that the 1995 proposed rule would conflict with Federal law and congressional intent because it would have an impact on the commerce of tobacco products.

FDA disagrees. Any proscriptive regulation of tobacco products inevitably imposes economic burdens upon commerce of those products. Thus, following the comments' line of argument, all proscriptive regulation of cigarettes is foreclosed by the Cigarette Act and the Smokeless Act. As explained in this section, however, by enacting 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), Congress chose the proper level of limitation on Federal regulations that it concluded was necessary to protect the commerce of tobacco products from being unduly economically burdened. Because requirements contained in the final rule are not precluded under those provisions, the fact that the requirements will have economic consequences upon the commerce of tobacco does not mean those requirements are foreclosed.

(8) One comment argued that the 1995 proposed rule is precluded because Congress could not have intended for any agency to have the authority to prohibit the sale of cigarettes. The comment derived this ''intent'' from pieces of legislation enacted by Congress that provide for the regulation of specific aspects of cigarettes but do not prohibit their sale.

FDA disagrees. Enactment of legislation giving other agencies authority over particular aspects of