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Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801, et al.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, 807, 820, and 897

[Docket No. 95N–0253]

RIN 0910–AA48

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents.

The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples and prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

These regulations will address the serious public health problems caused by cigarettes and smokeless tobacco products. They will reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and will significantly decrease the amount of positive imagery that makes these products so appealing to that age group.

The regulations are predicated on the agency's assertion of jurisdiction under the Federal Food, Drug, and Cosmetic Act over cigarettes and smokeless tobacco as delivery devices for nicotine, incorporated as part of the regulations for purposes of, and to facilitate, congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996.

DATES: *Effective date.* The regulation is effective August 28, 1997, except that § 897.14(a) and (b) are effective February 28, 1997 and § 897.34(c) is effective February 28, 1998.

Compliance dates. Manufacturers and distributors are required to comply with the requirements of 21 CFR parts 803 and 804 August 28, 1997; manufacturers are required to comply with the requirements of 21 CFR parts 807 and 820 February 28, 1998.

ADDRESSES: References listed in the footnotes of this document have been placed on public display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy Yeates, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0867.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Introduction

A. Purpose and Overview of the Rule

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing FDA's determination that it has jurisdiction over these products under the Federal Food, Drug, and Cosmetic Act (the act). As described in ''Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination'' (the 1996 Jurisdictional Determination), annexed hereto, FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of ''drug'' and ''device.'' The nicotine in cigarettes and smokeless tobacco is a ''drug,'' which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.

FDA has chosen to regulate cigarettes and smokeless tobacco under the act's device authorities. This rule allows the continued marketing of these products, while employing measures to prevent future generations of Americans from becoming addicted to them. As discussed in section I.B. of this document, most people who use cigarettes and smokeless tobacco begin their use before the age of 18 and, therefore, before they fully understand the addictive nature and serious health risks of these products. Even though the sale of tobacco products to minors is illegal in 50 States, the tobacco industry has adopted extensive marketing campaigns which appeal to children and adolescents. Therefore, the rule effects measures that would both complement the existing State restrictions on access and prevent

tobacco companies from marketing their products to children and adolescents.

In determining the best course of action, the agency considered the highly addictive nature of cigarettes and smokeless tobacco and the fact that these products have previously been lawfully marketed to millions of adult Americans. The agency has determined that the approach outlined in this document—restrictions to reduce the use of cigarettes and smokeless tobacco by individuals under the age of 18 while leaving these products on the market for adults—is the available option that is the most consistent with both the act and the agency's mission to protect the public health.

The agency intends to assist affected entities, including retailers, distributors, and manufacturers, in complying with the rule. The agency also will issue a small entities guide in easy to understand language. In addition, the agency will conduct workshops throughout the country to assist affected entities in complying with the rule.

B. Background

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco.[1] In the Federal Register of August 11, 1995 (60 FR 41314), FDA published a proposed rule entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (the 1995 proposed rule). As stated in the preamble to the 1995 proposed rule, tobacco use is the single leading cause of preventable death in the United States.[2] More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths.[3] Tobacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.[4]

Tobacco products have historically been legal and widely available in this country. It was only after millions of people became addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has become one of the most serious public health problems facing the United States today. Because of the grave health consequences of the use of tobacco products, some have argued that they should be removed from the market.

However, a ban would have adverse health consequences and would not be likely to prevent individuals from gaining access to these products. Of the 50 million people who use cigarettes, 77 to 92 percent are addicted.[5] Data suggest that almost as many smokeless tobacco users may be addicted.[6] Adverse health consequences could result if these people were suddenly deprived of the nicotine these products deliver. As stated in the preamble to the 1995 proposed rule:

> Because of the high addiction rates and the difficulties smokers experience when they attempt to quit, there may be adverse health consequences for many individuals if the products were to be withdrawn suddenly from the marketplace. Our current health care system and available pharmaceuticals may not be able to provide adequate or sufficiently safe treatment for such a precipitous withdrawal.

(60 FR 41314 at 41348)

A similar situation would exist for addicted smokeless tobacco users.

It is probable also that a black market and smuggling would develop to supply addicted users with these products. As stated in the preamble to the 1995 proposed rule, and discussed further in section II.C.5. of this document, ''[t]he products that would be available through a black market could very well be more dangerous (e.g., cigarettes containing more tar or nicotine, or more toxic additives) than products currently on the market'' (60 FR 41314 at 41349). Thus, the agency has concluded that, while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others, the record does not establish that such a ban is the appropriate public health response under the act.

To effectively address the death and disease caused by tobacco products, addiction to cigarettes and smokeless tobacco must be eliminated or substantially reduced. The evidence demonstrates that this can be achieved only by preventing children and adolescents from starting to use tobacco. Most people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin their use before they reach the age of 18, an age when they are not prepared for, or equipped to, make a decision that, for many, will have lifelong consequences. These young people do not fully understand the serious health risks of these products or do not believe that those risks apply to them. They are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence. When cigarette and smokeless tobacco use by children and adolescents results in addiction, as it so often does, these youths lose their freedom to choose whether or not to use the products as adults.

The facts on underage use confirm this pattern. As stated in the preamble to the 1995 proposed rule, approximately 3 million American adolescents currently smoke and an additional 1 million adolescent males use smokeless tobacco.[7] Eighty-two percent of adults who ever smoked had their first cigarette before the age of 18, and more than half of them had already become regular smokers by that age.[8] Among smokers ages 12 to 17 years, 70 percent already regret their decision to smoke and 66 percent say that they want to quit.[9]

Moreover, children and adolescents are beginning to smoke at younger ages than ever before. Despite a decline in smoking rates in most segments of the American adult population, the rates among children and adolescents have recently begun to rise.[10] Data reported

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[1] ''National Household Survey on Drug Abuse: Population Estimate 1993, Department of Health and Human Services (DHHS), Public Health Service (PHS), Substance and Mental Health Services Administration (SAMHSA), Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94–3017, pp. 89 and 95, 1994.

[2] ''Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990,'' *Mortality and Morbidity Weekly Report*, (MMWR) CDC, DHHS, vol. 42, No. 33, pp. 645–649, 1993; Lynch, B. S., and R. J. Bonnie, editors, *Growing Up Tobacco Free—Preventing Nicotine Addiction in Children and Youths*, Committee on Preventing Nicotine Addiction in Children and Youths, Division of Biobehavioral Sciences and Mental Disorders, Institute of Medicine, National Academy Press, Washington, DC, p.3, 1994, (hereinafter cited as ''IOM Report'').

[3] ''Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990,'' *MMWR*, CDC, DHHS, vol. 42, No. 33, pp. 645–649, 1993.

[4] IOM Report, pp. 3–4.

[5] See authorities cited at 1996 Jurisdictional Determination, Section II(B)(2)(a).

[6] *Id.*

[7] ''Preventing Tobacco Use Among Young People: A Report of the Surgeon General,'' DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, the Office on Smoking and Health (OSH), Atlanta, GA, p. 5, 1994, (hereinafter cited as ''1994 SGR'').

[8] 1994 SGR, p. 65.

[9] ''Teen-Age Attitudes and Behavior Concerning Tobacco,'' The George H. Gallup International Institute, p. 54, September 1992.

[10] ''Cigarette Smoking Among Adults—United States, 1991,'' *MMWR*, DHHS, CDC, vol. 42, No. 12,

in December 1995, after publication of the 1995 proposed rule, showed increases in 30-day prevalence rates of cigarette smoking for 4 consecutive years for 8th- and 10th-graders, and 3 consecutive years for high school seniors. [11] Daily use of cigarettes by 8th-, 10th-, and 12th-graders has also increased in each of the last 3 years. [12] The percentage of 8th- and 10th-graders who reported smoking in the 30 days before the survey had risen by one-third since 1991 to about 19 percent and 28 percent, respectively. [13] Similarly, the percentage of high school seniors saying that they had smoked in the 30 days before the survey had increased by more than one-fifth since 1991, to about 33.5 percent or one in three. [14]

An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease. [15] Moreover, the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking. [16] Approximately one out of every three young people who become regular smokers each day will die prematurely as a result. [17]

Similar problems exist with underage use of smokeless tobacco. As stated in the 1995 proposed rule, the market for smokeless tobacco has shifted dramatically toward young people since 1970 (60 FR 41314 at 41317). School-based surveys in 1991 estimated that 19.2 percent of 9th to 12th-grade boys use smokeless tobacco. [18] Among high school seniors who had ever tried smokeless tobacco, 73 percent did so by the 9th grade. [19]

As long as children and adolescents become addicted to cigarette and smokeless tobacco use in these numbers, there is little chance that society will be able reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin. [20]

On the basis of this evidence, the agency has determined that establishing restrictions to substantially reduce the number of children and adolescents who become addicted to cigarettes and smokeless tobacco best serves its public health obligations. Because such a small percentage of the U.S. population begins tobacco use after the age of 18, limiting the use of these products to the adult population would substantially reduce the principal source of new users. Thus, the appropriate emphasis is on reducing the use of tobacco products by children and adolescents.

Evidence in the administrative record demonstrates that the most effective way to achieve such a reduction is by limiting the access to, and attractiveness of, cigarettes and smokeless tobacco to young people. FDA concludes that the act provides sufficient authority to issue regulations that, while leaving these products on the market for adult use, restrict access to and promotion of cigarettes and smokeless tobacco to those under 18 years of age.

C. Provisions of the Rule

After considering numerous comments submitted in response to the 1995 proposed rule, the agency is adopting the rule in modified form. New part 897 is being added to Title 21 of the Code of Federal Regulations and contains the regulations governing the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco to children and adolescents.

FDA is regulating nicotine-containing cigarettes and smokeless tobacco as restricted devices within the meaning of the section 520(e) of the act (21 U.S.C. 360j(e)). While leaving these products on the market for adults, the final rule prohibits the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits all free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. In addition, billboards and other outdoor advertising are prohibited within 1,000 feet of schools and public playgrounds. The rule also prohibits the sale or distribution of brand-identified promotional, nontobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name. This rule is intended to complement the regulations issued by SAMHSA implementing section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) regarding the sale and

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pp. 230–233, 1993; Johnston, L. D., P. M. O'Malley, and J. G. Bachman, ''National Survey Results on Drug Use from the Monitoring the Future Study 1975–1993, vol. I: Secondary School Students,'' Rockville, MD, DHHS, PHS, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, pp. 9 and 19, 79, 80, and 101, 1994; ''Smoking Rates Climb Among American Teen-agers, Who Find Smoking Increasingly Acceptable and Seriously Underestimate the Risks,'' The University of Michigan News and Information Service, Table 1., July 17, 1995.

[11] ''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.

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] McGinnis, J. M., and W. H. Foege, ''Actual Causes of Death in the United States,'' *Journal of the American Medical Association (JAMA),* vol. 270, No. 18, pp. 2207–2212, 1993; ''Reducing Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General,'' DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), OSH, DHHS Pub. No. 89–8411, p. 5, 1989, (hereinafter cited as ''1989 SGR''); See generally ''The Health Consequences of Smoking: Chronic Obstructive Lung Disease: A Report of the Surgeon General,'' DHHS, PHS, OSH, 1984, (hereinafter cited as ''1984 SGR''); ''The Health Consequences of Smoking: Cardiovascular Disease—A Report of the Surgeon General,'' DHHS, PHS, OSH, 1983 (hereinafter cited as ''1983 SGR''); ''The Health Consequences of Smoking: Cancer—A Report of the Surgeon General,'' DHHS, PHS, OSH, 1982, (hereinafter cited as ''1982 SGR'').

[16] Taioli, E., and E. L. Wynder, ''Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood,'' *The New England Journal of Medicine,* vol. 325, No. 13, pp. 968–969, 1991; Escobedo, L. G., et al. ''Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among U.S. High School Students,'' *JAMA,* vol. 269, No. 11, pp. 1391–1395, 1993; see also 1994 SGR, p. 65.

[17] Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet (based on J. P. Pierce, M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, ''Trends in Cigarette Smoking in the United States: Projections to the Year 2000,'' *JAMA,* vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., ''Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from National Vital Statistics,'' Oxford University Press, Oxford, 1994).

[18] Kann, L., W. Warren, J. L. Collins, J. Ross, B. Collins, and L. J. Kolbe, ''Results from the National School-Based 1991 Youth Risk Behavior Survey and Progress Toward Achieving Related Health Objectives for the Nation,'' *Public Health Reports,* vol. 108, (Supp. 1), pp. 47–54, 1993.

[19] 1994 SGR, p. 101.

[20] *Id.,* pp. 5, 58, and 65–67.

distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule).

In this document, FDA: (1) Presents its analysis of its authority to issue regulations that impose the enumerated restrictions on the sale and promotion of cigarettes and smokeless tobacco to those under the age of 18, while leaving cigarettes and smokeless tobacco on the market for adults; and (2) responds to comments on the proposed rule.

II. Legal Authority

In the 1996 Jurisdictional Determination, annexed hereto, the Food and Drug Administration (FDA)[21] has determined that cigarettes and smokeless tobacco are combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body. The agency may regulate a drug/device combination product using the Federal Food, Drug, and Cosmetic Act's (the act's) drug authorities, device authorities, or both. The agency exercises its discretion to determine which authorities to apply in the regulation of combination products to provide the most effective protection to the public health. FDA has determined that tobacco products are most appropriately regulated under the device provisions of the act, including the restricted device authority in section 520(e) of the act (21 U.S.C. 360j(e)).

A. Legal Principles Applicable to Combination Drug/Device Products

The agency's discretion to choose the appropriate regulatory tools under the act is based, in part, on the authority provided under the Safe Medical Devices Act of 1990 (the SMDA). FDA's interpretation, supported by the language of the statute and its legislative history, is embodied in the agency's implementing regulations codified at part 3 (21 CFR part 3), the delegations of premarket approval authority to FDA's Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER) that enable all three Centers to administer statutory authority for drugs, devices, and biologics (56 FR 58758, November 21, 1991), and the ''intercenter agreements'' that guide the agency in allocating Center responsibility for various categories of combination products (56 FR 58760, November 21, 1991). In addition to the authority provided by the SMDA, the agency's discretion is also based on the principles recognized by the Supreme Court in cases such as *United States* v. *An Article of Drug * * * Bacto-Unidisk*, 394 U.S. 784 (1969). In *Bacto-Unidisk*, for example, the Supreme Court upheld the agency's decision to regulate a diagnostic test kit under its drug authorities on the grounds that ''[i]t is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health * * *.'' (*Bacto-Unidisk* 394 U.S. at 791–792.)

The discussion that follows describes in more detail FDA's interpretation of the combination product provisions of the SMDA, the agency's understanding of combination products, and the way in which the agency has exercised its discretion in determining the most appropriate authorities to apply to regulate combination products.

1. The SMDA Recognized Combination Products for the First Time

Congress enacted the SMDA's combination product provisions to recognize combination products as distinct entities subject to regulation under the act and to alleviate the difficulty the agency had experienced in regulating such products, especially those consisting of components of both a drug and a device. First, the SMDA explicitly recognized the existence of products that ''constitute a combination of a drug, device, or biological product'' (section 503(g)(1) of the act (21 U.S.C. 353(g)(1))). Second, the statute provided a mechanism for determining which agency component would be assigned the administrative responsibility of regulating a particular combination product (*Id.*).

In accordance with its recognition of combination products, the SMDA changed the statutory definitions of ''drug'' and ''device'' at section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)). Before the enactment of the SMDA, section 201(g) of the act provided that a drug ''does not include devices or their components, parts, or accessories.'' The SMDA removed this language from the definition of ''drug'' so that the terms ''drug'' and ''device'' were no longer mutually exclusive, thereby making it possible for a combination product consisting of both a drug and device to be regarded as an independent entity subject to regulation. The legislative history indicates that this definitional change was made ''to accommodate the principle of [combination products in] section 20'' (S. Rept. 101–513, 101st Cong. 2d sess., at 30 (1990)). For the first time it was possible, as a legal matter, for a single product to have both drug and device components.

The SMDA also permitted a wider range of products to meet the definition of a device. Prior to its amendment by the SMDA, section 201(h) of the act defined a ''device'' as an instrument or other item that, among other things, ''does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.'' The SMDA changed the phrase ''any of its principal intended purposes'' in the definition to read, ''its primary intended purposes.'' This change broadened the definition of device and allowed more products to be categorized as devices.

2. The SMDA Leaves to FDA's Discretion the Determination of Which Regulatory Authorities to Apply to Particular Combination Products

Having recognized combination products, the SMDA also provided a clear mechanism for determining which agency component a particular combination product should be directed to for review. Under the SMDA, the agency must:

> [d]etermine the primary mode of action of the combination product. If the [agency] determines that the primary mode of action is that of—
>
> (A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,
>
> (B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or
>
> (C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(Section 503(g)(1) of the act)

This section of the SMDA ''provide[d] the [agency] with firm ground rules to direct products promptly to that part of FDA responsible for reviewing the article that provides the primary mode of action of the combination product'' (S. Rept. 101–513, 101st Cong., 2d sess., 30 (1990)).

Although the SMDA provided a mechanism for determining which agency component, i.e., a Center, should review a particular combination product, the legislation left to FDA the discretion to decide which statutory authorities it would use in regulating a particular combination product. The

[21] The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) has the authority to carry out functions under the act through the Commissioner of Food and Drugs (the Commissioner). (See section 903 of the act (21 U.S.C. 393); 21 CFR 5.10 and 5.11.) Throughout this document, references to FDA include the Secretary and the Commissioner.

language of the SMDA makes this clear, as does the legislative history of the statute. Indeed, an earlier version of the bill, S. 3006, would arguably have removed this discretion by requiring the agency to regulate a product based only on its Center assignment. Thus, for example, if the primary mode of action were that of a drug, the product would be subject to regulation by CDER under the act's drug authorities. The earlier version's language, which Congress chose to strike from the final enactment, provided in relevant part:

> The [agency] shall require only one market clearance route for an article that constitutes a combination of a device, drug, or biological product. If the [agency] determines that the primary mode of action of the combination article is that of—
>
> (A) a drug (other than a biological product), neither the combination article nor any part of the article shall be treated as a device or as a biological product for market clearance purposes;
>
> (B) a device, neither the combination article nor any part of the article shall be treated as a drug or a biological product for market clearance purposes; or
>
> (C) a biological product, neither the combination article nor any part of the article shall be treated as a drug or a device for market clearance purposes.

(136 Congressional Record, S.12493, 101st Cong., 2d sess., August 4, 1990)

The omission of this language from the statute indicates that while Congress considered dictating which regulatory authority must be applied to particular combination products, and knew how to craft language to accomplish such a result, Congress ultimately chose to rely on FDA's expertise in determining the most appropriate regulatory tools needed to ensure the safety and effectiveness of the combination products that it regulates.

Moreover, Congress enacted language that recognizes that the agency may choose the appropriate regulatory authority for a particular combination product. Section 503(g)(2) of the act provides that nothing ''shall prevent the [Agency] from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.'' Since the enactment of the SMDA, the agency has interpreted the phrase ''any agency resources'' to include administrative resources and all applicable statutory authorities. See Drug/Device Intercenter Agreement, p. 2, contemporaneous interpretation that:

> [u]nder the provisions of the Safe Medical Devices Act of 1990 and regulations promulgated to implement the combination product provisions of the Act, [the Center for Drug Evaluation and Research] and [the Center for Devices and Radiological Health] each may use both the drug and device provisions of the Federal Food, Drug, and Cosmetic Act as appropriate to regulate a combination product.

(See 21 CFR Part 3).

(See also 56 FR 58754 at 58759, November 21, 1991 (FDA amending its procedural regulations at part 5 by adding delegations of authority relating to the premarket review of combination products to state that those specified officials in CBER, CDRH, or CDER ''who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products: * * *'' (21 CFR 5.33).) Thus, when a combination product, a single entity, consists of a component that may be regulated as a drug, the act's drug provisions and device provisions are ''resources'' available to the agency for regulating the product.

(1) One comment disputed the agency's interpretation of section 503(g)(2) of the act, stating that the language of section 503(g)(2) can be construed to mean only ''people, laboratories, and other agency support. The term 'Agency resources' does not mean 'legal authorities' as FDA would like to believe.''

FDA disagrees with this comment. The agency notes that there is nothing in the statute itself or the legislative history that suggests any reason that the expansive phrase ''any FDA resources'' should be narrowly interpreted given the important public health benefit (''ensuring an adequate premarket review'') that is the goal of this section of the SMDA. The agency's interpretation of this language is supported by the SMDA's legislative history, which is discussed more fully in section II.A.2. of this document. More importantly, as discussed previously, the agency has the discretion under the statute as enacted to choose the regulatory authorities most appropriate to the specific product at issue.

3. Interpreting the SMDA to Allow the Agency to Determine Which Regulatory Scheme Best Serves the Public Health is Consistent With 50 Years of Case Law

Construing the act as allowing the agency discretion to choose the most appropriate regulatory tools for a particular combination product is consistent with over 50 years of judicial precedent. The importance of interpreting the act in a manner that is consistent with the public health purposes of the act was recognized by the Supreme Court in *United States* v. *Dotterweich*, 320 U.S. 277 (1943). This case, decided shortly after substantial changes were made to expand the agency's authority by the 1938 act, addressed the breadth of the term ''person'' in determining who was subject to prosecution for violations of the act. The Court described the spirit in which the statute should be interpreted:

> By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

(*Id*. at 280)

The approach in *Dotterweich* was followed by a number of cases in which FDA's interpretation of the statute, especially in the area of selecting how to regulate a product to achieve a public health purpose, has been granted deference and has been upheld. In *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784 (1969), FDA's interpretation of the definition of the term ''drug'' and the applicability of the premarket review requirements were at issue. The Court upheld the agency's expansive interpretation of the definition of ''drug'' to include a laboratory screening product, in large part because this interpretation resulted in greater protection of the public health by virtue of the premarket review that the product would be subject to as a drug. As the Court reasoned:

> It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment.

(*Bacto-Unidisk*, 394 U.S. at 791–792)

The Court further stated:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow * * *. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is

to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with 'efficacy' and 'safety.'

(*Id.* at 798); (See also *U.S.* v. *25 Cases, More or Less, of An Article of a Device, * * * Sensor Pads*, 942 F.2d 1179 (7th Cir. 1991) (upholding FDA's determination that a latex bag filled with a layer of silicone lubricant that was intended to aid women in self-examinations for early detection of breast cancer was a device, because, among other reasons, the court deferred to the agency's discretion to interpret its own statute based on the legislative history of the act and on the principles announced in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); *AMP, Inc.* v. *Gardner*, 389 F.2d 825, 830 (2d Cir.), *cert. denied, sub nom. AMP, Inc.* v. *Cohen*, 393 U.S. 825 (1968) (upholding FDA's classification of appellant's product for tying off severed blood vessels as a drug because, in part, the court was reluctant to give a narrow construction to the act, ''touching the public health as it does'').)

These cases stand for two principles: (1) FDA's interpretations of its own statute should be given deference, and (2) the act should be interpreted expansively to achieve its primary purpose, protecting the public health. These principles support the agency's determinations, carefully made after applying its considerable scientific expertise to the evaluation of the evidence before it, that cigarettes and smokeless tobacco are drug delivery devices and that these combination products are most appropriately regulated using the device authorities of the act. The agency's decision regarding tobacco products is consistent with other determinations that the agency has made, which have been upheld and endorsed by the courts, to regulate products in the most reasonable manner that will result in the best protection of the public health.

4. The Implementing Regulations and the Delegations of Authority Reflect FDA's Interpretation That Section 503(g) of the Act Authorizes the Agency to Determine the Appropriate Regulatory Authorities

FDA's implementing regulations and delegations of authority, adopted shortly after passage of the SMDA, reflect the agency's contemporaneous interpretation of section 503(g) of the act as authorizing the agency to apply the most appropriate regulatory authorities to any given combination product. In § 3.2(e)(1), FDA defined a combination product to include, in relevant part:

> A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity[.]

In a final rule that published in the Federal Register of November 21, 1991 (56 FR 58754), the agency explained that ''the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic * * *'' or that are produced together as a single entity, packaged together, or used together to achieve the intended effect. Thus, the fact that a single product contains elements of two or more regulated entities does not change the regulatory status of the individual elements. Each ''different regulated entit[y]'' of the combination continues to satisfy the criteria of its relevant statutory definition; that is, a drug component must satisfy the definition in section 201(g) of the act, and a device component must comply with the definition in section 201(h) of the act. Because the elements of a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to the product.

In the same issue of the Federal Register in which the agency published the final regulations governing combination products, the agency published delegations of authority that allow the officials in CDER, CDRH, and CBER to utilize the premarket approval authorities for any product that is a drug, device, biologic, or any combination of two or more of these (56 FR 58758, November 21, 1991 (21 CFR 5.32)). These delegations allow the officials of one Center to conduct a premarket review of a product under another Center's regulatory authority, thereby making it possible, for example, for CDER to review a drug/device combination product under the device authorities. While the combination product regulations created the procedure for making the proper Center assignment, the delegations were necessary in order for FDA to exercise its discretion to determine which regulatory authority is most appropriate and to make it possible to apply that authority to review a particular product. If the primary mode of action of a combination product having drug and device components resulted in the assignment of the product to CDER, for example, but the agency determined that the device component of the product presented the most important regulatory and scientific questions, the delegations make it possible for CDER officials to conduct the premarket review of the product under the device provisions of the act.

The regulations and the delegations of authority constitute the agency's contemporaneous interpretation of section 503(g) of the act as granting the agency discretion to choose the premarket approval authority that provides the best public health protection. Such contemporaneous interpretations by an agency are entitled to considerable deference by the courts. (See *Young* v. *Community Nutrition Institute*, 476 U.S. 974 (1986).)

5. The Intercenter Agreements and Administrative Precedent Recognize That FDA May Determine Which Regulatory Authority to Apply to a Particular Product

In addition to the regulations and delegations of authority implementing section 503(g) of the act, FDA has also adopted and made public three guidance documents, entitled ''Intercenter Agreements,'' that describe the agreements reached among the Centers about regulatory pathways for specified products or classes of products as of October 31, 1991. (See Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health; Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the Drug/Device Agreement); and Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.)

These documents detail which Center generally will have the lead responsibility for regulating particular types of products. The Intercenter Agreements also state which regulatory authority usually will be applied to specific products. For example, the Drug/Device Agreement provides that a device with the primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., ''prefilled delivery system'') will be regulated by ''CDER using drug authorities and device authorities, as necessary'' (Drug/Device Agreement, p. 6). Examples given of such combination products include a nebulizer, prefilled syringe, and transdermal patch (Drug/Device Agreement, p. 6). The Drug/Device Agreement specifically provides that such combination products may be regulated under either the drug or

device authorities, whichever is more appropriate for a particular product.[22]

FDA's implementation of the Intercenter Agreement reflects these understandings. For example, one drug delivery product that has been regulated under the device authorities under the Drug/Device Agreement is the prefilled, intravenous infusion pump, manufactured by two companies. These are pumps designed to be sold prefilled with a diluent, either a sodium chloride solution or a dextrose solution. FDA regulates the diluents in the pumps as drugs under section 201(g)(1)(B) of the act because they are intended for use in the treatment of disease. The pumps are combination products consisting of a device component, the pump, and a drug component, the diluent; and the product's purpose is to deliver the diluent to be mixed by the doctor or other health care provider attending the patient with another drug substance for infusion into the patient. These pumps prefilled with diluents are clearly ''a device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose'' that would be regulated as a drug according to the general principle stated in the Drug/Device Agreement (Drug/Device Agreement, p. 14). However, the agency exercised its discretion and determined that these drug delivery products should be regulated under the device authorities.

The agency based its determination on the fact that the drugs that were delivered by the products, saline and dextrose, are two ingredients very commonly used in intravenous infusions about which the agency had a wealth of scientific information and thorough regulatory experience. The pumps, the device component of this combination, however, operated on novel design principles. Because the device components of these combination products were new and raised significant regulatory questions, the agency determined that the products would receive the most appropriate premarket review if the device authorities were applied.

[22] A later section of the Drug/Device Agreement states that a ''device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated as a drug by CDER.'' While this is the approach that FDA will usually take with such products, the earlier language of the Drug/Device Agreement expressly recognizes that FDA may use its device authorities where appropriate, and as discussed in the text, there are several examples of this type of prefilled delivery system being regulated using the device authorities.

Another example of the agency's use of its discretion and its ability under the guidance in the Intercenter Agreements to make a sensible decision about product assignment is its decision regarding regulation of a catheter flush solution containing a blood-thinning drug and an antibiotic. The solution is intended as a flush solution to prevent the catheter (or tube) inserted into a patient's body from becoming clogged with blood and to prevent dangerous bacteria from growing in the catheter. Under the Drug/Device Agreement, this product would appear to fit into the category of a ''liquid * * * or other similar formulation intended only to serve as a component * * * to a device with a primary mode of action that is physical in nature [and] will be regulated as a device by CDRH'' (see Drug/Device Agreement, p. 13). The agency did determine that the product's premarket review would be conducted under the device authorities, but it assigned the review responsibility to CDER. The decision to follow an approach different from the one generally suggested in the Drug/Device Agreement was based on the fact that the inclusion of the blood-thinning and anti-infective drugs in the flush solution represented an innovation in such solutions and raised important scientific and regulatory questions that were most properly reviewed by the scientists in CDER. Because CDER was assigned the lead, the sponsor of this product was informed that the clinical investigations of this product should proceed under the investigational drug provisions of the act (section 505(i) of the act (21 U.S.C. 355(i)). This determination tailored the act's premarket review provisions, incorporating the most appropriate sections of both the drug and device authorities without being redundant, to the special features of this original product.

The agency has thus in the past made its jurisdiction decisions by determining the most reasonable course of action to protect public health given the scientific questions presented by each product. FDA considers essential its ability to continue to assess the individual circumstances of particular products. This will allow the agency to respond to technological developments, expanded scientific understanding, or additional factual information concerning a specific product or class of products.

B. Cigarettes and Smokeless Tobacco Have Both a Drug and a Device Component and Are Therefore Combination Products

As discussed in detail in the 1996 Jurisdictional Determination, the agency has concluded that the nicotine in cigarettes and smokeless tobacco is a drug within the meaning of section 201(g)(1)(C) of the act. The agency has also concluded that cigarettes and smokeless tobacco contain, in addition to the drug nicotine, delivery device components that deliver a controlled amount of nicotine to the body. Thus, cigarettes and smokeless tobacco are combination products that contain both a ''drug'' and a ''device.''

The agency further concluded that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is a combination product.

C. FDA's Choice of Legal Authorities

1. FDA Will Regulate Cigarettes and Smokeless Tobacco Under the Act's Device Authorities

Having established that cigarettes and smokeless tobacco are combination products consisting of both a drug component and device components, the agency has the discretion to choose whether it will regulate these products under the act's drug authorities, device authorities, or both if appropriate. Making this determination requires FDA to consider how the public health goals of the act can be best accomplished.

The act's drug and device provisions have a common objective: To ensure the safety and effectiveness of regulated products. They also provide the agency with similar authorities to regulate drugs and devices. In certain ways, however, the device provisions offer FDA more flexibility. The Medical Device Amendments of 1976 (the Medical Device Amendments) were enacted nearly 40 years after the act itself. During that period of time, Congress observed FDA's efforts to regulate devices under the authority of the act, noting that the agency's authority over devices became increasingly inadequate as the nature of the devices on the market changed (H. Rept. 94–853, 94th Cong., 2d sess., 6–10 (1976)).

In 1938 most of the devices in use were ''relatively simple items which applied basic scientific concepts * * *'' (H. Rept. 94–853, 6). However, by the time the Medical Device Amendments were enacted, the universe of device products had evolved from primarily simple products, such as tongue depressors and bandages, to include a

variety of scientifically and technologically sophisticated products, such as cardiac pacemakers, lasers, and magnetic resonance imaging equipment. This wide range of technology posed many more varied regulatory concerns than those posed by drugs, which as a group of products are less diverse in nature.

Congress recognized the need for specific authority for devices that would take into account ''the great diversity among the various medical devices and their varying potentials for harm as well as their potential benefit to improved health'' (S. Rept. 94–33, 94th Cong., 1st sess., 10 (1975)). Thus, with the Medical Device Amendments, Congress enhanced FDA's authority to tailor regulatory controls, from an array of statutory tools, to fit the particular safety and effectiveness issues presented by individual devices.

Because of this additional flexibility, the agency has determined that the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco. Because millions of Americans are addicted to cigarettes and smokeless tobacco, regulation of these products presents unique safety problems that require careful, tailored solutions. The Medical Device Amendments provide the agency with regulatory options that are well suited to the unique problems presented by cigarettes and smokeless tobacco.

Although the agency has determined that the device authorities are the most appropriate authorities for regulating cigarettes and smokeless tobacco, the agency disagrees with the comments that suggest that the agency could not regulate cigarettes and smokeless tobacco as drugs. To the contrary, as discussed in section II.D. of this document, the agency could have used its drug authorities to implement similar types of controls on cigarettes and smokeless tobacco as it is imposing under the somewhat more flexible device authorities.

2. Cigarettes and Smokeless Tobacco Will be Subject to the Full Range of Device Authorities

In regulating cigarettes and smokeless tobacco, FDA will follow the regulatory scheme created by Congress for devices. Because the universe of devices is extremely diverse, presenting a broad spectrum of safety and effectiveness issues, the Medical Device Amendments include a wide range of regulatory controls. Some of these controls, such as the adulteration and misbranding requirements, are applicable to all devices, while others, such as premarket approval and restrictions on sale, distribution, and use, are to be applied only where FDA concludes that they are necessary to provide reasonable assurance of safety and effectiveness for particular devices. The Medical Device Amendments are thus designed to allow the agency to regulate individual devices with controls that are tailored to address the safety and effectiveness problems raised by those devices.

As devices, cigarettes and smokeless tobacco will be subject to all mandatory provisions of the act, except where exemption is permitted by statute and is appropriate for these products. In addition, cigarettes and smokeless tobacco will be subject to other discretionary provisions of the act that the agency has concluded are necessary to address the special safety issues posed by these products.

The basic requirements of the act applicable to all devices include: Adulteration and misbranding provisions (sections 501 and 502 of the act (21 U.S.C. 351 and 352)), labeling requirements (section 502), establishment registration, device listing, and premarket notification (section 510 (21 U.S.C. 360)), recordkeeping and reporting requirements (section 519 (21 U.S.C. 360i)), and good manufacturing practice (GMP) requirements (section 520(f)). As described in more detail in section II.C.4. of this document, FDA intends to apply these requirements, where appropriate, to cigarettes and smokeless tobacco at a future time. In addition, the act requires the agency to classify devices into one of three classes. Depending on the class into which a product is classified, additional regulatory requirements may apply: Class I (general controls), class II (special controls), and class III (premarket approval). As described in more detail in section II.C.5. of this document, as the act contemplates, FDA intends to classify cigarettes and smokeless tobacco at a future time, and will impose any additional requirements that apply as a result of their classification.

The agency has determined that the safety of cigarettes and smokeless tobacco cannot be assured without restrictions on the sale, distribution, and use of these products to children and adolescents. Accordingly, FDA is imposing restrictions under the authority granted in section 520(e) of the act.

(2) Several comments argued that the regulatory requirements proposed by FDA for cigarettes and smokeless tobacco distort the regulatory scheme for devices established by Congress. These comments contended that FDA has: (1) Selectively applied the provisions of the Medical Device Amendments; (2) inappropriately relied on section 520(e) of the act (restrictions on sale, distribution, or use) while ignoring other mandatory provisions of the act, such as classification; and (3) determined that cigarettes and smokeless tobacco are unsafe and yet failed to invoke provisions of the act that, according to the comments, require the agency to remove them from the market.

FDA disagrees with these comments. As already described, FDA intends to apply to cigarettes and smokeless tobacco all of the mandatory provisions of the Medical Device Amendments. Thus, FDA is neither selectively applying the provisions of the act nor ignoring mandatory provisions.

Although FDA intends to impose on cigarettes and smokeless tobacco all requirements applicable to devices, the act does not provide that these requirements should all be imposed immediately. Classification serves the purpose of identifying which devices need to be subject to special controls (class II) or premarket approval (class III) in addition to the general controls applicable to all devices. Classification requires FDA to institute a separate rulemaking proceeding. The act does not require the agency to classify a device before general controls become applicable to it. Rather, the general controls provisions of the act apply to all devices both before and after classification and irrespective of the class into which a device is ultimately classified. Because the classification process involves many steps and can take years to complete, FDA does not ordinarily complete the classification process before regulating the device under its general controls.

Moreover, the statute contains no requirement that the agency complete a classification rulemaking before invoking the general controls that apply to all devices. For example, each of the literally thousands of medical devices that have been classified by rulemaking under section 513 of the act (21 U.S.C. 360c) were subject to the general controls of the statute—such as the provisions on adulteration, misbranding, registration, investigational device controls, and GMP—in advance of the completion of the classification rulemaking proceedings. (See, e.g., *Contact Lens*

Mfrs. Association v. *FDA*, 766 F.2d 592, 603 (D.C. Cir. 1985), *cert. denied* 474 U.S. 1062 (1986).) Indeed, in some cases, the general controls provisions were applicable to marketed devices for many years before completion of classification.

Consistent with the agency's practice, FDA has made a decision to apply the general controls provisions of the act to cigarettes and smokeless tobacco, including restrictions on their distribution, sale, and use under section 520(e) of the act, before classifying cigarettes and smokeless tobacco. As described in section II.C.5. of this document, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. In the meantime, the general controls will apply.

FDA also disagrees that the act requires the agency to remove cigarettes and smokeless tobacco from the market. As described in the preamble to the 1995 proposed rule (60 FR 41314), although cigarettes and smokeless tobacco pose very grave risks, the agency cannot conclude that removing them from the market would most effectively meet the statutory goal of providing reasonable assurance of safety and effectiveness. Because millions of Americans are addicted to cigarettes and smokeless tobacco, the consequences of their removal from the market, as discussed in greater detail in section II.C.5. of this document, would include adverse health effects from sudden withdrawal, the likely development of a black market, and the possibility that the products that would be available through a black market would pose greater risks than those currently on the market. None of the statutory sections cited by the comments require the agency to remove products from the market where the agency concludes that such action would be contrary to the public health. Here, FDA has determined that the unique safety issues presented by highly addictive and long-marketed products like cigarettes and smokeless tobacco can most effectively be addressed by actions to prevent new users from becoming addicted to these devices.

In section II.C.3. of this document, FDA discusses its authority to impose restrictions on sale, distribution, and use to prevent children and adolescents from becoming addicted to cigarettes and smokeless tobacco. In section II.C.4 of this document, FDA discusses imposition of other general controls, and, in section II.C.5 of this document, FDA discusses classification of cigarettes and smokeless tobacco.

3. The Restricted Device Provision Authorizes FDA to Establish Access and Advertising Restrictions

Congress provided FDA with authority to prevent the use of a device by those not competent to use it safely in the restricted device provision (section 520(e) of the act). Specifically, section 520(e) of the act states in part:

> (1) The [agency] may by regulation require that a device be restricted to sale, distribution, or use—
>
> (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or
>
> (B) upon such other conditions as the [agency] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the [agency] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Section 520(e) is one of the act's ''general controls'' (see section 513(a)(1)(A) of the act). As a general control, section 520(e) of the act can be used by FDA to regulate any class of device (section 513(a) of the act). Because its applicability does not depend upon the outcome of the classification process, 520(e) of the act—like the other general controls—can be used by FDA to regulate a device prior to the classification of the device.

In applying section 520(e) of the act to restrict the sale, distribution, or use of a device, FDA must find that without the restriction ''there cannot otherwise be reasonable assurance of its safety and effectiveness.'' This provision requires FDA to find that the restrictions in section 520(e) of the act are necessary to assure the safety and effectiveness of the device, but FDA does not have to find that the restrictions are sufficient to assure safety and effectiveness. During the classification process, FDA determines whether additional controls beyond section 520(e) of the act and the other general controls applicable to all devices are needed to assure the safety and effectiveness of the device.

The restricted device provision in section 520(e) of the act authorizes FDA to adopt regulations that ensure that children and adolescents, who by State law are not competent to use cigarettes and smokeless tobacco, will not be able to obtain them. In particular, FDA has determined that section 520(e) of the act authorizes the access and advertising restrictions in the final rule because without these restrictions ''there cannot otherwise be reasonable assurance of * * * safety * * *.''

As described more fully later in this section of this document, the agency's use of section 520(e) of the act in this rule is consistent with the plain language of section 520(e), the legislative history, and the agency's prior use of section 520(e) in, for example, restricting the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 through 9398, March 5, 1982).

As discussed in section II.C.5. of this document, the agency intends to classify cigarettes and smokeless tobacco under the procedures contained in section 513 of the act. The classification process is the time at which the agency determines what degree of regulation is necessary to provide a ''reasonable assurance of safety and effectiveness'' for a particular product, such as tobacco products. However, the act does not specify the timing of the application of device authorities, and the agency is therefore able to issue restrictions under section 520(e) of the act prior to initiating the classification process. The agency also did so in its regulation of hearing aids. In 1977, FDA adopted regulations under section 520(e) of the act containing restrictions on the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 and 9398, March 5, 1982), but did not classify these products until 1986 (51 FR 40378 at 40389, November 6, 1986).

FDA is following a similar course here. The agency has determined that unless measures are taken now to prohibit the sale and promotion of these products to young people under the age of 18, there cannot otherwise be reasonable assurance of safety. Therefore, FDA is acting under section 520(e) of the act to restrict the sale, distribution, and use of cigarettes and smokeless tobacco.

a. *The restricted device provision authorizes FDA to prevent access to persons who cannot use a device safely or effectively.* Section 520(e) of the act is in part the device counterpart to section 503(b), the act's prescription drug provision. Section 503(b)(1) of the act, for instance, authorizes FDA to restrict access to potentially dangerous drugs by requiring that they be dispensed ''only upon a * * * prescription of a practitioner licensed by law to administer such a drug * * *.'' Similarly, section 520(e)(1)(A) of the act authorizes FDA to restrict access to potentially dangerous medical devices ''only upon the * * * authorization of a practitioner licensed

by law to administer or use such device * * *.''

The restricted device provision, however, is significantly broader than the prescription drug provision. Not only may FDA restrict sale, distribution and use by prescription, but it may do so upon ''*such other conditions as [it] may prescribe in such regulation*'' (section 520(e)(1)(B) of the act (emphasis added)). There is no counterpart to this ''other conditions'' authority in the prescription drug provisions.

Section 520(e) of the act was designed to deal with the risks that are created by improper use of a device. The legislative history of the Medical Device Amendments specifically states that section 520(e) of the act was intended to ''supersede[ ]'' and ''add[ ]'' to the prescription authority derived from section 503(b) of the act (H. Rept. 94–853, 94th Cong. 2d sess., 24–25 (1976)). This confirms that Congress intended to give FDA broad authority to restrict access to potentially dangerous devices. (See also ''Medical Device Regulation: The FDA's Neglected Child,'' Report of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, 98th Cong., 1st sess., 31 (1985).)

Congress' use of the phrase ''could include'' indicates that this discussion was intended to be illustrative rather than exhaustive. The examples of possible restrictions described in the legislative history demonstrate that Congress intended to give the agency authority to restrict access to devices in a variety of ways, depending upon the type of risk posed by the device and the measures needed to ensure that the device is not used inappropriately. In short, the legislative history supports the statutory language and establishes that Congress intended FDA's authority to restrict the sale, distribution, and use of devices ''upon such other conditions as the [agency] may prescribe'' to be a flexible authority that allows FDA to tailor restrictions on sale, distribution, and use according to the circumstances posed by the device being regulated.

b. *The restricted device provision also authorizes FDA to restrict promotional activities that encourage uses that are inconsistent with the regulatory scheme.* Section 520(e) of the act is a broad grant of authority. The Secretary, and by delegation FDA, is authorized to restrict the sale, distribution, or use of a device ''upon such other conditions as the [agency] may prescribe in such regulation.'' This broad grant of authority covers all aspects of the sale of a device, including the offer of sale.

How a device is sold involves many elements. It involves not only the circumstances surrounding the exchange of money for the device, but also whether the device must be sold only on the authorization of a practitioner, whether age limits on users are appropriately established, and how the device is represented to potential users. It is in the latter regard that advertising plays a role and may be restricted under section 520(e) of the act.

The Supreme Court cases on commercial speech recognize that a State's interest in regulating sales extends to advertising promoting the sale. In *Edenfield* v. *Fane*, 507 U.S. 761, 767 (1993), the Supreme Court said that commercial transactions are ''linked inextricably'' with the commercial speech that proposes the transaction, and that the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. Likewise, under section 520(e) of the act, the sale of a device is ''linked inextricably'' to the advertising that promotes the sale, giving FDA concomitant authority to impose necessary restrictions on the advertising.

FDA's regulation of hearing aids exemplifies this aspect of section 520(e) of the act. One of the most important purposes of the restrictions on sale, distribution, and use imposed on hearing aids was to respond to widespread inappropriate promotion of hearing aids to consumers for whom the devices are not effective (see 41 FR 16756 at 16757 (April 21, 1976)). In that regulation, in addition to restricting sales to persons who had been medically evaluated for hearing aids, FDA relied upon section 520(e) of the act to require that an instructional brochure be distributed to each prospective hearing aid user. These brochures described the adverse reactions and side effects associated with hearing aids and encouraged prospective users to seek medical evaluations. The distribution of the brochure was required as a means of ensuring that advertising for hearing aids did not inappropriately induce persons who had not been medically evaluated to purchase the hearing aids.

The agency's authority to use section 520(e) of the act to restrict advertising is especially strong when limits on advertising are necessary to ensure that advertising does not undermine the conditions on sale, distribution, or use that the agency adopts under section 520(e). The agency should not be—and under section 520(e) of the act is not—powerless to prevent advertising that encourages sales that the agency has barred under section 520(e). Rather, the agency may use its authority to impose ''such other conditions as the [agency] may prescribe'' to restrict advertising that directly undercuts the agency's restrictions on sale, distribution, and use.

c. *The restricted device provision authorizes FDA's restrictions on youth access and on advertising designed to make cigarettes and smokeless tobacco appealing to youth.* The restricted device provision authorizes the restrictions on youth access and on advertising in this final rule. Section 520(e) of the act contemplates these types of restrictions on sale and distribution. Moreover, they are necessary if FDA ever were to be able to find that there is a reasonable assurance of the safety of cigarettes and smokeless tobacco under the act. As section 520(e) of the act provides, without these restrictions ''there cannot otherwise be reasonable assurance of safety and effectiveness.''

The provisions in the final rule that restrict the access of minors to cigarettes and smokeless tobacco are clearly restrictions on ''sale, distribution, or use'' of a device within the meaning of section 520(e) of the act. FDA's access restrictions are designed to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco. These restrictions directly limit the sale of cigarettes and smokeless tobacco by, for instance, banning the sale of these products to persons under 18. They also directly limit the distribution of cigarettes and smokeless tobacco by, for instance, banning the distribution of free samples. Hence, these access restrictions are within the plain language of section 520(e) of the act.

The advertising restrictions in the final rule are also among the types of restriction that section 520(e) of the act authorizes. As in the case of the restrictions imposed on hearing aids, the advertising restrictions are designed to address inappropriate promotion of cigarettes and smokeless tobacco to individuals for whom the potentiality for harm is particularly great. The advertising restrictions are necessary to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions. The effectiveness of the restrictions on youth access

would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions. In this circumstance, restrictions on advertising are properly treated as restrictions on ''sale, distribution, or use'' within the meaning of section 520(e) of the act.

The final requirement of section 520(e) of the act is that the agency establish that without the restrictions on the device ''there cannot otherwise be reasonable assurance of its safety and effectiveness.'' This requirement is plainly met in the case of the access and advertising restrictions for cigarettes and smokeless tobacco. Without effective restrictions on sale and distribution of cigarettes and smokeless tobacco to children and adolescents under 18, young people will continue to become addicted to these products and, once addicted, will as adults continue to use them in spite of their potential for harmful effects. As stated in section I.B. of this document, the earlier tobacco use begins, the greater the risk of disease caused by, or associated with, the use of these products. Thus, there can be no doubt that without the access and advertising restrictions imposed in this final rule, no finding that there is a reasonable assurance of safety for cigarettes and smokeless tobacco would be possible.

Although FDA finds that the restrictions under section 520(e) of the act are *necessary* for providing a reasonable assurance of safety, FDA is not required under section 520(e) of the act to show that the restrictions are *sufficient* by themselves to provide a reasonable assurance of safety or effectiveness. Under section 520(e) of the act, all that FDA must establish is that without the section 520(e) restrictions, the device could not be found to be safe.

It is in the classification process—not in the application of section 520(e) of the act—that FDA must determine what controls are necessary if the agency is to find that there is a reasonable assurance that a device is safe and effective for its intended use. As discussed in section II.C.5. of this document, FDA intends to classify cigarettes and smokeless tobacco in a future rulemaking.

d. *Response to other comments.* FDA received several comments on whether section 520(e) of the act authorizes restrictions on youth access and advertising. Most of the comments were from tobacco trade associations, tobacco companies, and advertisers, arguing that section 520(e) of the act does not provide authority for either the access or advertising restrictions. A comment from a public interest group, however, fully supported FDA's reliance on section 520(e). FDA also received a large number of comments from a broad cross-section of the public that expressed support for, or opposition to, the proposed restrictions without delving into the legal issues analyzed in the 1995 proposed rule.

(3) One comment said that FDA uses the term ''conditions'' in section 520(e)(1)(B) of the act to mean any regulatory imposition that the agency believes would bring about an improvement in safety in some way related to the device in question. The comment argued that FDA has used this term in such an overinclusive way that it would authorize FDA to impose many of the requirements that Congress imposed in other provisions of the act. For example, the comment argued that under FDA's interpretation it could require premarket approval of a device with a potentiality for harmful effect as a ''condition'' on the ''sale, distribution, or use'' of the device, on the theory that without premarket approval it would be impossible for there to be ''reasonable assurance of its safety.''

FDA disagrees with this comment. FDA's interpretation of section 520(e) of the act does not create any redundancy with the other provisions of the Medical Device Amendments. Most of the general controls authorized under the act, and the major thrust of the provisions on performance standards and premarket approval, are geared toward ensuring that finished devices, when ready for use, will be free from defects and will provide a reasonable assurance of safety and effectiveness for their labeled use. Restrictions under section 520(e) of the act, on the other hand, are imposed because the device's ''potentiality for harmful effect or the collateral measures necessary to its use,'' and the determination that, without such restrictions, there cannot otherwise be a reasonable assurance of safety and effectiveness. The restrictions under section 520(e) of the act on cigarettes and smokeless tobacco focus on those who may *not* purchase and use these products rather than on those who will be using the products. Without successful restrictions on sale, distribution, and use of cigarettes and smokeless tobacco to children and adolescents under 18, there will never be reasonable assurance of the safety of these products because they would continue to be available to these young people, who, by State law, are not competent to use them.

(4) With regard to access, industry comments contended that FDA's authority under the provisions of the act relating to restricted devices was intended to be no broader than its prescription drug authority and, accordingly, could not extend to restrictions such as those in the 1995 proposed rule.

FDA disagrees with this view and believes that it is unsupported by the clear language of the act and the legislative history (see H. Rept. 94–853, 94th Cong., 2d. sess., 24–25 (1976)). Had Congress meant for the authority granted FDA under section 520(e) of the act to be no broader than the authority granted in section 503(b)(1) of the act to limit drugs to prescription use, it could simply have amended section 503(b)(1) of the act to add ''or device'' after ''drug'' each time the term is used. Indeed, as discussed in *Becton, Dickinson and Company* v. *Food and Drug Administration*, 589 F.2d 1175 (2d Cir. 1978) that approach was the one used in early versions of the legislation that became the 1976 amendments but was abandoned in favor of the broader ''restricted device'' approach that has been a part of the law for 20 years. The plain language of the enacted provision contains no limitation on the types of restrictions that can be imposed and certainly is not limited by its terms to restriction to prescription use. Moreover, as previously discussed, the legislative history specifically states that the agency's authority under section 520(e) of the act is broader than its authority under the prescription drug provisions (H. Rept. 94–853, 94th Cong., 2d sess., 24–25, 1976).

(5) An industry comment contended that ''FDA uses what is merely the medical device version of prescription drug status as the sole legal justification for an elaborate system of controls far broader and more intrusive than is authorized even for true medical devices.''

As discussed in section II.C.3. of this document, FDA's restricted device authority is significantly broader than suggested by this comment. Given the potentiality for harm from cigarettes and smokeless tobacco, FDA has ample authority to impose the conditions on their sale, distribution, and use that it is adopting.

As is the case with other medical devices, cigarettes and smokeless tobacco are subject to those regulatory controls that are appropriate for medical devices generally (e.g., registration, labeling, and inspection), along with those tailored to the product in question

and the risks that it presents (access restrictions and advertising controls). Thus, FDA is treating cigarettes and smokeless tobacco in a manner that is consistent with how it treats other medical devices.

(6) Turning to the advertising restrictions, several comments argued that section 520(e) of the act authorizes only restrictions on ''sale, distribution, or use,'' and that it does not include the words ''offer for sale.'' These comments pointed out that Congress used the words ''offer for sale'' elsewhere in the act (sections 301(m) and (o) (21 U.S.C. 331(m) and (o)) and 503(c)), and they therefore drew the inference that if Congress had intended section 520(e) of the act to authorize restrictions on how medical devices are offered for sale, it would have made this fact explicit.

FDA is not persuaded by this argument. In each of the instances cited in the comments where Congress has included the phrase ''offer for sale'' in the act, it was defining a prohibited act, that is, an act whose commission would violate the statute, in which the prohibition focused, at least in part, on the sale of a food, drug, or device. By including the phrase ''offered for sale'' in these provisions, Congress sought to ensure that the statutory objective of preventing the actual sale of products where advertising or labeling does not meet the statutory requirement would be met by including products merely ''offered for sale'' within the statute's coverage. The agency notes that, similarly, the words ''offered for sale'' appear in section 502(q) of the act, the provision that the agency would use to enforce section 520(e) of the act. Thus, Congress did in fact include ''offer for sale'' in the scope of conduct regulated under section 520(e) of the act and its enforcement clause, section 502(q). The comment's argument, however, misses the significance of section 520(e) of the act.

As discussed in section II.C.3. of this document, the authority to restrict the ''sale, distribution, or use'' of a device includes the authority to restrict the circumstances surrounding the sale and distribution of the device, including the device's advertising. The use of section 520(e) of the act to restrict advertising is particularly appropriate when the advertising restrictions are necessary to ensure that access restrictions issued under section 520(e) of the act are not undermined by a manufacturer's advertising. Here, FDA is restricting the sale of cigarettes and smokeless tobacco because of their potential harmful effects on individuals who start using them before the age of 18 and who lack the competency to decide to do so. FDA has determined, as explained in sections VI.B. and D. of this document, that how cigarettes and smokeless tobacco are advertised plays a material role in the decision of children and adolescents under 18 to purchase and use these products. Thus, if the restrictions on how cigarettes are sold, distributed, and used that FDA is adopting under section 520(e) of the act are to be effective, they must include restrictions on how cigarettes and smokeless tobacco are advertised.

(7) The comments also argued that section 520(e) of the act on its face says nothing about advertising. Thus, according to these comments, FDA's authority to regulate the advertising of restricted devices is limited by section 502(q)(1) of the act, which prohibits false or misleading advertising, and section 502(r) of the act, which prescribes certain statements in the advertising for these devices. One comment implied that FDA's interpretation of section 520(e)(1) of the act had rendered section 502(q)(1) and (r) of the act superfluous.

FDA is not persuaded by these comments. The interpretation of section 520(e) of the act that FDA has adopted in this proceeding would not render either section 502(q)(1) or (r) of the act inoperative or superfluous. These sections impose requirements on advertising of the permissible sale, distribution, and use of restricted devices. They set out conditions on advertising to which manufacturers must adhere in offering these devices for sale. Section 520(e) of the act, on the other hand, is the means by which FDA demarcates permissible and nonpermissible conditions of sale, distribution, and use of these devices. In so doing, as has been explained in response to the previous comments, FDA may by regulation impose limits on advertising that it finds are necessary to ensure that advertising is not used to undermine the conditions on sale, distribution, or use that the agency adopts. This is what §§ 897.30, 897.32(a), and 897.34, the regulations that set out the restrictions on advertising, are designed to accomplish. In fact, section 502(q)(1) of the act reinforces this authority because any advertisement that promotes the sale of a device for a use that is inconsistent with a restriction established by FDA would be false and misleading because it would represent that the device is appropriate for that use, which would not be the case.

Thus, Congress clearly intended section 502(q)(1) and (r) of the act and any restrictions that FDA adopts under section 520(e) of the act to be complementary. This intent is further evidenced by the fact that section 502(q)(2) of the act provides that a restricted device is misbranded if it is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act. Section 502(q)(2) of the act thus complements sections 502(q)(1) and (r) of the act, which, as previously explained, address different aspects of the regulation of restricted devices than does section 520(e) of the act.

FDA's interpretation of section 520(e) of the act accordingly does not render either section 502(q)(1) or (r) of the act superfluous. Rather, the three provisions support and reinforce each other.

(8) An additional argument advanced by two tobacco trade associations was that the interpretation of section 520(e)(1)(B) of the act, which authorizes FDA to restrict the sale of a device upon such ''other conditions'' as it deems necessary, is governed and limited by the rule of *ejusdem generis*. This rule of statutory construction provides that, where general words follow an enumeration of persons or things of a particular and specific meaning, such general words are not to be construed in their widest extent but are to be held as applying to only persons or things of the same general kind or class as those specifically mentioned. Thus, the comment argued that here, *ejusdem generis* limits the scope of ''other conditions'' in section 520(e)(1)(B) of the act to restrictions similar in nature to the restriction to prescription use in section 520(e)(1)(A) of the act. The comment argued that it would be totally inconsistent with the rule of *ejusdem generis* to expand the scope of ''other conditions'' to include a provision as dissimilar to a prescription requirement as a restriction on advertising. FDA does not agree that *ejusdem generis* is controlling, or that it has any application here. In *Norfolk & Western* v. *American Train Dispatchers Ass'n*, the Supreme Court held that this canon does not control ''when the whole context dictates a different conclusion'' (499 U.S. 117, 129 (1991)). The context involving section 520(e) of the act does not support the application of *ejusdem generis* to it. There is no indication that Congress thought that it was providing a list of similar measures in section 520(e)(1)(A) and (e)(1)(B) of the act. In fact, the face of the act is to the contrary. After specifying one means of restricting

the sale, distribution, and use of a device, Congress granted the Secretary broad authority to impose ''such other conditions as [she] may prescribe in such regulation.'' Congress, rather than limiting the Secretary's options, left it to the Secretary to decide what conditions are necessary for a particular device. Nor does the legislative history support the comments. As stated in section II.C.3.a. of this document, Congress intended section 520(e) of the act to add to the agency's authority beyond providing for use by prescription only (H. Rept. 94–853, 94th Cong., 2d sess., 24–25 (1976)).

Moreover, the ''or'' connecting section 520(e)(1)(A) of the act with section 520(e)(1)(B) is properly read here as disjunctive rather than conjunctive. (See *Garcia* v. *United States*, 469 U.S. 70, 73 (1984).) Section 520(e) of the act is intended to authorize such conditions on the sale, distribution, or use of a device as are necessary to ensure that the device is not improperly used and without which a reasonable assurance of its safety and effectiveness cannot be provided. There is no basis on the face of the act or in the legislative history to conclude that Congress was trying to limit the conditions that FDA could impose to achieve that end (other than the admonition not to base a physician restriction on board certification).

(9) One comment argued that the interpretation of section 520(e) of the act that FDA is advancing in this proceeding is contrary to the interpretation that the agency offered in imposing restrictions on hearing aids in 1977. The comment pointed out that FDA stated at that time: ''The Commissioner notes, however, that the [Act] regulates the safety * * * of the [device] itself'' (42 FR 9286 at 9287, February 15, 1977). The comment asserted that, for this reason, FDA concluded that it could not prescribe competency standards for hearing health professionals, fix the price of hearing aids, or control the promotional practices of hearing aid dispensers, all matters that were being handled by the Federal Trade Commission (FTC) (42 FR 9286 at 9287). The comment argued that, for the same reasons, FDA may not, under section 520(e) of the act, regulate attire, contests, or athletic or cultural events.

FDA does not agree that the hearing aid proceeding provides any support for the view that the agency has been inconsistent in its interpretation of section 520(e) of the act. In that proceeding, FDA was aware that FTC had developed a proposed trade regulation rule that included a prohibition of certain selling techniques (42 FR 9286 at 9287). FDA said that it was avoiding any duplication of effort with FTC. Thus, it was not necessary for FDA to consider the extent of its authority to specifically regulate selling techniques of hearing aid dispensers.

Contrary to the comment's assertion, this proceeding is consistent with the hearing aid proceeding. Although FDA did not duplicate FTC's effort and directly regulate selling techniques, FDA imposed various restrictions that were tailored to restrict inappropriate promotion of hearing aids including requiring a medical evaluation before purchase and distribution of a user instructional brochure. In the case of cigarettes and smokeless tobacco, FDA is imposing restrictions that are tailored to promotion of tobacco products to ensure that advertising does not induce the use of cigarettes and smokeless tobacco by children and adolescents under 18.

(10) Finally, several comments argued that FDA lacks statutory authority for the advertising restrictions that it is imposing. Some of these comments sought to analogize this rulemaking to *American Pharmaceutical Ass'n* v. *Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharmaceutical Ass'n* v. *Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam). That case involved an attempt by FDA to limit the distribution of methadone to certain designated facilities under the drug authorities of the act. The court held that the statutory drug authority did not authorize the agency to impose these limitations on the distribution of methadone, even though methadone posed unique problems of medical judgement, law enforcement, and public policy.

FDA regards the *American Pharmaceutical Ass'n* case as a questionable precedent. The case predates both the Supreme Court's decision in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984), and the Medical Device Amendments. In *Chevron*, the Court stated that ''considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer * * *'' (467 U.S. at 844). Moreover, when Congress enacted section 520(e) of the act, one of its objectives was to provide FDA with precisely the kind of authority over medical devices that the court found that the agency did not have over drugs in *American Pharmaceutical Ass'n*. Thus, FDA now has explicit authority under section 520(e) of the act to impose conditions on the sale, distribution, and use of a medical device to prevent its misuse, including the access and advertising restrictions in the final rule. FDA is imposing controls on the sale of cigarettes and smokeless tobacco to ensure that individuals under 18 will not be able to purchase them. Further, to ensure that these controls on sale, distribution, and use are not undermined, FDA has found that they must include restrictions on how these products are advertised, so that individuals under 18 are not encouraged to purchase or use them. These actions are consistent with the language and purpose of section 520(e) of the act.

4. Application of Other Device Authorities

As described in section II.C.2. of this document, FDA intends to follow its normal course and apply the ''general controls'' provisions of the Medical Device Amendments to cigarettes and smokeless tobacco pending classification of these products. The general controls authorized by the Medical Device Amendments include adulteration and misbranding (sections 501 and 502 of the act), establishment registration, device listing, and premarket notification (section 510), labeling requirements (section 502), recordkeeping and reporting requirements (section 519), and GMP (sections 501 and 520(f)).

(11) Tobacco industry comments claimed that FDA had ignored a number of mandatory provisions of the act applicable to devices, ''presumably because they again recognize that those provisions would mean the prohibition of tobacco sales.'' The comments also asserted that FDA had picked and chosen among statutory provisions and had misinterpreted *Heckler* v. *Chaney*, 470 U.S. 821 (1985), as authorizing this selective regulatory approach. These comments also argued that FDA had ignored section 520(a) of the act, which provides that the adulteration, misbranding, and records and reports requirements are applicable to devices until the applicability of these requirements is changed by an action under the classification, premarket approval, standard-setting, or investigational device provisions of the act.

The agency disagrees with these comments. FDA is applying to cigarettes and smokeless tobacco the general controls applicable to all devices.

In the following discussion, the agency elaborates on the applicability of the general controls provisions to

cigarettes and smokeless tobacco, and on matters the agency has reconsidered in response to comments (the applicability of labeling requirements to cigarettes and smokeless tobacco is discussed in sections V. and VI. of this document). Overall, FDA believes that it has developed a regulatory system for cigarettes and smokeless tobacco that is consistent with the statutory scheme and the record of this rulemaking.

a. *Adulteration and misbranding.* Cigarettes and smokeless tobacco will be subject to the adulteration and misbranding provisions in sections 501 and 502 of the act, and the implementing regulations, with one exception that is permitted by statute. Section 502(f) of the act authorizes the agency to grant exemptions from section 502(f)(1) of the act under certain circumstances. As described in section V.E. of this document, FDA has determined that an exemption from section 502(f)(1) of the act is appropriate for cigarettes and smokeless tobacco. In addition, section VI.E.6. of this document also contains a more detailed description of the applicability of specific labeling requirements to cigarettes and smokeless tobacco.

The adulteration and misbranding provisions are largely self-executing and do not require the agency to impose requirements by regulation.

b. *Device registration and listing.* Section 510 of the act and part 807 (21 CFR part 807) of the regulations require that device manufacturers and importers register their establishments with the agency. Every year an annual registration form is sent to all registered establishments to be completed and returned to the agency (§ 807.22(a)). Any significant changes of information to the original must be reported to FDA within 30 days of the change (§ 807.26).

Manufacturers are also required to list their devices that are in commercial distribution in the United States (part 807). Foreign manufacturers may, but are not required to, register (§ 807.40). However, they are required to list their devices (§ 807.40(b)). Manufacturers are required to update their listing if there are significant changes to listing information.

Manufacturers of cigarettes and smokeless tobacco will be subject to the establishment registration and device listing requirements in section 510 of the act and part 807 of FDA's regulations. The application of these provisions to cigarettes and smokeless tobacco derives from their status under the device provisions of the act and does not require rulemaking by the agency.

Section 510(k) of the act requires submission of a premarket notification to the agency whenever a manufacturer markets a device for the first time, whenever there is a major change in the intended use of an already marketed device, or whenever an already marketed device is to be modified in a way that could significantly alter its safety or effectiveness (§ 807.81). The device may not be commercially distributed unless the agency issues an order finding the device substantially equivalent to one or more predicate devices already legally marketed in the United States for which premarket approval is not required (section 513(i) of the act (§ 807.100), or unless the agency approves a premarket approval application for a device subject to an approval requirement under section 515 of the act (21 U.S.C. 360(e)). Substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device; or has the same technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness (section 513(i) of the act). The premarket notification submission must include either a summary of the safety and effectiveness information upon which a substantial equivalence determination may be based, or state that safety and effectiveness data will be made available to anyone upon request (section 513(i)(3)(A) of the act (21 U.S.C. 360c(i)(3)(A)), and §§ 807.87(h) and 807.92).

c. *Records and reports.* Section 519 of the act contains several requirements relating to the keeping of records and making of reports on devices. In addition to implementing the specific requirements of the act, the agency has used its authority under section 519 of the act to issue several regulations. As nicotine delivery devices, which are drug-device combination products that FDA is regulating under its device authorities, cigarettes and smokeless tobacco are subject to the requirements of section 519 of the act and the implementing regulations unless otherwise exempted.

Section 519(a) of the act requires manufacturers, importers, and distributors of devices to establish and maintain records, and make reports and other information available to the agency, to ensure that a device is not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Similarly, section 519(b) of the act requires medical device user facilities to make reports to device manufacturers and the agency when they become aware of information suggesting that a device has caused or contributed to a death, serious injury, or serious illness. Under this authority, the agency has issued part 803 (21 CFR part 803), on medical device reporting, and part 804 (21 CFR part 804), on medical device distributor reporting (the MDR requirements). These regulations were recently amended by a final rule published in the Federal Register of December 11, 1995 (60 FR 63578) (the 1995 reporting requirements final rule), reflecting changes in the reporting requirements of section 519 of the act that were mandated by the SMDA and the Medical Device Amendments of 1992.

The 1995 proposed rule would have amended parts 803 and 804 to exempt cigarettes and smokeless tobacco from the MDR requirements. These proposed exemptions were based on the fact that ''the adverse health effects attributable to cigarettes and smokeless tobacco products are extensive and well-documented'' (60 FR 41314 at 41342). The agency stated that it did not anticipate any real benefit in requiring manufacturers and distributors of these products to report such information (*Id.*).

(12) The agency received several comments criticizing this proposed exemption. One comment from a trade association stated that, although it disagreed with the agency's classification of cigarettes as medical devices, the agency had no authority to exempt manufacturers from this reporting requirement. This trade association also stated that, because the agency has concluded that cigarettes are not safe for individual users, this exemption cannot be reconciled with the standard under section 519(c) of the act for exempting this product. (Section 519(c)(3) of the act provides for exemptions upon a finding that compliance with recordkeeping and reporting is not necessary to ensure that a device is not adulterated or misbranded or to otherwise ensure its safety and effectiveness.) Another trade association claimed that the agency did not follow the proper exemption procedures under the act. A trade association also noted that the agency did not propose to require such user facility reports for cigarettes and also noted that such reports are not ''suitable'' for cigarettes.

In view of these comments, the agency has reconsidered its tentative position regarding the application of the MDR requirements in parts 803 and 804. The adverse health effects attributable to these products are extensive and well-documented. As a result, the cost of processing the enormously high volume of MDR reports related to the use of cigarettes and smokeless tobacco would likely be prohibitive in light of the small benefit to be gained from reports documenting adverse health effects already known to the agency.

Nevertheless, there would be a benefit to receiving information regarding adverse events that are not well-documented and thus, not well-known or anticipated. Therefore, the agency has determined that it will require MDR reporting in certain limited circumstances, and is amending §§ 803.19 and 804.25 of its regulations to make this clear.

In the preamble to the 1995 reporting requirements final rule, the agency clarified that it may grant a written exemption, variance, or alternative to some or all of the MDR requirements ''when it determines compliance with all MDR requirements is not necessary to protect the public health'' (60 FR 63578 at 63592). The agency cited, as an example for an appropriate exemption, devices for which ''adverse events that are known and well documented, are occurring at a normal rate, and do not justify the initiation of remedial action * * *'' (*Id*.).

To limit the volume of reports that could otherwise be required, the agency is modifying the MDR requirements for adverse events relating to tobacco. The agency has added § 803.19(f) to the regulation's ''Exemption, variances, and alternative reporting requirements'' section in order to limit the medical device reports concerning cigarettes and smokeless tobacco; specifically, new paragraph (f) requires reports from manufacturers only for those adverse events related to contamination, a change in any ingredient or any manufacturing process, or any serious adverse event that is not well-known or well-documented by the scientific community.

The agency notes that user facilities are not likely to have direct knowledge of even these limited adverse events required to be reported by manufacturers. Therefore, the agency is adding § 897.19(g) to exempt user facilities from the MDR requirements relating to cigarettes and smokeless tobacco.

For similar reasons, FDA is also modifying the MDR requirements for distributors of cigarettes and smokeless tobacco. Because distributors handle these products, break open cartons, and even affix the tax stamp, the agency believes that distributors could be responsible for, or aware of, contamination of these products. The agency does not believe, however, that distributors are likely to have direct knowledge of any change in ingredient or manufacturing process or any serious adverse event that is not well-known or well-documented by the scientific community. Therefore, the agency is limiting the MDR requirements for distributors to require reports concerning cigarettes and smokeless tobacco only for adverse events relating to contamination.

The agency notes that it has granted similar variances in the past for circumstances that justify modifications to the MDR requirements and has issued guidance that establishes criteria for modified reporting. Examples where reporting has been modified include events involving health care professionals being stuck by needles and certain events involving defibrillators. These modifications were made in order to clarify which events would provide valuable information to the agency given the inherently risky circumstances surrounding the use of these devices. A variance from the MDR requirements has also been granted to the manufacturers of breast implants in order to limit the frequency of reports for events already known to the agency.

(13) Industry comments also questioned why FDA had not proposed to apply device tracking and premarket surveillance provisions to cigarettes and smokeless tobacco. Section 519(e) of the act, governing device tracking, applies only to products that are permanently implantable, life-sustaining or life-supporting, or have been designated by the agency to be tracked. Cigarettes and smokeless tobacco do not fall within the first two categories, and the agency has not designated them for tracking.

For the reasons cited in the previous discussion of 519(e) of the act, postmarket surveillance will not be required unless, at a future date, the agency specifically designates these products under section 522 of the act (21 U.S.C. 360l).

Section 519(f) of the act, which requires FDA to issue regulations to require reports on device removals and corrections, will apply to manufacturers, importers, and distributors of cigarettes and smokeless tobacco. To implement section 519(f) of the act, FDA issued a proposed rule in the Federal Register of March 23, 1994 (59 FR 13828), that would require manufacturers, importers, and distributors of devices to report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. The agency expects that the final rule will publish in 1996. This rule will apply to removals and corrections of medical devices including cigarettes and smokeless tobacco.

d. *GMP*. In the preamble to the 1995 proposed rule, FDA specifically recognized that the GMP regulations may be appropriate for tobacco products (60 FR 41314 at 41352). In this final rule, FDA is requiring that the manufacturers of cigarettes and smokeless tobacco comply with GMP regulations in part 820 (21 CFR part 820), which the agency is currently revising. (See 58 FR 61952, November 11, 1993.) Application of GMP's to cigarettes and smokeless tobacco will assist the tobacco industry in avoiding such situations as the recall of Marlboros in 1995 because of a contamination mishap in processing and, in such cases, may advance public health by reducing to some degree the overall risk associated with these products.

(14) A comment from a tobacco trade association urged that FDA provide ample time for compliance with GMP and requested a 2-year period for compliance.

FDA recognizes that manufacturers will need an adequate amount of time to comply with GMP requirements and is accepting the suggestion in the comment by adopting a 2-year period for compliance. The tobacco industry already has a sophisticated approach to quality control with the production of their products. Thus, much of what is required to meet the requirements of part 820 appears to be in place already, and therefore, 2 years should be a sufficient time for compliance.

(15) In response to comments from tobacco distributors expressing concern about present or future applicability of the GMP regulations, FDA advises that it is exempting distributors from part 820. The agency has decided to amend part 820 by adding a new § 820.1(f) to exempt distributors from the requirement of complying with GMP regulations because it has concluded that compliance with GMP requirements

by distributors is not necessary to assure that these devices will be safe and effective or otherwise in compliance with the act.

5. FDA Will Classify Cigarettes and Smokeless Tobacco Under Section 513 of the Act

In addition to applying the general device authorities previously described to cigarettes and smokeless tobacco, the agency will classify cigarettes and smokeless tobacco under section 513 of the act. The agency relies on classification to determine what level of control of the device is required to provide a reasonable assurance of safety and effectiveness. For devices classified into class I, general controls (sections 501, 502, 510, 516, 518, 519, and 520 of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j, respectively)) are sufficient to provide a reasonable assurance of safety and effectiveness. For devices classified into class II, special controls (such as performance standards under section 514 of the act (21 U.S.C. 360d)) are needed in addition to the general controls to provide a reasonable assurance of safety and effectiveness. For devices classified into class III (premarket approval), neither general nor special controls are sufficient to provide a reasonable assurance of safety and effectiveness, without the added safeguard of premarket approval. Therefore, these devices are subject to ''premarket approval'' under section 515 of the act.

The process of classification is an important component of device regulation, but it includes numerous procedural steps and thus cannot be part of this final rule. Under section 513 of the act, FDA is required to convene or use a classification panel, which should consist of experts who ''possess skill in the use of, or experience in the development, manufacture, or utilization of,'' the device and who provide ''adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions'' (section 513(b)(2) of the act). The classification panel is required to ''provide an opportunity for interested persons to submit data and views on the classification'' and, after consideration of these data and views, to submit to FDA its ''recommendation for the classification of the device'' (section 513(c)(1) and (c)(2) of the act). Upon receipt of the panel recommendation, FDA must publish in the Federal Register ''the panel's recommendation and a proposed regulation classifying such device'' and provide interested persons ''an opportunity to submit comments on such recommendation and the proposed regulation'' (section 513(d) of the act). After reviewing the comments, FDA must classify the device ''by regulation'' (*Id*.).

As required by section 513 of the act, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. Without prejudging that proceeding, the agency recognizes that it will involve consideration of both the known risks of tobacco products and the public health concerns that could be raised by withdrawal from the market of cigarettes and smokeless tobacco to which many adults are addicted. Moreover, the agency's restrictions on access and advertising in this final rule, which are carefully designed to help prevent young people from becoming addicted, will need to be factored in as well.

Consistent with the statute and the agency's normal practice, however, FDA is not postponing regulation of cigarettes and smokeless tobacco under its general authorities pending classification. Such a postponement would serve no useful purpose, because the general authorities will be applicable to cigarettes and smokeless tobacco regardless of the outcome of the classification proceeding. To the contrary, postponing application of FDA's general authorities would have adverse consequences for public health because, during the several years that it may require to complete classification, the applicability of the controls put in place by this final rule, as well as the registration, GMP, and other general controls discussed in this document, would be delayed with respect to cigarettes and smokeless tobacco. During this period, millions of children and adolescents would be likely to use cigarettes and smokeless tobacco for the first time and, in the absence of FDA regulation under its general authorities, become addicted to these dangerous products.

The tobacco industry argues that FDA cannot classify cigarettes and smokeless tobacco because, given ''FDA's view of the health effects'' of cigarettes and smokeless tobacco, classification would inevitably lead to a ban of the products. According to the industry, FDA cannot classify cigarettes under class I or class II because neither the general nor the special controls will provide what FDA will regard as a reasonable assurance of safety, leaving FDA with only one option: To classify cigarettes and smokeless tobacco under class III. According to the industry, classifying cigarettes and smokeless tobacco under class III would lead to a ban of cigarettes and smokeless tobacco because FDA cannot grant premarket approval of a class III device until it is satisfied that there is reasonable assurance that the device is safe. The tobacco industry argues that the inability of FDA to classify cigarettes and smokeless tobacco without triggering a ban of the products demonstrates that the act was never intended to apply to cigarettes and smokeless tobacco.

It would not be appropriate for FDA to make a final determination at this time as to whether the application of all appropriate regulatory controls identified in a classification proceeding would result in a reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco for any users. This determination must await completion of the classification process and of any regulatory steps identified in the classification process (section 513 of the act). Nonetheless, it seems clear that the best public health result is one that prevents access to tobacco products by children and adolescents while allowing their continued availability for adults. Moreover, the agency disagrees with industry comments that argue that it does not have the authority to permit the sale of tobacco products to adults because the agency has found that tobacco products are unsafe.

In considering this issue, the agency reiterates that tobacco products are dangerous. As discussed more fully in section I. of this document and in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco cause great pain and suffering from illness, such as cancer, respiratory illnesses, and heart disease. More than 400,000 people die each year as a result of tobacco use.[23]

If the act required that the agency limit its consideration to the risks of tobacco products, then it could not find that there is a reasonable assurance of safety. To the contrary, tobacco products are unsafe, as that term is conventionally understood. However, as reflected in the act and in judicial decisions, the determination as to whether there is a ''reasonable assurance of safety'' involves consideration of not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of

[23] ''Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost—United States, 1990,'' *MMWR*, CDC, vol. 42, No. 33, pp. 645–649, 1993.

not permitting the product to be marketed. Thus, section 513(a)(2)(C) of the act declares that, with respect to safety and effectiveness, the agency must ''weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (see also 21 CFR 860.7(d)(1)). According to the legislative history of the Medical Device Amendments, ''[the reasonable assurance of safety standard] is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury'' because ''[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits derived'' (H. Rept. 94–853, 94th Cong., 2d sess., 16, 17 (1976); see also *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979)).

An example of the balancing of risks of using a product against the risks of not using a product can be found in the agency's approval of a number of drugs used in the treatment of various cancers. These drugs are highly toxic to patients who receive them, and in approving these drugs for chemotherapy, FDA balances the seriousness of the diseases these drugs were intended to treat against the drugs' toxicity. In cases where the risks of not treating the cancer outweighed the risks of the drugs, FDA has approved these products.

Similarly, in the case of tobacco products, the agency must weigh the risks of leaving cigarettes and smokeless tobacco on the market against the risks of removing these products from the market. For children and adolescents, the serious health consequences of using tobacco products support an approach designed to reduce their use, as all 50 States and many of the tobacco companies themselves recognize. It is also relevant that many children who use tobacco products are in the period of initiation and are not addicted, and thus a prohibition of the sale and promotion to this segment of the population will effectively reduce their use of tobacco products. Although some children and adolescents are addicted to tobacco products, the agency has concluded that the approach that most effectively takes into account the health of young people is one that prohibits the sale and promotion of tobacco products to children and adolescents under 18 years of age.

The issue is more difficult with respect to adults, particularly adults who are addicted to cigarettes and other tobacco products. There are approximately 50 million Americans who currently smoke and another 6 million who use smokeless tobacco.[24] It is particularly relevant that 77 to 92 percent of all smokers are addicted[25] and that a substantial number of all users of smokeless tobacco are addicted.[26]

The agency believes that these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products. The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products.[27] It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.[28]

Whether individuals who use these products have an opportunity to make an informed choice is also relevant. Most individuals who use these products begin as children and adolescents, at an age when they are not prepared for or equipped to make a decision that for many will have lifelong consequences.

In contrast, adults generally have the capacity to make informed decisions. In the case of cigarette and smokeless tobacco, very few adults who have not used tobacco as children and adolescents choose to use these products as adults.[29] Unfortunately, for the many individuals who have become addicted, their capacity to choose whether to use cigarettes or smokeless tobacco in large measure no longer exists. Thus, the agency must take their addiction into consideration when developing its regulatory scheme.

Serious health consequences follow both from the option of leaving tobacco products on the market and from the option of banning tobacco products. However, on balance, an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while permitting the sale to adults seems most appropriate. It is consistent with the statutory standard of reasonable assurance of safety and is more effective in achieving public health goals than a ban on all tobacco products. Therefore, FDA is adopting this approach in this final rule.

There is also a basis for finding that these products are ''effective'' for adults who are addicted to tobacco products because such products sustain with great efficacy the individual's continued need for the active ingredient nicotine. Tobacco products are effective for preventing withdrawal symptoms in individuals addicted to nicotine in much the same way that methadone is effective in preventing withdrawal.

Section 516 of the act supports this analysis. Section 516 of the act is the provision that gives the agency the authority to ban medical devices. Under that provision, the agency ''may'' ban a device if it finds that the device presents ''an unreasonable and substantial risk of illness or injury.'' There are two elements of discretion which plainly allow the agency to leave these products on the market—the word ''may'' which applies to the entire banned device authority; and the standard of ''*unreasonable* * * * risk of illness or injury,'' which gives the agency ample discretion to balance the unique circumstances surrounding this product.

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[24] ''National Household Survey on Drug Abuse: Population Estimate 1993,'' DHHS, PHS, SAMHSA, Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94–3017, pp. 89 and 95, 1994.

[25] 1996 Jurisdictional Determination, section II(B)(2)(a).

[26] *Id*.

[27] That a black market and smuggling will occur can be predicted by examining the current situation with illegal drugs in the United States and past experience with prohibition of respect to alcoholic beverages. In both situations, individuals continued using the products. Moreover, in the case of cigarettes, even increased cost due to tax disparities can lead to smuggling and black markets. S. Rept. 95–962, 95th Cong., 2d Sess., (June 28, 1978); Joossens, L., and M. Raw, ''Smuggling and Cross Border Shopping of Tobacco in Europe,'' *British Medical Journal*, vol. 310, May 27, 1995.

[28] Such has been the case with illegally produced alcohol. See ''Elevated Blood Lead Levels Associated with Illicitly Distilled Alcohol—Alabama, 1990–1991,'' *MMWR*, CDC, DHHS, vol. 41, No. 17, pp. 294–295, 1992; Pegues, D. A., B. J. Hughes, C. H., Woernle, ''Elevated Blood Lead Levels Associated with Illegally Distilled Alcohol,'' *Archives of Internal Medicine*, vol. 153, pp. 1501–1504, 1993.

[29] 1994 SGR, pp. 5, 58, and 65–67.

D. The Fact That the Act's Drug Authorities Authorize the Imposition of Similar Restrictions Supports the Reasonableness of the Restrictions That the Agency Has Imposed

(16) At least one tobacco industry comment argued that the agency's proposed access and advertising restrictions were an affront to ''common sense''—i.e., that the types of restrictions the agency had proposed, under the device provisions of the act, went well beyond what the plain language of the act could be read to support. The agency, however, could have chosen to impose similar restrictions using the act's drug authorities. As this section demonstrates, the agency has restricted the marketing of a number of drug products, using the adulteration, misbranding, and marketing provisions governing drug products. That similar restrictions can be invoked under either the act's device authorities or under the act's drug authorities supports the reasonableness of restrictions adopted in the final rule.

As discussed in the 1995 proposed rule and in sections II.A. and B. of this document, cigarettes and smokeless tobacco are drug delivery systems—i.e., they combine a drug component and a device component in a single combination product (60 FR 41314 at 41347 through 41349). As such, cigarettes and smokeless tobacco are subject to regulation under the device provisions of the act, the drug provisions of the act, or a combination of the two. The agency has determined that it should use the act's device authority to regulate these products because the device provisions of the act offer the agency greater regulatory flexibility than do the drug provisions of the act (see section II.B. of this document and the 1995 proposed rule at 60 FR 41314 at 41347 through 41349). However, if there were no device component to cigarettes and smokeless tobacco, or if the agency had chosen to regulate these combination products under the act's drug authorities, the agency nevertheless could have limited the access to and advertising of these products in order to protect children and adolescents.

Although the agency's authority to impose access restrictions on a drug product is not as explicit as it is under the device provisions of the act (see section 520(e) of the act authorizing controls over the ''sale, distribution, or use'' of a device to protect against a potentially harmful or unsafe use), the agency has in fact drawn from several statutory sources to achieve some of the same regulatory results for a drug. The agency routinely imposes restrictions to protect against unsafe uses of drug products—even where those uses are otherwise unlawful, wholly irrational, or in contravention of express warnings. From the time of the product's development and manufacture through its retail sale, the agency is authorized to ensure that drug products are neither unsafe, misbranded, nor adulterated. (See sections 201(n), 301, 501, 502, 503 and 505 of the act; *United States* v. *Sullivan*, 332 U.S. 689, 696 (1948) (Congress intended ''to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer'').)

Consistent with this broad grant of authority, Congress also authorized the agency to issue regulations for the ''efficient enforcement'' of the act, such as regulations that set forth the conditions under which a drug must be marketed to ensure that it will not be deemed violative of the act (see section 701(a) of the act (21 U.S.C. 371); *United States* v. *Nova Scotia Food Products Corp*., 568 F.2d 240, 246 (2d Cir. 1977); and *Pharmaceutical Manufacturers Association* v. *FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980) (FDA has broad authority to issue drug regulations reasonably related to the public health purposes of the act, so long as the regulations further congressional objectives evidenced elsewhere in the act)).

With this authority, the agency has imposed restrictions on the advertising, labeling, and packaging of drug products, as well as restrictions on access to drug products, without which the products could not be lawfully marketed. For example, the agency has used its authority to ensure that drug products are not adulterated to require special packaging requirements for over-the-counter (OTC) drugs, to protect against product tampering (see 47 FR 50442 at 50447, November 5, 1982); § 211.132 (21 CFR 211.132)). Thus, the agency has imposed industry-wide packaging requirements to protect against product contamination as well as unintended, unsafe uses of drug products. (Compare § 897.14(d) (prohibiting retailers from breaking open cigarette and smokeless tobacco packages to sell loose cigarettes or smokeless tobacco).)

Similarly, the agency has authority to control carefully the package size of drug products to protect persons who fail to follow the directions from taking a lethal dose of the product (see 60 FR 52474 at 52491, 52502, and 52503, October 6, 1995, and § 355.20 (21 CFR 355.20) (final monograph setting package size limitations on OTC anticaries drugs to prevent individuals from ingesting an acutely toxic dose)). (Compare § 897.16(b) (setting minimum package size for cigarettes).)

Along the same lines, the agency has used its authority to ensure that drugs are not misbranded to restrict the marketing of certain drug products where consumers simply were unable or unwilling to heed the warnings on these products. In some instances, the agency has banned altogether the marketing of persistently misused drug products. (See, e.g., 47 FR 41716 at 41719, September 21, 1982 (camphorated oil products deemed misbranded because, despite label warnings, consumers continued to misuse the product); 47 FR 34636, August 10, 1982 (proposing withdrawal of all drugs containing phenacetin because of persistent abuse, and associated health risks, despite label warnings contained on those products).) In other instances, the agency has restricted the product to prescription use. (See, e.g., § 250.12 (21 CFR 250.12) (requiring prescription dispensing of OTC stramonium preparations because, despite package warnings, young people continued to abuse and misuse them); § 250.100 (21 CFR 250.100) (switching amyl nitrite inhalant from OTC to prescription dispensing because of persistent off-label use and abuse); see also 60 FR 38643, July 27, 1995 (proposing to restrict ephedrine drug products to prescription marketing because of the illicit use of OTC ephedrine in the manufacture of certain controlled substances).)

Finally, the agency has approved drug products with strict limits on distribution, to ensure that the drug will be safe for use under the conditions, prescribed, recommended, or suggested in the product's labeling. For example, the drug Clozaril® (clozapine), used in the treatment of schizophrenia, can cause the onset of a potentially fatal blood condition, agranulocytosis. However, early detection of agranulocytosis through routine blood testing can substantially reduce the risk of death. FDA, therefore, approved the drug with labeling that provides that the drug is available ''only through a distribution system that ensures weekly [white blood cell] testing prior to delivery of the next week's supply of

medication.'' [30] This labeling was intended to ensure that Clozaril® would not continue to be administered to those for whom it presents an unreasonable risk of harm. The marketing of Clozaril® in contravention of the labeling would result in the product being deemed misbranded and subject to regulatory action. More recently, the agency issued regulations authorizing generally restrictions on the distribution of drug products in instances where ''a drug product shown to be effective can be safely used only if distribution or use is restricted * * *'' (see § 314.520 (21 CFR 314.520)). (Compare § 897.16 (setting conditions on the manufacture, sale, and distribution of cigarettes and smokeless tobacco); § 897.14(b)(1) (requiring retailers to verify the consumer's age to ensure that the product will not be used by minors) § 897.16(c)(1) (prohibiting use of self-service displays at retail establishments).) [31]

These examples illustrate how the agency has interpreted sections 501, 502, 503, and 505 of the act (in conjunction with sections 201(n), 301, and 701(a) of the act) as authorizing an array of controls to prevent unsafe uses of drug products. The minimum age requirement for cigarettes and smokeless tobacco (see § 897.14(a)), and the controls on packaging (see §§ 897.14(d) and 897.16(b) and (d)), vending machine sales (see §§ 897.14(b) and 897.16(c)), and self-service displays (see §§ 897.14(c) and 897.16(c)), follow this same path. Without these restrictions, cigarettes and smokeless tobacco as drug products could be deemed misbranded or adulterated drug products and could present too great a safety risk to be marketed at all.

The final rule also regulates the advertising used to promote cigarettes and smokeless tobacco (see §§ 897.30, 897.32, and 897.34). While the act's device provisions provide the most direct and extensive basis for regulating the advertising of these products (see section VI. of this document), the drug provisions of the act also would have allowed the agency to regulate the advertising of these products.

Whether a drug is marketed on a prescription basis or OTC, the agency has authority to prohibit advertising that promotes the product for a use for which it would be unapproved or misbranded (see sections 201(n), 301, 502, and 505 of the act; see also § 201.128 (21 CFR 201.128) (advertising of a drug product may be used to establish that the product is being marketed for a use for which it is neither labeled nor approved)). Though the agency generally will defer to FTC with respect to the advertising of OTC drugs (see Food and Drug Administration and Federal Trade Commission Memorandum of Understanding (36 FR 18539, September 16, 1971)), the agency retains authority to take action against an OTC drug that is promoted for an unapproved use. (See § 330.1(d) (21 CFR 330.1(d)) (for an OTC drug to be generally recognized as safe and effective, and not misbranded, the advertising for the drug must not prescribe, recommend, or suggest its use under conditions not stated in the labeling); see, e.g., § 310.519 (21CFR 310.519) (prohibiting the marketing of any OTC drug that is ''labeled, represented, or promoted as an OTC daytime sedative (or any similar or related indication)''.)

The agency also has authority to require that a drug product not be advertised in a manner that would undercut or counteract the product's labeling, including label-based warnings. (See *McNeilab, Inc.* v. *Heckler,* Food Drug Cosm. L. Rep. (CCH 1985) (Transfer Binder) ¶38,317, p. 39, 787 (D.D.C. 1985) (while FDA ''cannot rely on advertising to make safe [an OTC] drug which is deemed too dangerous to be sold with label warnings alone,'' it would be ''proper for the agency * * * to ensure that ads do not undercut otherwise sufficient labeling''); see also 57 FR 13234 at 13237, April 15, 1992 (preamble to Accelerated Approval Regulations discussing requirement of submission of promotional materials to ensure that the drugs approved under this section will not be put to inappropriate or unsafe uses).) And, irrespective of whether a drug is marketed OTC or by prescription, the agency has authority to prohibit the distribution of ''false or misleading'' product ''labeling'' (see section 502(a) of the act).

Last, had the agency chosen to use the act's drug authorities to regulate these products, one possible means of limiting their access would have been to require some form of prescription dispensing. In that case, the agency's authority to regulate the advertising of cigarettes and smokeless tobacco would be extensive (see section 502(n) of the act; § 202.1 (21 CFR 202.1); § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i))). The agency, for example, has discretion under the act to regulate both the presentation and format of prescription drug advertising. According to the House Conference Report on section 502(n) of the act, Congress contemplated that:

> [I]n administering the requirement contained in the conference substitute that advertisements contain brief summaries of side effects, *etc.*, the Secretary under the conference substitute has sufficient discretion to exercise due regard to *the size of the advertisement, the need for protecting the public health, and the conditions for which the drug is offered in the advertisement.*

(Report of the Committee of Conference, H. Conf. Rept. 2526, 87th Cong. 2d sess., (Oct. 3, 1962) *reprinted in* 1962 U.S. Code Cong. and Admin. News 2927, 2934 (emphasis added).)

Further, the agency may take action against a prescription drug advertisement to the extent it lacks ''fair balance'' or is otherwise ''false or misleading'' (see sections 201(n), 502(a), and (n) of the act; § 202.1 (21 CFR 202.1)). Thus, had the agency chosen to regulate these products as prescription drugs, the agency's existing prescription drug advertising regulations themselves would require significant changes to the content and format of the tobacco industry's advertising campaigns.

The final concern—had the agency regulated these products as drugs—is whether cigarettes and smokeless tobacco could continue to be marketed to adults. As discussed in greater detail

[30] Clozaril® (clozapine tablets) product labeling, Sandoz Pharmaceuticals, March 1994, in Physician's Desk Reference, 50th edition, p. 2252, 1996.

[31] ''The Federal Food, Drug, and Cosmetic Act provides authority for FDA to restrict the conditions for use, including the channels of distribution and use, of any drug, or withdraw approval of an NDA, if a drug cannot otherwise safely be used'' (H. Rept. No. 93–884, 93d Cong., 2d Sess., p.4, 1974, reprinted in U.S. Cong. & Admin. News, pp. 3029–3032). But see *American Pharmaceutical Ass'n* v. *Weinberger,* 377 F.Supp. 824, 829 (D.D.C. 1974) (striking down an FDA regulation restricting the distribution of methadone), *aff'd per curiam sub nom. American Pharmaceutical Ass'n* v. *Mathews,* 530 F.2d 1054 (D.C. Cir. 1976). The *American Pharmaceutical Ass'n* case, however, was decided before the emergence of cases such as *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), in which the Court signaled the importance of deferring to an agency's interpretation of its own statute, provided the interpretation is sufficiently rational. The case also involved some unique circumstances: the agency had withdrawn approval of the NDA for the drug (methadone), but nevertheless permitted the drug to be marketed under a regulation to certain treatment programs and pharmacies. Also, because methadone is a controlled substance within the provisions of the Controlled Substances Act, the district court concluded that issues regarding restrictions on the distribution of the drug were more properly within the jurisdiction of the Department of Justice than FDA. In most other instances, however, where a drug is not subject to the Controlled Substances Act, and where certain marketing restrictions are necessary to ensure that the drug will be used safely and effectively, under the conditions contemplated in a new drug application, the *American Pharmaceutical Ass'n* case is distinguishable.

in section II.C.5. of this document, there are compelling public health reasons for permitting the continued marketing of these products to adults. The same rationale would apply had these products been regulated as drugs. As is the case with respect to devices, there is a basis for concluding that an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, yet allows these products to continue to be marketed to adults who are addicted to these products, could be found to be consistent with the statutory standard of ''safe'' and ''effective'' under section 505 of the act for these products.

It is, of course, essential to this analysis that the agency's youth access restrictions in new part 897 be implemented. These restrictions are necessary to help ensure that the most alarming safety issue associated with these products will have been contained. Absent these restrictions, the risks associated with the continued marketing of these products, even to adults, may be overwhelming. The close issue of whether the public health is better served by allowing adults to continue to use these products, such that the agency could find that cigarettes and smokeless tobacco are ''safe'' and ''effective,'' depends heavily on the agency's ability to prevent the most alarming use of these products, namely, use by substantial numbers of children.

Moreover, the approach of allowing the continued marketing of these products to adults, so long as youth access is carefully controlled, would be consistent with the agency's inherent discretion to take enforcement action against some uses of a drug product, but not others. Such an exercise of discretion would be unreviewable (*Heckler* v. *Chaney*, 470 U.S. 821 (1985)). [32]

In resolving that there is a presumption against judicial review of agency determinations not to take enforcement action, the *Chaney* Court reasoned that an agency's nonenforcement policy generally involves a complex weighing of factors ''peculiarly'' within the agency's expertise. (*Id*. at 831). These factors include, ''whether agency resources are best spent on this violation or another,'' ''whether the agency has enough resources to undertake the action at all,'' and ''whether the particular enforcement action requested best fits the agency's overall policies.'' (*Id*. at 831–832).

A decision by the agency to focus its resources on youth access to cigarettes and smokeless tobacco involves the same ''ordering of priorities''—i.e., the same balancing of agency-specific factors—on which the rule crafted in *Chaney* rests. Thus, were the agency to enforce the act only with respect to the promotion and sale of these products to children and adolescents, such a decision would enjoy the full force of the *Chaney* Court's presumption of nonreviewability. [33]

Thus, while the agency finds that cigarettes and smokeless tobacco are more appropriately regulated as restricted devices, as the discussion in section II.C. of this document demonstrates, the agency could have crafted a serviceable regulatory scheme for these products under the drug provisions of the act. Contrary to the comments that have argued that the act is inherently unfit for regulation of these products, or that the agency's proposed restrictions exceeded the common sense boundaries of the act, both the device provisions and the drug provisions of the act provide sound authority for controlling the access to and promotion of these drug delivery devices.

E. Constitutional Issues Regarding Authority

1. Separation of Powers

The doctrine of Separation of Powers refers to the distribution under the Constitution of the Federal Government's powers among the legislative, executive, and judicial branches. In particular, under this scheme only Congress has the constitutional authority to make law.

(17) Numerous comments by industry, media, and retailer trade associations and by State legislators and individuals argued that FDA's assertion of jurisdiction over tobacco products supersedes Congress' legislative judgment, and, some argued, therefore violates the doctrine of Separation of Powers. The comments contended that Congress has provided statutory authority over tobacco products to the Executive Branch only under the statutes that it has enacted that expressly apply to tobacco products, such as the Comprehensive Smokeless Tobacco Health and Education Act (the Smokeless Act) (15 U.S.C. 4401 *et seq*.) and the Federal Cigarette Labeling and Advertising Act (the Cigarette Act) (15 U.S.C. 1331 *et seq*.) and not at all under the act. The comments cited the history of proposals in Congress further to regulate tobacco products, none of which came to fruition, as evidence that Congress has exercised its legislative will not to act further on tobacco regulation.

The agency does not agree that the rule violates the Separation of Powers Doctrine. The relevant legal standards are set out in *Youngstown Sheet and Tube Co*. v. *Sawyer*, 343 U.S. 579 (1952), and *Chrysler Corp*. v. *Brown*, 441 U.S. 281 (1979), which are cited in the comments. Justice Black's opinion for the Court in *Youngstown* stands for the proposition that the Executive Branch may not act unless authorized by the Constitution or by statute to do so. In particular, lacking Constitutional authority, the Executive Branch may act only under the aegis of a statute passed by Congress under its ''law making power'' (see *Youngstown*, 343 U.S. at 585–586, 589).

Executive Branch agencies frequently act by rulemaking. In *Chrysler*, the Supreme Court considered the prerequisite for an agency's ''legislative'' or ''substantive'' rules to have the ''force and effect of law'' (see *Chrysler*, 441 U.S. at 301–302). ''The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes'' (*Id*. at 302). Therefore, for legislative rules to have the ''force and effect of law,'' they must be ''reasonably within the contemplation of [the statutory] grant of authority'' (*Id*. at 306). The ''thread''

[32] See *Cutler* v. *Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) (''The FDC act imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act''); *Schering Corp*. v. *Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA's agreement not to take enforcement action against an unapproved product for a period of 18 months was unreviewable); see also *Cutler* v. *Kennedy*, 475 F.Supp. 838, 856 (D.D.C. 1979) (while FDA may not formally authorize the sale of drugs that it has found do not comply with the safety and effectiveness provisions of the act, the agency may use its enforcement discretion not to move against these unapproved drug products).

[33] In a number of other contexts, the agency has declined to take enforcement action against particular uses of unapproved drug products. Indeed, the agency has on occasion set forth detailed guidelines outlining the conditions under which it will, as a general matter, refrain from taking regulatory action. (See, e.g., FDA Compliance Policy Guide, (CPG) 7132b.15 (stating that pending completion of the OTC Drug Review, FDA generally will not take regulatory action against unapproved or misbranded OTC drugs prior to completion of a final monograph); CPG 7125.06 (setting conditions exempting extra-label use of new animal drugs from regulatory action); Regulatory Procedures Manual 9–71 (setting conditions under which FDA generally will permit the import of small quantities of unapproved drugs for personal use which are not available domestically).)

between the regulations and the statute relied upon may not be ''so strained that it would do violence to established principles of separation of powers to denominate the[] particular regulations 'legislative' and credit them with the 'binding effect of law''' (*Id*. at 307–308).

This is not to say that any grant of legislative authority to a Federal agency by Congress must be specific before regulations promulgated pursuant to it can be binding on courts in a manner akin to statutes. What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued.

(*Id*. at 308.)

Youngstown therefore requires that FDA act under a statutory grant by Congress, while *Chrysler* demands a ''nexus between [FDA's] regulations and some delegation of the requisite legislative authority by Congress'' (see *Chrysler*, 441 U.S. at 304).

As discussed elsewhere in this document, Congress exercised its lawmaking power to provide FDA with the authority to regulate any product that is a drug or device as defined in section 201 of the act. The evidence cited in both the 1995 Jurisdictional Analysis and the 1996 Jurisdictional Determination annexed hereto demonstrates that cigarettes and smokeless tobacco meet the statutory definitions of drug and device. FDA may therefore act to regulate tobacco products, and in doing so, it is acting ''pursuant to an express or implied authorization of Congress,'' and the executive branch's ''authority is at its maximum * * *'' (see *Youngstown*, 343 U.S. at 635 (Jackson, J., concurring)). Moreover, *Chrysler* does not require that the act specifically refer to tobacco products, as the comments suggested (see *Chrysler*, 441 U.S. at 308). In fact, most products regulated by FDA are not specifically referred to in the act. In addition, as discussed in sections X.A. and X.B. of this document, neither the Smokeless Act nor the Cigarette Act precludes regulation under the act of cigarettes and smokeless tobacco as drug delivery devices. FDA's assertion of jurisdiction over cigarettes and smokeless tobacco is therefore reasonably contemplated by the laws as enacted by Congress. Consequently, in regulating tobacco products under the act, FDA is not asserting the lawmaking power reserved by the Constitution to Congress.

2. Nondelegation Doctrine

The Nondelegation Doctrine, broadly speaking, imposes constraints on Congress' authority to delegate to others the legislative power vested in it by the Constitution.

(18) While maintaining that Congress has not granted FDA the authority to regulate tobacco products, an industry comment argued that FDA seeks to assume authority that, under the Nondelegation Doctrine, Congress could not have delegated to the Executive Branch. In particular, the comment argued that the act requires FDA to approve a new drug as safe and effective, or to ban it, and to classify a device into one of three categories in which it will be required to meet conditions that ensure that it is safe and effective. Because FDA proposed to do neither with respect to nicotine and cigarettes and smokeless tobacco, the comment contended, the agency is free to choose any course it wishes; and had Congress delegated to FDA such unlimited authority, it would have violated the Nondelegation Doctrine. The comment can also be read to suggest that, if FDA has the flexibility to regulate medical devices, and in particular tobacco products, as it proposed, then Congress provided the agency without a standard, that is, with too much discretion.

The agency disagrees with this comment. The act, while vesting FDA with broad discretion to regulate foods, drugs, and devices, does so by precisely defining the agency's jurisdictional ambit in section 201 of the act and by establishing a range of requirements and enforcement provisions—for example, in sections 301, 302, 303, 304, 501, 502, 505, 510, 513, 514, 515, 516, 517, 518, 519, 520, and 701 of the act (21 U.S.C. 331, 332, 333, 334, 351, 352, 355, 360, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, and 371 respectively)—for it to pursue when, in its discretion, *Heckler* v. *Chaney*, 470 U.S. 821 (1985), it has found the operative facts established by Congress. The act therefore involves no delegation of Congress' legislative power that violates the Nondelegation Doctrine, as the courts have repeatedly held. (See, e.g., *United States* v. *Shreveport Grain and Elevator Co*., 287 U.S. 77, 85 (1932); *United States* v. *Garfinkel*, 29 F.3d 451, 457–59 (8th Cir. 1994); *White* v. *United States*, 395 F.2d 5, 9–10 (1st Cir.), *cert. denied*, 393 U.S. 928 (1968)); *United States* v. *62 Packages, More or Less, of Marmola Prescription Tablets*, 48 F. Supp. 878, 884 (W.D. Wis. 1943), aff'd, 142 F.2d 107 (7th Cir.), *cert. denied*, 323 U.S. 731 (1944).)

The Supreme Court has only infrequently invalidated a congressional delegation to the Executive Branch. (See, e.g., *Panama Refining Co.* v. *Ryan*, 293 U.S. 388, 418 (1935) (holding statute authorizing the President to prohibit interstate shipment of ''hot oil'' determined by State law or regulation to be ''excess'' to be unconstitutional delegation because ''Congress left the matter to the President without standard or rule, to be dealt with as he pleased''); *Schechter Poultry Corp*. v. *United States*, 295 U.S. 495, 541–542 (1935) (reversing convictions for violations of code of conduct for poultry suppliers because ''the discretion of the President in approving or prescribing [such] codes, and thus enacting laws for the government of trade and industry throughout the country, is virtually unfettered'').)

More recently, the courts have applied the Nondelegation Doctrine to reach, or require from an agency, a narrow interpretation of a statutory provision that would otherwise be too broad a delegation. (See, e.g., *Industrial Union Dep't., AFL-CIO* v. *American Petroleum Inst*., 448 U.S. 607, 646 (1980); *International Union, UAW* v. *OSHA*, 37 F.3d 665, 668–69 (D.C. Cir. 1994); International Union, UAW v. OSHA, 938 F.2d 1310, 1316–17 (D.C. Cir. 1991).)

Unlike the statutes under review in *Panama Refining* and *Schechter*, the act sets standards for FDA to follow. The agency need not narrowly interpret the act to avoid an otherwise over-broad delegation, and courts have repeatedly directed that the act be construed liberally in light of its public health purpose (see sections I.B. and II.A. of this document). The agency's rulemaking with respect to tobacco products is a legitimate application of those standards to the facts before the agency. The agency therefore concludes that neither the act nor this rulemaking violates the Nondelegation Doctrine.

III. Overview of Comments, Smoking Prevalence Rates Among Minors, Scope, Purpose, and Definitions

A. Overview of Comments

From the time the 1995 proposed rule was published on August 11, 1995 (60 FR 41314), until January 2, 1996, the Food and Drug Administration (FDA) accepted public comments. This comment period was the opportunity for the public to speak to FDA about the matter of regulating nicotine-containing tobacco products. On March 18, 1996, the agency reopened the comment period for 30 days to make additional information relevant to this rulemaking available for public comment.

The 1995 proposed rule generated more responses than the agency had received at any other time in its history on any other subject. Altogether, the agency received more than 700,000 pieces of mail, representing the views of nearly 1 million individuals. Most of the submissions were form letters or post cards. The agency identified more than 500 different types of form letters.[34] Others were petitions with sometimes hundreds of signatures. More than 95,000 submissions expressed individual comments on the 1995 proposed rule, including more than 35,000 from children who were overwhelmingly supportive. The individual comments included one from an industry trade association which delivered a single submission of some 45,000 pages on the last day of the announced comment period.

As may be expected, comments differed sharply on the overarching issues of whether FDA should regulate cigarettes and smokeless tobacco, and whether the 1995 proposed rule would have the desired effect of reducing the availability and attractiveness of these products to children and adolescents.

Several Government officials commented, including U.S. Senators and Congressmen, other Federal agencies, State governors and legislators, and law enforcement officials. Comments came from every corner of the country. FDA heard from smokers who could not understand why the Government was meddling in their lives, and from smokers who desperately wanted to quit, but could not. It heard from employers and employees in the affected industries, including tobacco farmers, wholesalers, cigarette manufacturers, and even laborers with the lowest paying jobs who feared that they might lose the only jobs they know. The agency even heard from school children who wanted to be protected from tobacco. ''It is not fair,'' wrote one 13-year-old, ''that the tobacco companies try to get kids to use tobacco.''

Although many of the comments were addressed to specific portions of the tobacco regulation proposal, tens of thousands of letters commented in general. Thousands of general comments supported the rule. Some, like this one, came from surprising sources: ''I support regulations restricting the sale, advertising, promotion and distribution of cigarettes and chewing tobacco. I grow tobacco, but I know it is wrong to sell death. I really feel sorry for people who are 'hooked' on nicotine.'' Other supporting comments came from more traditional sources, especially the medical and public health communities. One letter from a coalition of medical associations that was addressed to President Clinton said: ''We, the undersigned 125 organizations, representing more than 18 million members and volunteers, urge your strong support for Food and Drug Administration actions to protect children and teenagers from tobacco.''

Many expressed strong overall opposition to the rule. One comment said: ''I am taking the time to write this letter to express my overwhelming dissatisfaction with the action of the FDA in trying to rewrite the Constitution and take control of the Tobacco Industry.''

Although many comments opposed FDA's regulation of tobacco products, there was nearly unanimous agreement—even from the tobacco companies and smokers—that children under the age of 18 should not be using nicotine-containing products, either cigarettes or smokeless tobacco. A few children, however, did write that, even if tobacco use is unhealthy, it should still be their choice, even if they are younger than 18. The agency received thousands of general comments about the addictive and harmful consequences of tobacco use, and they called on the agency to act.

A summary of the general issues reflected in the thousands of comments, and the agency's responses, follows:

(1) The agency received several thousand comments stating that FDA should focus on the products it already regulates. In addition, many comments said that FDA should not expand its responsibilities because the agency's resources already are inadequate. Others stated that the regulation of tobacco is a responsibility that Congress has reserved for itself.

In contrast, many supporters of the 1995 proposed rule argued that it was appropriate for FDA to take action on this issue. One woman wrote: ''As the Federal agency designed to protect consumers from harmful consumer products, FDA clearly has both the right and the responsibility to take these actions against the most serious health threat to our young people.''

The regulation of drugs and medical devices sold through interstate commerce is central to FDA's established role. Based on recently available information, as stated in section II. and in the 1996 Jurisdictional Determination annexed hereto, FDA has determined that nicotine is an addictive drug, and that cigarettes and smokeless tobacco are drug delivery devices, which are combination products under section 503(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(g)). As such, these products fall within the traditional scope of FDA's jurisdiction. Therefore, by regulating these products, FDA is carrying out its traditional role.

(2) FDA received thousands of comments about how smoking was an issue of free choice for adults. Most of the comments focused either on the ideological issue of freedom to choose anything, even something dangerous, or on related economic issues, such as the freedom to receive discount or specialty tobacco products by mail. Many comments said the Government must not attempt to regulate human behavior, especially for adults, even when there are health consequences. Letters like this were typical: ''As individuals we too have been promised the freedom of choice and this should continue to be. I don't want the government regulating my personal freedoms.''

Supporters of the rule countered that because nicotine addiction is a pediatric disease, the choice to start smoking is not being made by adults, but by adolescents who constitute a most vulnerable population. Because they are not yet mature individuals, they are not really expressing a free choice, the comments said. In addition, supporters of the rule stated that adolescents, who are so impressionable, are being manipulated by the tobacco companies, especially through advertising, and therefore, are actually being denied a free choice. Instead, the comments urged that adolescents not be allowed to choose something addictive that may damage their health or shorten their lives.

FDA believes that adults should continue to have the freedom to choose whether or not they will use tobacco products. However, because nicotine is addictive, the choice of continuing to smoke, or use smokeless tobacco, may not be truly voluntary. Because abundant evidence shows that nicotine is addictive and that children are not equipped to make a mature choice about using tobacco products, the agency believes children under age 18 must be protected from this addictive substance.

(3) Numerous comments, many from adult smokers, expressed the fear that FDA's true goal is a total ban of all

[34] Opponents and proponents of the rule organized letter-writing campaigns. One, a massive tobacco company-orchestrated campaign, generated some 300,000 pieces of mail—nearly half of all of the mail received by the agency on this topic.

tobacco products. Some asserted that the 1995 proposed rule is a prelude to prohibition. One woman wrote: ''The most insidious insight into this proposed regulatory act is the Federal Government's thinly veiled motive of the eventual prohibition of tobacco sales in the United States to appease a small minority of fanatical anti-smoking zealots.''

FDA strongly disagrees with these comments and reiterates that it has no intention of banning cigarettes and smokeless tobacco. FDA is aware that at least one tobacco manufacturer, in letters sent to its customers encouraging them to submit comments opposing the rule, claimed that the ''real agenda is Backdoor Prohibition of all tobacco products.'' These allegations are baseless and ignore statements made by the President and FDA to the contrary. For example, when the President announced the proposed FDA regulations on August 10, 1995, one reporter asked whether an outright ban would be more logical than a ''regulatory partial step.'' The President replied:

> I think it would be wrong to ban cigarettes outright because, number one, it's not illegal for adults to use them * * * tens of millions of adults do use them. And I think it would be as ineffective as prohibition was. But I do think to focus on our children is the right thing to do.

(Transcript, ''Press Conference by the President,'' dated August 10, 1995) The preamble to the 1995 proposed rule expressed a similar view that removing cigarettes and smokeless tobacco from the market would not be in the best interest of public health (60 FR 41314 at 41348 and 41349).

Rather than instituting prohibition, the agency's rule will inhibit the spread of smoking behavior from one generation to the next. As a result, fewer and fewer adolescents will become addicted to nicotine-containing products. As current smokers either quit or die, the total number of smokers will gradually decline as they are replaced by fewer and fewer new smokers. The agency wants to reassure those who fear that FDA is taking the first steps that would lead inexorably to a ban on the sale of these products to those 18 and over that FDA will not ban these products for adults. Thus, any claim that the rule is a prelude to or would lead to prohibition is totally without merit.

(4) FDA received many comments from politicians, industry representatives, and private citizens who argued that the agency does not need to regulate tobacco because the product is already highly regulated. Many comments observed that all 50 States have passed their own laws prohibiting the sale of tobacco products to minors younger than 18. Comments on existing State enforcement programs primarily came from those opposed to FDA's proposed regulation, including legislators from more than a dozen States. These comments claimed that this should remain a State matter, that State laws are either sufficient or superior to the 1995 proposed rule, that State officials, unlike FDA, are responsive to the concerns of State citizens, and that States and private groups are more responsible and effective than a Federal agency. Comments like this were common: ''Many states have strict restrictions on tobacco sales to minors already and in my State (Maryland) these regulations are being enforced with great success.''

Many supporters of the 1995 proposed rule, however, pointed out that State rules generally have failed to stop minors from purchasing tobacco products. One individual wrote: ''I currently live in a State where there is absolutely no enforcement of the laws banning sales of tobacco to minors,'' and numerous other comments referred to specific instances in which they said State laws were not observed. A joint letter sent by attorney generals from 25 States, as well as Guam and Puerto Rico, welcomed the 1995 proposed rule, saying:

> Although every State bans the sale of tobacco to minors, studies show that children have easy access to tobacco. * * * We believe the proposed rule, which emphasizes reducing access and limiting the appeal of tobacco products to children, should be a crucial component of a national effort by Federal, State and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products.

Many comments stated that the tobacco industry has in place guidelines to prevent the sale of tobacco products to minors. Said one comment: ''I fail to see why the government is so quick to dismiss voluntary action on the part of the industry.'' Other comments recommended that voluntary education programs aimed at retailers, or, more specifically, at retail sales clerks, would be sufficient. These educational programs would either be based on voluntary efforts by the affected industries or in-house, employee training programs.

Supporters of the rule, however, expressed widespread distrust of the industry and of its promise to use voluntary programs to prevent minors from smoking. One woman wrote: ''Thirty years of experience in compromising with the tobacco industry has proven that the industry can not be trusted. After the release of the Surgeon General's report in 1964, the tobacco industry promised to abide by a voluntary advertising code, but the code was quickly ignored after the threat of government regulation had passed.'' Another comment said: ''When tobacco companies fear government regulation, they often adopt voluntarily the restrictions the government is considering. However, there is no penalty for violating a voluntary guideline. The tobacco industry has a track record that speaks for itself. Please don't play the tobacco industry's game!''

The agency believes that the comments opposing the rule on the basis that the States already have restrictions have misinterpreted its scope and application. FDA, under the act, regulates human and animal drug products, certain foods, and devices that are, or have been in interstate commerce. The fact that these products move across State lines makes their regulation a Federal matter.

Other statutes and regulations provide further evidence that tobacco regulation is not reserved to States. The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) (Cigarette Act) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) (Smokeless Act), among other things, place federally-required statements and warnings on cigarettes and smokeless tobacco and require manufacturers to submit reports to the Federal Government. These products are also subject to Federal taxes (see, e.g., 26 U.S.C. 5701) and Federal, rather than State, laws and regulations intended to guard against contraband cigarettes (see 18 U.S.C. 2341 *et seq.*; 27 CFR part 296, subpart F). Thus, tobacco regulation is clearly both a Federal and State matter.

FDA also disagrees with those comments suggesting that States and private groups may be more responsible or efficient than FDA or that FDA may not be as responsive to citizens' concerns. Federal regulation of these products has several significant advantages over State or private group oversight alone; for example, the rule establishes minimum, national standards for the sale and distribution of these products whereas State or private group efforts may be limited to a specific locality or to group members. FDA's regulations also create enforceable obligations whereas private

group efforts, voluntary codes, and industry policies do not.

FDA notes that this regulation does not necessarily preclude States from enforcing their own laws. In fact, under section 1926 of the Public Health Service Act (the PHS Act) (42 U.S.C. 300x-26), States are expected to enact and to enforce laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under age 18.

Moreover, States may choose to regulate areas that are not addressed in this rule and not authorized by the act, such as requiring licenses for retailers. FDA agrees with the comments from State attorneys general that effective regulation of cigarettes and smokeless tobacco, in order to protect children and adolescents, will involve cooperation and joint efforts by Federal and State officials and FDA's rule will enhance, rather than hinder, State tobacco control efforts.

Moreover, States are not precluded from taking action in areas that are addressed in this rule. Although some of these requirements may be preempted, the State may petition the agency for an exemption from the act's preemptive effect under section 521(b) of the act (21 U.S.C. 360k(b)). A more detailed discussion of preemption can be found in section X. of this document.

Finally, regarding the comments questioning FDA's response to State or citizen concerns, mechanisms do exist for States and individual citizens to seek regulatory action or changes by FDA. FDA regulations permit any person to petition the agency to request an action (such as issuance, amendment, or revocation of a rule), to reconsider an action, or to stay an administrative action (see §§ 10.30, 10.33, and 10.35 (21 CFR 10.30, 10.33, and 10.35)). Less formal mechanisms for communicating with FDA, such as letters or meetings, exist as well.

(5) Many comments opposing this rule argued that the tobacco industry already is intensely regulated, and that more regulation is unneeded and unjustified. One person wrote: ''As you know the tobacco industry is already one of the most heavily regulated industries in the United States. Current laws would accomplish the stated objective of the proposed FDA regulations.'' Others disagreed: ''I believe that the tobacco industry has a long, sorry, and cynical record * * *. It is an industry that greatly deserves to be regulated further.''

While it is true that production of tobacco products is regulated, and the industry is heavily taxed, virtually none of these measures is aimed at the product's impact on the health of the individuals using them or on public health. FDA regulation of tobacco products is intended to have a completely different effect than any of the rules that currently applies to the tobacco industry. The agency's regulatory effort will attempt to reduce the number of young people who smoke or use tobacco products, consistent with FDA's mission to protect public health by existing laws.

(6) Many comments objected to the 1995 proposed rule, stating that cigarettes and smokeless tobacco are legal products and should be treated like any other legal consumer product.

FDA believes that the comments misunderstand the regulatory basis for the rulemaking. FDA has determined that these products contain both a drug and device component as defined in section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)), respectively, because the products, and the nicotine in the products, are intended to affect the structure and function of the body. The agency has further determined that these products should be regulated as devices. Thus, the issue is not merely whether the products themselves have been legally marketed, but how they may be most appropriately regulated to protect the public health, given their status under the act and potential to do harm.

(7) Some comments suggested that if the Government begins regulating tobacco, it will soon regulate many other consumer products that are now legal, but judged to be harmful to health, including alcohol and caffeine. They expressed fear that, once FDA begins to regulate one consumer product, it will be obligated to regulate others. Said one man: ''The FDA thinks it is being sly by defining cigarettes as 'nicotine delivery devices.' A shot glass must then be described as a device for alcohol consumption. A coffee mug must be a device for caffeine consumption. Will the FDA be regulating my morning coffee by restricting the size of my cup?'' Some supporters of the proposed rule said that FDA should regulate some of the other consumer products associated with medical disorders. Wrote one: ''Bud frogs are no different than Joe Camel.''

FDA strongly disagrees with these comments and believes that the concerns they express are misplaced. In no way does the agency's regulation of cigarettes and smokeless tobacco as nicotine delivery devices justify or require the regulation of coffee cups and shot glasses.

First, the agency notes that currently it regulates both caffeine and alcohol under the authority of the act. Caffeine naturally occurs in coffee, tea, and other foods. It is also used as an ingredient in soft drinks. The act defines ''food'' as ''articles used for food or drink for man or other animals'' (section 201(f)(1) of the act (21 U.S.C. 321(f)(1))). When caffeine naturally occurs in products that are foods, such as coffee, or when caffeine is used in soft drink products in accordance with section 402 of the act (21 U.S.C. 342), the product is a ''food'' under section 201(f)(1) of the act and thus explicitly excepted from the definition of ''drug'' in section 201(g)(1)(C) (21 U.S.C. 321(g)(1)(C)). Caffeine used in soft drinks in accordance with section 402 of the act is appropriately regulated as a food under 201(f)(1) of the act. Caffeine is also used as an active ingredient in several products regulated as drugs by the agency, including over-the-counter stimulants, internal analgesics and menstrual discomfort relief products.

Likewise, alcohol is used as an ingredient in products regulated as drugs under the act, including over-the-counter cough and cold preparations. There is no evidence to suggest that the agency's current regulation of these substances is inappropriate or inadequate to protect the public health. Therefore, there is no factual or scientific basis for the agency to change the manner in which these substances are now being regulated.

FDA's attention was drawn to tobacco rather than caffeine and alcohol because of certain fundamental differences among the substances. Nicotine is a highly addictive drug. As discussed in section I.B. of this document, studies estimate that as many as 92 percent of all smokers are addicted to the nicotine in cigarettes. There is no evidence that either caffeine or alcohol pose this kind of health problem. Moreover, cigarettes and smokeless tobacco are dangerous products that are associated with lung cancer, heart disease, and many other serious illnesses and conditions.

Yet these factors only served to draw FDA's attention to the tobacco problem. What ultimately separates caffeine and alcohol from nicotine and tobacco products is that caffeine and alcohol are currently being appropriately regulated as foods or drugs based on their intended use. Nicotine and tobacco products, on the other hand, are drugs

and medical devices, respectively, that, in large measure, are not being appropriately regulated. FDA is moving to correct this situation, and the public health will undoubtedly benefit as a result.

(8) Several comments argued that it is the responsibility of parents and teachers, not the Federal government, to educate young people about cigarette and smokeless tobacco use. Some comments feared that FDA's effort to reduce the use of nicotine-containing cigarettes and smokeless tobacco by youth might interfere with the relationship between parents and their children. Many comments voiced the argument that this rule is a sign of big Government getting in the way of parents educating their children. One comment stated, ''This is obviously a case of misplaced priorities * * *. The battle will really be won on the home front. Parental guidance will go a long way in curbing underage smoking.''

Other parents, however, were grateful for any assistance they could get to help protect their children from nicotine addiction. One person said: ''The parents cannot do it all alone.'' Furthermore, most parents who submitted comments stated that a strong national approach to reducing these products' accessibility and appeal would reinforce messages that their children get at home. One comment stated, ''While I am in no way an advocate of government in my life, this to me is a totally different circumstance * * * children should not be expected to make these choices.'' One comment from a middle school student said, ''Giving school age children the opportunity to purchase things that will endanger them is inexcusable.''

The agency recognizes the unique role that parents and teachers have in educating young people and has no intention of intervening in that relationship. Rather, FDA expects the rule to complement parental and educational efforts by reducing the availability and appeal of tobacco products. The preamble to the 1995 proposed rule contained ample evidence as to how these products are easily accessible to and appeal to young people and how a comprehensive approach, aimed at reducing both access and appeal, will be more effective than an educational approach alone. Educating young people about health risks may deter some young people from trying cigarettes and smokeless tobacco, but educating them and simultaneously reducing their ability to acquire the products, as well as reducing the appeal of the products themselves, will prevent more young people from using the products.

FDA also emphasizes that cigarettes and smokeless tobacco are combination drug-device products that are subject to regulation under the act. Consequently, the rule properly addresses issues relating to the sale, distribution, and use of these products by children and adolescents. The rule does not adversely affect a parent's or teacher's ability to discuss cigarette and smokeless tobacco use with young people.

(9) Comments suggested that, for some, illegal drugs and crime evoke stronger emotions than tobacco use. Many comments stated that the Government, although not FDA specifically, should spend more of its resources on fighting crime instead of trying to regulate a legal product such as tobacco. One of the form letters stated it this way: ''Federal dollars would be much better spent addressing inner-city violence, illegal drug sales, and this country's deteriorating education system.''

FDA's authority is defined by the act. FDA lacks the authority to help with other social ills such as crime and illicit drug sales.

(10) One comment urged FDA to institute policies that would facilitate ''whistleblowing.'' The comment said that FDA should encourage tobacco company employees to disclose allegedly illegal or dishonest practices.

Any person, regardless of the industry that employs that person, can provide records and information to FDA for law enforcement purposes with the assurance that his or her identity, and the information and records that he or she provides, will not be publicly disclosed. Current Federal statutes and FDA regulations already protect records or information compiled for law enforcement purposes from public disclosure. For example, the Freedom of Information Act exempts law enforcement records and information from public disclosure. FDA's regulations governing public disclosure elaborate on this exemption, stating, among other things, that the agency may withhold from public disclosure records or information compiled for law enforcement purposes to the extent that disclosure of such records or information could reasonably be expected to disclose the identity of a confidential source and information furnished by a confidential source in the case of a record compiled by FDA or any other criminal law enforcement authority in the course of a criminal investigation (§ 20.64 (21 CFR 20.64(a))).

B. Smoking Prevalence Rates Among Minors

The agency received some comments stressing the importance of accurately measuring youth consumption of tobacco products, reiterating the problem of growing use among young people, and stressing the need to curb such growth to improve health and to reduce the tremendous health care costs attributable to tobacco-related illnesses. However, several disputed the statistics FDA cited on the number of youth smokers and challenged the data sources used. These comments are discussed below.

(11) One comment objected to FDA's description of smoking as a ''pediatric problem,'' arguing that ''TAPS II [Teenage Attitude and Practice Survey II] demonstrates that smoking in any meaningful sense is a phenomenon that occurs in the later teenage years, not in the pre-teen or early teen years.'' It further charged that the agency's use of the term ''pediatric'' is intended to serve ''emotive and/or political purposes, not to describe the problem of underage smoking in scientific or medical terms.''

A comment from a public health association, however, cited the TAPS II survey as showing that ''the average teen smoker initiates smoking at age 13, and becomes a regular smoker by age 14.5.'' It also referred to the Center for Disease Control and Prevention (CDC's) 1992 Youth Risk Behavior Survey, which showed ''similar patterns of early initiation rates, with smoking initiation rates rising rapidly between 10 and 14 years of age.''

The agency maintains its position that smoking is a pediatric disease. It agrees with the comment citing TAPS II and Youth Risk Behavior Survey data showing that the average teen smoker begins smoking in the early teens or even preteens, rather than later years.

Furthermore, the American Academy of Pediatrics' Council on Child and Adolescent Health states that the purview of pediatrics includes the physical and psychosocial growth, development, and health of the individual beginning before birth through early adulthood, and that ''[t]he responsibility of pediatrics may therefore begin with the fetus and continue through 21 years of age.'' This definition of pediatrics obviously includes the age group FDA has targeted to reduce smoking.

(12) One comment from the tobacco industry charged that FDA's assertion

that smoking has increased among 8th- and 10th-grade students ignored CDC's TAPS II data showing that the incidence of underage smoking declined between 1989 and 1993. TAPS II, the comment maintained, showed that ''[a]lthough total smoking in the interview sample [1993] has increased as minors have aged since 1989, comparing the results for minors of a given age indicates that the incidence of underage smoking declined between the two surveys'' and that ''between the two surveys both daily smoking and any smoking in the past 30 days declined among minors.''

The introduction to TAPS II stated that its prevalence findings were comparable to or lower than those of other national surveys. It explained that the survey method used in TAPS II, computer-assisted telephone interviews, had several limitations that may have led to the lower estimates. For example, young people may be fearful of disclosing smoking behavior if a parent is present in the room during the telephone interview. Further, telephone interviews do not afford the same opportunity for building a rapport between the interviewer and the respondent as do in-person interviews. As a result, young people being interviewed in this manner may be less likely to disclose their real smoking behavior. For these reasons, the introduction stated, ''prevalence estimates from TAPS II may be lower than they would have been had the entire TAPS I cohort been successfully reinterviewed and therefore, should be interpreted with caution.'' [35]

(13) One comment challenged FDA's claim that 3,000 young people become new smokers every day. The comment maintained that ''the study from which the '3,000 per day' number was derived did *not* refer to children at all,'' but to smokers ''*aged 20 years old*'' (Pierce et al., 1989) (emphasis from original). [36]

The agency agrees that the study surveyed individuals who were 20-years-old, although the agency referred to these individuals in essentially the same terms used by the authors of the study—''young persons.''

Any potential confusion is mitigated by the fact that subsequent surveys indicate that the vast majority of 20-year-olds begin smoking at a younger age. For example, according to the Combined National Health Interview Surveys for 1987 to 1988, 92 percent of 20-year-old smokers started smoking by age 18. Taking into account the comment and these data, the agency believes that it is accurate to state that approximately 3,000 young people begin to smoke each day, regardless of whether young people is defined as under 18, or 20 years and under, although the agency would note that of the 3,000 young people who begin smoking each day, 2,722 are under age 18.

C. Scope

Proposed § 897.1(a) would have stated that ''[t]his part is intended to establish the conditions under which cigarettes and smokeless tobacco products that contain or deliver nicotine, because of their potential for harmful effect, shall be sold, distributed, or used under the restricted devices provisions of the Federal Food, Drug, and Cosmetic Act.'' Proposed § 897.1(b) would have stated that ''[r]eferences in this part to regulatory sections to the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.'' The final rule is being amended to explicitly state that failure to comply with any applicable provision would render the product misbranded.

The preamble to the 1995 proposed rule stated that ''[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act'' (60 FR 41314 at 41322). The preamble stated that ''FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products'' (*Id.*).

(14) A comment opposing this provision stated that FDA does not have authority to regulate cigarettes under the restricted device (or any other) provision of the act.

The agency disagrees. A full discussion of the agency's authority can be found in section II. of this document.

(15) Several comments supported the provision. Some comments recommended that the scope of the rule should also apply to adult smokers. One comment stated that:

[I]t is evident from the FDCA [the Federal Food, Drug, and Cosmetic Act] that the FDA has clear and unambiguous authority to regulate and restrict the sale of the subject products not only to minors but also to adults, who suffer equally from the mortality and morbidity effects of the toxic components of cigarette smoke and tobacco.

As discussed in section I.B. of this document, the agency believes that, on balance, it is better for cigarettes and smokeless tobacco to remain available for use by adults.

(16) Several comments urged that the scope should be expanded to include all nicotine containing products, including cigars and pipes. Another comment expressed concern that the sale and use of big cigars and pipe tobacco by youth may be increasing, and therefore recommended that FDA expand the scope ''to include all presently marketed nicotine delivery devices,'' or to ''include regular monitoring of youth's use of these products, and should that use increase, provide a means to extend the FDA's rulings to include those products.''

Another comment stated that since ''federal regulations often take seven to ten years to enact and enforce, it is essential that the regulation be written pro-actively to adequately address the problem at the outset.'' The comment stated that ''[i]t is therefore, important to write regulations to protect the public from all 'nicotine delivery devices' that in the future, might be placed in something other than tobacco'' because ''[a]ny product containing the addictive substance of nicotine has a future market because of its addictive nature.''

Finally, this comment asserted that FDA should broaden the scope of the rule to include all products that deliver nicotine, because the comment stated that smoking mothers are at greatest risk for reproductive hazards, such as low birth weight babies. The comment stated that ''[c]onsidering that over 50% of births are unplanned, and that people believe they can always quit smoking, it is too late to avoid damage by smoking mothers by the time they realize they are pregnant.''

The preamble to the 1995 proposed rule stated that ''[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act'' (60 FR 41314 at 41322). The preamble stated that ''FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products'' (60 FR 41314 at 41322).

The agency advises that, at this time, there is insufficient evidence of cigar or pipe tobacco use by children and

[35] ''1993 Teenage Attitudes and Practices Survey, Public Use DataTape,'' CDC, OSH, p. 3, 1993 (unpublished data).

[36] Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, ''Trends in Cigarette Smoking in United States: Projections to the Year 2000,'' *JAMA*, vol. 261, pp. 61–65, January 6, 1989.

adolescents to support the inclusion of cigar, pipe tobacco, or ''all presently marketed nicotine delivery devices'' within the scope of the final rule (section III.E. of this document).

In response to the comment stating that the agency should monitor youths' use of products such as cigars or pipe tobacco, and that the agency should provide a means to ''extend FDA's rulings to include these products,'' the agency advises that, as stated in the 1995 proposed rule, the objective of the final rule is to meet the goal of the report ''Healthy People 2000,'' by reducing roughly by half children's and adolescents' use of tobacco products. The agency is not asserting jurisdiction over pipes and cigars at this time because it does not have sufficient evidence that these products satisfy the definitions of drug and device in the act. However, the agency will consider any additional evidence that becomes available, including any new evidence that these products meet the statutory definitions as well as evidence that indicates that cigars and pipe tobacco are used significantly by young people.

FDA also disagrees with the comment claiming that Federal regulations take 7 to 10 years to enact and enforce. While it may be true that rulemaking, in general, can be a time-consuming task, the agency can and has taken prompt action to issue rules with significant public health implications. For example, the proposed rule for this final rule appeared in the Federal Register of August 11, 1995 (60 FR 41314). (See also 56 FR 60366 et al., November 27, 1991, and 58 FR 2066 et al., January 6, 1993 (15 months to issue Nutrition Labeling and Education Act regulations); 60 FR 5530, January 27, 1995, and 60 FR 63372, December 8, 1995 (11 months to issue regulations to facilitate communications between FDA and State and foreign governments in order to enhance regulatory cooperation).) If it is necessary to amend this regulation, the agency will also be able to do so expeditiously.

The agency agrees with the comment stating that smoking mothers are at risk for certain reproductive hazards. FDA has chosen to tailor its regulation to address only children and adolescents. However, other agencies within the Department of Health and Human Services (DHHS) have programs that currently address tobacco use by persons of all ages.

FDA, on its own initiative, has revised § 897.1 to simplify and to clarify the scope of the rule. As revised, § 897.1(a) states that part 897 ''sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.'' This sentence is comparable to proposed § 897.1(a), but more accurate because the 1995 proposed rule only referred to FDA's restricted device authority. FDA has also added a new § 891.1(b) stating that ''[t]he failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.'' This sentence is intended to remind parties that violations of a regulation for a restricted device and other actions relating to the sale of a device may cause a device to be ''misbranded'' under the act. Proposed § 897.1(b), which would have stated that regulatory references are to title 21 of the Code of Federal Regulations, has been renumbered as § 891.1(c) in the final rule and has not been changed.

D. Purpose (§ 897.2)

Proposed § 897.2(a) would have stated that:

> [t]he purpose of this part is to establish conditions for the sale, distribution, and use of cigarettes and smokeless tobacco products in order to: * * * [r]educe the number of people under 18 years of age who become addicted to nicotine, thus avoiding the life-threatening consequences associated with tobacco use and to provide important information regarding the use of these products to users * * *.

The agency has modified the final rule to provide information regarding the use of these products only to users; it has deleted potential users because the final rule no longer includes an education program for young people. Proposed § 897.2(b) stated that this part of the provision is intended to ''[p]rovide important information regarding the use of these products to users and potential users.'' The agency's response to more specific comments follows.

The preamble to the 1995 proposed rule stated that the proposed rule would reduce ''the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age,'' but ''would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older'' (60 FR 41314 at 41322).

This rule is designed to complement the regulations (sometimes referred to as ''the Synar regulations'') issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) (the SAMHSA rule) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to individuals under the age of 18. The SAMHSA rule contains standards for determining State compliance with section 1926 relating to the enactment and enforcement of State laws prohibiting the sale and distribution of tobacco products to individuals under the age of 18. Both sets of regulations are designed to help address the serious public health problem caused by young people's use of nicotine-containing tobacco products. By approaching this pediatric disease from different perspectives, these regulations together will help achieve the Administration's goal of reducing the number of young people who use tobacco products by 50 percent.

(17) One comment opposing this provision stated that ''it will have little effect on tobacco use by young people, is beyond FDA'S statutory authority, is unjustified as a matter of policy, and would violate the Constitution.''

The agency believes that the comment opposing this provision misinterprets § 897.2. This particular provision merely states the purpose of the entire rule and is not intended, in and of itself, to impose any new restrictions. The agency disagrees that the entire rule will have little effect on tobacco use by young people; that it is beyond the agency's statutory authority; that it is unjustified as a matter of policy; and that it violates the Constitution. All of these issues are discussed in detail elsewhere in this document.

(18) Several comments supported the provision, stating that a national policy is essential because State laws are ineffective and inconsistent.

The agency agrees with these comments and advises that the final rule complements the existing efforts by States to enforce restrictions on young people's access to cigarettes and smokeless tobacco. As stated in the comments, all States currently have laws prohibiting the sale of tobacco products to minors. Section 1926 of the PHS Act creates an incentive for the States to reduce the unlawful sales of tobacco products to young people by ''requiring States to have in effect laws which prohibit the sale of tobacco products to minors as a condition of receipt of substance abuse grants.'' This rule would only preempt individual State requirements that are different from or in addition to these regulations (see section 521(a) of the act (21 U.S.C. 360k(a))). Thus, a State restriction on the sale of cigarettes and smokeless tobacco to individuals under the age of 18 will continue to be enforced by the State. (See preemption discussion,

section X. of this document.) While the agency expects the State laws to reduce smoking among young people, those laws unlike FDA's rule, only reduce access and not the appeal of smoking to young people. Thus, the agency believes that the rule will help States achieve their goals under the substance abuse programs.

(19) One comment supporting the provision stated that although the focus of the rule should be on children, ''the needs of adult smokers should not be abandoned.'' Another comment stated that:

> Cigarettes and smokeless tobacco products are nicotine delivery devices and they regularly cause addiction in their users. Because addiction often leads to serious illness and death, it is important to reduce the number of people under 18 years of age who become addicted to nicotine. Similarly, it is important to provide accurate information about the use of these products to users and to potential users.

The agency appreciates the comment's suggestion, but advises that, for reasons explained in section I.B. of this document, the final rule focuses principally on children and adolescents.

FDA, on its own initiative, has revised § 897.2 to state that the purpose of part 897 is ''to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.'' FDA believes this revision is a simpler and more accurate statement of the rule's purpose.

E. Definitions (§ 897.3)

Proposed § 897.3 would have contained definitions for the terms ''cigarette,'' ''cigarette tobacco,'' ''distributor,'' ''manufacturer,'' ''nicotine,'' ''package,'' ''point of sale,'' ''retailer,'' and ''smokeless tobacco.'' The agency received several comments on the definition section of the proposal, regarding either the specific definitions provided or requesting definitions for additional terms. In response to the comments, the agency has clarified several terms, including ''distributor'' and ''retailer,'' and has modified the term ''cigarette'' to exclude little cigars.

Proposed § 897.3(a)(3) would have provided a definition of ''cigarette'' which included the following language, modeled after the definition of ''little cigar'' contained in the Cigarette act:

> (a) *Cigarette* means * * *
>
> (3) [a]ny roll of tobacco wrapped in leaf tobacco or any substance containing tobacco * * * and as to which 1,000 units weigh not more that 3 pounds.

(20) Several comments supported the inclusion of ''little cigars'' in the definition of ''cigarette'' and suggested that the definition be broadened to include other tobacco products as well. These comments argued that all tobacco, including ''snuff,'' chewing tobacco, cigars, and pipes, should be regulated in the same manner as cigarettes, as these products are also nicotine delivery systems. These comments further stated that there is evidence to show that cigar smoking is becoming increasingly popular among young adults and adolescents.

In contrast, several comments from industry indicated that little cigars are unique products which should not be regulated as cigarettes. One comment stated that the agency has no studies to support the inclusion of little cigars in the rule. Moreover, the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) submitted a comment opposing the inclusion of little cigars in the ''cigarette'' definition, as this would require little cigars to be labeled and advertised as a cigarette under the FDA regulations, but taxed and labeled as a ''cigar,'' under the Internal Revenue regulations enforced by BATF.

The agency has decided, based upon the comments and the record of this proceeding, not to include little cigars in the definition of ''cigarettes'' for the purposes of the regulation. The differences between little cigars and cigarettes are significant—the products are easily distinguishable, taxed at different levels, and marketed to different consumers. Moreover, little cigars are neither advertised extensively nor sold in vending machines. Most importantly, the agency is not currently aware of sufficient evidence of use of little cigars by children or adolescents to support inclusion of such products in the rule. Therefore, FDA has deleted little cigars from the definition of ''cigarette'' in § 897.3(a). Moreover, FDA will continue to coordinate definitions with BATF as appropriate.

Additionally, FDA has deleted ''components, accessories, or parts'' from § 897.3(a). The reference to ''components, accessories, or parts'' was unnecessary because the statutory definition of ''device'' includes ''any component, part, or accessory.''

Proposed § 897.3(b) would have defined ''cigarette tobacco'' as ''any loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette.'' The proposed definition also would have stated that ''[u]nless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.''

(21) One comment by manufacturers of ''roll-your-own'' (RYO) cigarette tobacco argued that the inclusion of RYO cigarette tobacco under the 1995 proposed rule was arbitrary and capricious, as the agency had no factual information about RYO's composition, marketing, and usage. This comment also asserted that there is no evidence of RYO tobacco usage by minors.

The agency disagrees that the inclusion of cigarette tobacco in the rule is arbitrary and capricious. RYO tobacco is nothing less than cigarettes that have not yet been assembled. Unquestionably, RYO cigarettes contain tobacco and are smoked. The comment did not challenge the agency's proposed finding that the smoke from RYO cigarettes is inhaled, that the RYO tobacco is processed, and that RYO cigarettes deliver nicotine. Unlike ''little cigars,'' discussed in paragraph 1 of this section of the document, the agency believes that there is no significant difference in the composition of RYO tobacco or in the reason consumers use it (to deliver nicotine) from cigarettes. The agency believes that, because a RYO cigarette is fundamentally the same product as a commercially manufactured cigarette posing the same risks, it should be subject to the restrictions in this rule in order to protect the public health.

Furthermore, it is important to include RYO tobacco because to exclude it would provide a simple and obvious way to avoid the restrictions in this regulation. If such an exception existed, cigarettes could be packaged and sold in such a way as to be considered RYO products. Tobacco companies would then be free to sell these products using all the marketing and promotion techniques currently used for cigarettes, techniques that are particularly successful with young people. An exception so broad would quickly undermine the entire purpose of the rule. Additionally, FDA has made a minor change to § 897.3(b) to have ''cigarette tobacco'' mean ''any product that consists of loose tobacco * * *.'' The addition of the words ''any product'' is intended to make § 897.3(b) conform with the format used for other definitions.

(22) In proposed § 897.3(c), ''distributor'' would have been defined as ''any person who furthers the marketing of cigarettes or smokeless tobacco products * * * from the

original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the * * * products.''

Several comments stated that the definition of ''distributor'' is vague and over broad, because:

[P]ersons 'who further the marketing of cigarettes or smokeless tobacco' [may include] literally everyone involved in the production, shipping, advertising, or promotion of cigarettes. Such 'distributors' could thus include, for example, cigarette manufacturers and their employees; truckers and shipping clerks involved in the physical movement of the product; advertising agencies; people involved in promotional activities and the manufacture of promotional materials; retailers and their employees; and conceivably even individuals who 'deliver' cigarettes to social acquaintances or family members as 'ultimate users.' Including such persons and entities within the definition of 'distributor' would, in turn, render them 'responsible,' * * * for ensuring that the cigarettes the 'marketing' of which they 'further' comply with 'all applicable requirements' of part 897.

(23) One comment suggested that an individual advocating a particular brand of cigarette would fall within the definition of ''distributor.''

The agency recognizes the concerns expressed about the proposed definition of ''distributor.'' Therefore, based upon the comments received, the agency has determined that the definition should be modified to clarify the term. The definition of ''distributor'' has been modified to mean ''any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption.'' The term does not include persons who do not manufacture, fabricate, assemble, process, or label a finished cigarette or smokeless tobacco product, and does not repackage or otherwise change the container, wrapper, or labeling of the cigarette or smokeless tobacco product, because such persons would be ''manufacturers'' under § 897.3(d).

Under this modified definition, one who manufactures cigarettes or smokeless tobacco is not considered a distributor, but is subject to the requirements applicable to manufacturers (see § 897.3(d), definition of ''manufacturer''). Similarly, one who ''sells or distributes the product to individuals for personal consumption'' is not a distributor, but is subject to the requirements applicable to retailers (see § 897.3(h), definition of ''retailer''). Furthermore, the modified definition clearly does not apply to advertising agencies. Although advertising agencies may be said to further the ''marketing'' of a product they advertise, they do not further the ''distribution'' of that product. As for truckers and other carriers, section 703 of the act only requires ''carriers engaged in interstate commerce'' and persons receiving or holding devices in interstate commerce to provide access to records showing the devices' movement or holding in interstate commerce. Thus, such carriers would not be subject to the requirements applicable to distributors under this part.

(24) Proposed § 897.3(d) would have defined ''manufacturer,'' in part, ''as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.'' One comment suggested that this definition be modified to exclude foreign manufacturers and manufacturers of products that make up less than 1 percent of the total U.S. cigarette market.

The agency disagrees that foreign manufacturers and ''small'' manufacturers should be excluded from the definition. A company that manufactures a small amount of a product is, nevertheless, a manufacturer. Thus, small manufacturers and foreign manufacturers of products marketed in the United States are included in the definition of ''manufacturer'' and are subject to the provisions of this rule. Furthermore, as discussed in more detail later, FDA regulates devices as a class without making exceptions for small market share.

Additionally, FDA, on its own initiative, has deleted the part of the definition which would have stated that a ''manufacturer'' ''does not include any person who only distributes finished cigarettes or smokeless tobacco products.'' FDA believes this text was unnecessary given the definition of ''distributor'' in § 897.3(c).

Proposed § 897.3(e) would have defined ''nicotine'' by its chemical formula, 3-(1-Methyl-2-pyrolidinyl) pyridine, and would have included any salt or complex of nicotine. FDA did not receive any comments that would warrant a change to § 897.3(e), and has finalized this definition without change.

Proposed § 897.3(f) would have defined ''package'' as a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

FDA did not receive any comments that would warrant a change to § 897.3(f) but has, on its own initiative, deleted the word ''products'' from ''smokeless tobacco products'' to correspond to similar changes throughout the rule.

(25) Proposed § 897.3(g) would have defined ''point of sale'' to mean ''any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco products for personal consumption.'' One comment stated that this definition is unconstitutionally vague and over broad, because ''a person can 'obtain' cigarettes from a social acquaintance or family member * * * in any number of * * * settings.'' The comment suggested that ''point of sale'' be limited to ''commercial establishments where tobacco products are *sold* in arm's-length commercial transactions.''

The agency agrees that obtaining a cigarette from a social acquaintance or family member should not render the venue of this ''transaction'' a ''point of sale.'' However, the agency does not believe that the definition of ''point of sale'' is vague or overly broad, or that it needs to be modified. The definition, as proposed, makes it clear that ''point of sale'' does not contemplate venues where cigarettes are lent or offered to social acquaintances or family members. The definition in § 897.3(d) refers to the ''location at which a *consumer* can purchase or otherwise obtain'' the product (emphasis added). The term ''consumer,'' means ''a person who buys goods or services for personal needs and not for resale or to use in the production of other goods for resale.'' [37] Thus, in its normal use, the term ''consumer'' implies a commercial relationship and precludes the possibility that, for example, the act of providing a cigarette to a travel partner would render the vehicle in which both are traveling the ''point of sale'' for that product.

(26) Proposed § 897.3(h) would have defined ''retailer'' to mean ''any person who sells or distributes cigarettes or smokeless tobacco products to individuals for personal consumption.'' One comment stated that this definition is unconstitutionally vague and over broad, because a ''manufacturer or wholesaler that 'distributes' complimentary cigarettes to its employees, or to guests at a private function, would be a 'retailer,' as would

[37] *Webster's New World Dictionary*, edited by V. Neufeldt, Third College Edition, Prentice Hall, New York, p. 299, 1991.

be any individual who gives any other individual a cigarette.''

The agency agrees that, although the intended meaning of the term is clear, a ''person who * * * distributes * * * [a product] to individuals for personal consumption'' may include transactions that the agency does not intend to regulate (i.e., noncommercial transactions). Therefore, the definition is modified to mean ''any person who sells cigarettes or smokeless tobacco to individuals for personal consumption.''

Additionally, under § 897.3(h) as revised, a retailer can be any person ''who operates a facility where vending machines and self-service displays are permitted under this part.'' This change complements a change to § 897.16(c) which permits vending machines and self-service displays in facilities where no person under age 18 is present, or permitted to enter, at any time. The agency addresses § 897.16(c) in greater detail below.

Proposed § 897.3(i) would have defined smokeless tobacco as ''any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity.''

FDA did not receive any comments that would warrant a change to § 897.3(i). However, FDA has revised the definition to refer to ''any product that consists of cut, ground, powdered, or leaf tobacco * * *.'' The agency made this change because the words ''smokeless tobacco'' are often understood as meaning a ''smokeless tobacco product'' or products. Additionally, elsewhere in this rule, FDA has replaced ''smokeless tobacco product'' with ''smokeless tobacco.''

(27) Several comments requested definitions for additional terms. Specifically, one comment requested that ''advertising'' be defined to distinguish between trade and consumer advertising; several comments requested that ''vending machine'' be defined to exempt machines which dispense cigarettes to cashiers, machines that dispense individual cigarettes, or machines that scan a driver's license or age of majority card before dispensing cigarettes; and several comments requested that ''playground'' be defined for clarity.

The agency disagrees that additional definitions are necessary for the terms ''advertising'' and ''vending machine.'' However, the agency has clarified the use of those terms in the relevant sections of the preamble. The agency has determined that a definition for the term ''playground'' is necessary, and has added some examples to § 897.30. A discussion of the comments regarding the definition of ''playground'' can be found in section VI. of this document.

IV. Access

Subpart B of part 897 (now retitled as ''Prohibition of Sale and Distribution to Persons Younger than 18 Years of Age'') contains the restrictions on access to cigarettes and smokeless tobacco by individuals under the age of 18. This subpart, by imposing restrictions on manufacturers, distributors, and retailers, is intended to ensure that children and adolescents cannot purchase these products.

In support of proposed subpart B, the preamble to the 1995 proposed rule cited studies showing that the majority of junior high and high school students—from 67 percent of 9th grade students in a 1990 survey to 94 percent of junior high and high school students in a 1986 survey—believed that purchasing cigarettes and smokeless tobacco was easy (60 FR 41314 at 41322, August 11, 1995). Other studies supported that belief. As noted in the preamble to the 1995 proposed rule, the 1994 Surgeon General's Report entitled ''Preventing Use Among Young People: A Report of the Surgeon General'' (the 1994 SGR) examined 13 studies of over-the-counter (OTC) sales and determined that approximately 67 percent of minors are able to purchase cigarettes illegally. The 1994 SGR examined nine studies and found that the weighted average rate of illegal sales to children and adolescents from vending machines was 88 percent.[38]

Significant numbers of children and adolescents successfully purchased smokeless tobacco as well, with the success rate ranging from 30 percent for junior high school students to 62 percent for senior high school students (60 FR 41314 at 41322). Ninety percent of smokeless tobacco users in junior high and high school in a 1986 survey said they bought their own smokeless tobacco (60 FR 41314 at 41322).

Studies indicate that a comprehensive approach to reducing young people's access to cigarettes and smokeless tobacco would be more effective than relying primarily on retailer education programs about the need to prevent sales to underage persons. For example, the preamble to the 1995 proposed rule cited a comprehensive community intervention in Woodridge, IL, involving retailer licensing, regular compliance checks, and penalties for merchant violations. The Woodridge program reduced illegal sales from 70 percent to less than 5 percent almost 2 years later (60 FR 41314 at 41322). Rates of both experimentation and regular smoking decreased more than 50 percent among seventh and eighth grade students (60 FR 41314 at 41322).

In contrast, another study cited in the 1995 proposed rule indicated that retailer education programs, alone, may have limited utility. In the study, retailers received informational packages on preventing illegal sales to young people, yet despite these informational packages, young people were able to buy cigarettes in 73 percent of the stores that received these informational packages, and, after a comprehensive retailer educational program was conducted, illegal sales were still found to occur in 68 percent of the stores (60 FR 41314 at 41322). When the program began issuing citations to violative establishments, the illegal sales rate dropped to 31 percent (*Id.*). This study, as well as other studies reviewed by the agency in the 1995 proposed rule and made available for public comment and review, led the Food and Drug Administration (FDA) to draft a comprehensive proposal to reduce young people's access to cigarettes and smokeless tobacco and to make explicit the responsibility of manufacturers, distributors, and retailers to prevent cigarette and smokeless tobacco product sales to persons under 18 years of age.

Subpart B to part 897 consists of four provisions. Section 897.10 establishes the general responsibilities of manufacturers, distributors, and retailers to ensure that the cigarettes and smokeless tobacco that they manufacture, label, advertise, package, distribute, sell, or otherwise hold for sale comply with the requirements in this subpart. The agency made one minor change to this provision, to change ''smokeless tobacco products'' to ''smokeless tobacco.''

Section 897.12 sets forth additional responsibilities of manufacturers. Proposed § 897.12(a) would have required manufacturers to remove from point of sale all violative self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items. In response to comments from manufacturers and sales representatives objecting to their responsibility for items not owned by them, the agency has amended this provision to require manufacturers only to remove from point of sale all violative self-service displays, advertising,

[38] 1994 SGR, p. 249.

labeling, and other items owned by the manufacturer.

Proposed § 897.12(b) would have required manufacturers' representatives who visit a point of sale in the normal course of business to visually inspect and ensure that products are labeled, advertised, and distributed in accordance with this subpart. In response to comments questioning the need for and operation of this requirement, FDA has deleted this provision.

Section 897.14 sets forth additional responsibilities of retailers. Many of the comments supported the requirements to verify age and to ban the sale of single cigarettes. Comments were divided on the requirement for a direct transaction. The comments opposing the 1995 proposed rule were taken into account in the modifications to the final rule.

The final rule contains a new § 897.14(a), which states that no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. This new paragraph codifies a concept that was implicit in the 1995 proposed rule.

Proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required that the retailer or an employee of the retailer verify by means of photographic identification showing the bearer's date of birth that no purchaser is younger than 18 years of age. In response to changes made to § 897.16 regarding mail-order and vending machine sales and self-service displays in facilities inaccessible to children and adolescents, the final rule excepts the requirements for proof of age under these limited circumstances. New § 897.14(b)(2) eliminates the verification requirement for consumers 26 years of age or older.

Proposed § 897.14(b) (now numbered as § 897.14(c)) would have required that cigarettes or smokeless tobacco be provided to the purchaser by the retailer or an employee of the retailer, without the assistance of an electronic or mechanical device, such as a vending machine. The final provision has been modified to reflect changes made to § 897.16 permitting vending machines and self-service displays in certain limited circumstances and to correspond more closely to the requirements in § 897.16(c)(1).

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee from opening any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any quantity of the product that is smaller than the quantity in the unopened products. In order to clarify the intent of this provision, the final rule prohibits retailers from breaking or otherwise opening ''any cigarette or smokeless tobacco product package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use.''

The final rule also adds § 897.14(e) to clarify that each retailer is responsible for removing all violative self-service displays, advertising, labeling, and other items located in the retailer's establishment or for bringing those items into compliance with the requirements in this rule. This provision complements § 897.12 which requires manufacturers to remove manufacturer-owned, violative items from retail establishments.

Section 897.16 establishes the conditions of manufacture, sale, and distribution. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product ''except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995.'' The only change to § 897.16(a) has been to clarify the agency's intent by amending the language to restrict manufacturers to those product names ''whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.''

Section 897.16(b) would have established a minimum package size of 20 for cigarettes. The final rule was amended only to provide a very limited exception consistent with the changes made to § 897.16(c)(2)(ii), discussed below.

Proposed § 897.16(c) would have prohibited vending machines, self-service displays, mail-order sales, and other ''impersonal'' modes of sale and required direct, face-to-face exchanges between retailers and consumers. In response to comments criticizing the restrictions as inconveniencing adults, the agency has amended this section. The final rule allows mail-order sales (except for mail-order redemption of coupons and the distribution of free samples through the mail). The final rule also allows vending machines (even those selling packaged, single cigarettes), and self-service displays (merchandisers) in facilities that are inaccessible to persons under the age of 18.

Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing any free samples of cigarettes or smokeless tobacco. FDA made one minor change to this provision, changing the words ''manufacturers, distributors, and retailers may not distribute'' to ''no manufacturer, distributor, or retailer may distribute'' free samples.

The final rule adds a new § 897.16(e) to prohibit manufacturers, distributors, and retailers from selling, distributing, or causing to be sold or distributed cigarettes or smokeless tobacco with advertising or labeling that does not comply with the rule's advertising and labeling requirements. This provision is intended to clarify that the rule's advertising and labeling requirements are conditions on the sale, distribution, and use of these products.

A. General Comments

The agency received many general comments both in support of and in opposition to proposed subpart B of part 897. Comments supporting the 1995 proposed rule often stated that the rule, if finalized, would help prevent young people from obtaining or using cigarettes and smokeless tobacco and would eventually lead to a healthier population and lower health care costs. The agency also received comments from attorneys general of more than 25 States concluding that, overall, the 1995 proposed rule ''should be a crucial component of a national effort by Federal, State, and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products.''

Comments opposing the 1995 proposed rule, in general, asserted that FDA regulation was unnecessary or unauthorized or that the proposed requirements would be ineffective. The following is an analysis of and response to these general comments.

(1) Several comments stated that the 1995 proposed rule violates the Commerce Clause of the Constitution. The comments argued that there is no equivalent to a congressional finding that the regulated activity at issue—the sale of tobacco products to children and adolescents—affects interstate commerce, nor is the regulation reasonably adapted to an end permitted by the Constitution. They argued that the regulation of tobacco products by

the Federal Government is impermissible based on *United States* v. *Lopez*, 115 S.Ct. 1624 (1995) (Congress lacked power under Commerce Clause to criminalize possession of a gun within 1,000 feet of a school).

The agency disagrees with these comments. The Constitution gives Congress the power ''[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.'' Under the Commerce Clause, Congress may ''regulate those activities having a substantial relationship to interstate commerce, i.e., those activities that substantially affect interstate commerce'' (*Lopez*, 115 S.Ct. at 1629–30 (citation omitted)). The Supreme Court has consistently held that Congress acted within its powers under the Commerce Clause when it enacted and subsequently amended the Federal Food, Drug, and Cosmetic Act (the act). (See *United States* v. *Sullivan*, 332 U.S. 689, 697–98 (1948); *United States* v. *Walsh*, 331 U.S. 432, 437–38 (1947); *Weeks* v. *United States*, 245 U.S. 618, 622 (1918); *Seven Cases of Eckman's Alternative* v. *United States*, 239 U.S. 510, 514–15 (1916); *McDermott* v. *Wisconsin*, 228 U.S. 115, 128 (1913); *Hipolite Egg Co*. v. *United States*, 220 U.S. 45, 58 (1911).) Regulation of tobacco products is a legitimate exercise of FDA's authority under the act to regulate drugs and devices and is therefore within the scope of Congress' power under the Commerce Clause.

The Supreme Court's recent opinion in *Lopez* does not affect this analysis. As the Court noted, ''[t]he 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.'' (See *Lopez*, 115 S.Ct. at 1634; see also *Id*. at 1640 (Kennedy, J., concurring) (''[H]ere neither the actors nor their conduct have a commercial character, and neither the purposes nor the design of the statute have an evident commercial nexus.'').)

By contrast, this tobacco regulation affects conduct that is distinctly commercial in character. In particular, the access restrictions—the national minimum age for purchase of tobacco products and the restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays—all involve actors (manufacturers, vendors, and consumers) and conduct (the marketing, sale, and purchase of products that are themselves in interstate commerce) that are quintessentially commercial (see, e.g., *Katzenbach* v. *McClung*, 379 U.S. 294, 298–304 (1964) (under the Commerce Clause, Congress may regulate activities of restaurants that serve food, a substantial portion of which has moved in interstate commerce)). In addition, the purpose and design of the regulation—to deter this commercial activity directed at persons under the age of 18 in order to reduce addiction to the nicotine in these products—has the requisite commercial nexus. (See, e.g., *Heart of Atlanta Hotel, Inc*. v. *United States*, 379 U.S. 241 (1964); *Perez* v. *United States*, 402 U.S. 146 (1971).) Moreover, because youths alone purchase an estimated $1.26 billion of tobacco products annually, the regulated activity—sales of tobacco products—substantially affects interstate commerce. [39]

As noted, tobacco products are in interstate commerce as defined in section 201(b) of the act (21 U.S.C. 321(b)). Cigarettes manufactured in the United States include myriad components that are in interstate commerce. For example, American-type blended cigarettes contain oriental tobacco imported from Greece, Turkey, Russia, Yugoslavia, or Bulgaria, and they may also contain imported flue-cured tobacco from, for example, Zimbabwe or Brazil. In addition, they contain other tobacco and tobacco products, filters, paper, ammonia, sugars, humectant, licorice, and cocoa, among nearly 600 other possible ingredients. (See generally Brown, C. L., *The Design of Cigarettes*, Hoechst Celanese Corp., Charlotte, NC (3d ed. 1990); ''Ingredients Added to Tobacco in the Manufacture of Cigarettes by the Six Major American Cigarette Companies,'' (April 12, 1994)). Similarly, smokeless tobacco is made from tobacco grown in Pennsylvania and Wisconsin or in Kentucky and Tennessee and contains other ingredients from a list of over 560, such as sugar, molasses, and licorice, which are in interstate commerce. (See *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, DHHS, PHS, p. 5, 1986; ''Smokeless Tobacco Ingredient List as of April 4, 1994, attached to letter of May 3, 1994, from Stuart M. Pape to the Hon. Henry A. Waxman and the Hon. Thomas J. Bliley, Jr.)

(2) The comments also suggested that Congress' Commerce Clause powers do not allow imposition of a national minimum age for the purchase of tobacco products.

The agency disagrees. The cases cited in these comments, *South Dakota* v. *Dole*, 483 U.S. 203 (1987) and *Oregon* v. *Mitchell*, 400 U.S. 112 (1970), do not address the Commerce Clause, and there is no case law suggesting that an agency may not impose regulations on commerce based on the age of people involved, under a statute passed pursuant to Congress' Commerce Clause power, and in particular that an agency may not set a national minimum age for sales of cigarettes and smokeless tobacco in order to reduce the risks of addiction and to health associated with their use by individuals under age 18. In fact, under its authority to regulate commerce, Congress may exclude from interstate commerce goods produced by children workers, *United States* v. *Darby*, 312 U.S. 100, 115–17 (1941) (overruling *Hammer* v. *Dagenhart*, 247 U.S. 251 (1918), which held that Congress lacked power to exclude products of child labor from interstate commerce), and criminalize, for example, the transportation in interstate commerce of pornography involving children (18 U.S.C. 2251 through 2259), or the sale of firearms and ammunition to individuals under the age of 18 (18 U.S.C. 922(b)(l)).

Moreover, '''[t]he authority of the Federal government over interstate commerce does not differ' * * * 'in extent or character from that retained by the states over intrastate commerce.''' (See *Heart of Atlanta Hotel*, 379 U.S. at 260 (quoting *United States* v. *Rock Royal Co-op., Inc*., 307 U.S. 533, 569–70 (1939)).) States may set a minimum age for sales of cigarettes and smokeless tobacco, and these products are in interstate commerce (and as devices, are presumed under section 709 of the act to be in interstate commerce for the purpose of jurisdiction under the act). Thus, it follows that the Federal Government may establish a national minimum age for sales of tobacco products.

In summary, the imposition of a national minimum age for purchase of tobacco products and restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays is within Congress' authority under the Commerce Clause.

(3) Several comments argued that the regulation's imposition of a national minimum age for purchase of tobacco products and its restrictions on impersonal sales, sales from opened packages, package size, vending

[39] DiFranza, J. R., and J. B. Tye, ''Who Profits from Tobacco Sales to Children?'' *JAMA*, vol. 263, No. 20, pp. 2784–2787, 1990.

machine sales, and self-service displays violate the Tenth Amendment to the Constitution. In particular, the comments argued that the regulation of tobacco products and decisions about eligibility and maturity are traditionally State functions, and that this fact required Congress to have made it unmistakably clear by statute that it intended FDA to regulate tobacco products.

The agency believes that this regulation does not violate the Tenth Amendment. The Tenth Amendment provides that ''[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.'' It follows that, ''[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States.'' (See *New York* v. *United States*, 505 U.S. 144, 156.) Because FDA is acting under the act, which Congress enacted under its Commerce Clause authority, there is no Tenth Amendment violation.

FDA disagrees that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions. Even if they were, however, that fact would not implicate the Tenth Amendment. ''As long as it is acting within the powers granted it under the Constitution, * * * Congress may legislate in areas traditionally regulated by the States'' (*Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991)). Because the agency is acting to regulate cigarette and smokeless tobacco sales in order to eliminate the health risks of those products, and is doing so under a statute passed under Congress' Commerce Clause power, these provisions do not violate the Tenth Amendment.

Further, Congress need not make its intention to regulate in such areas ''unmistakably clear in the language of [a] statute,'' *Will* v. *Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) (quotations omitted), as suggested in the comments. This requirement only applies to Federal statutes that ''go[] beyond an area traditionally regulated by the States'' to affect ''decision[s] of the most fundamental sort for a sovereign entity,'' *Gregory*, 501 U.S. 460, because such statutes ''alter the usual constitutional balance between the States and the Federal Government,'' *Will*, 491 U.S. 65 (quotations omitted); see also *Seminole Tribe of Florida* v. *Florida*, 116 S.Ct. 1114, 1123–1132 (1996) (holding that, even if Congress, acting under the Commerce Clause, makes its intention to subject unconsenting States to Federal suits by private parties absolutely clear, the Eleventh Amendment bars such suits). Regulation of the sale of cigarettes and smokeless tobacco does not fundamentally affect the States' prerogatives under the Constitution (such as abrogating the States' sovereign immunity), and so Congress need not have made it unmistakably clear by statute that it intended FDA to regulate their sale.

In summary, the agency is imposing a national minimum age for purchase of tobacco products and restrictions on impersonal sales, sales from opened packages, package size, vending machine sales, and self-service displays in order to eliminate the health risks to young people associated with products in interstate commerce. These provisions therefore do not violate the Tenth Amendment.

(4) A comment from an industry trade association stated that the Ninth Amendment to the Constitution is a ''barrier to federal laws that would restrict freedom of adults as well as others to use tobacco products.'' Several comments from adults expressed similar arguments regarding an adult's ''freedom'' to purchase or use tobacco products.

The agency disagrees that its imposition of a national minimum age for purchase of tobacco products and its restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays impinge on unenumerated rights protected by the Ninth Amendment.

The Ninth Amendment provides that ''[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.'' Although not a source of rights itself, the Ninth Amendment nevertheless ''show[s] the existence of other fundamental personal rights'' and that 'liberty' protected by the Fifth * * * Amendment[] from infringement by the Federal Government * * * is not restricted to rights specifically mentioned in the first eight amendments.'' *Griswold* v. *Connecticut*, 381 U.S. 479, 493 (1965) (Goldberg, J. concurring).

The final rule regulates commercial transactions involving tobacco products to limit young people's access to them. Young people do not have an unenumerated, fundamental right protected by the Constitution to have commercial access to tobacco products. (See *Bowers* v. *Hardwick*, 478 U.S. 186, 190 (1986).) Nor does the agency believe that it is merely a specific manifestation of a broader right, *Id*. at 199 (Blackmun, J., dissenting), whether styled as the right to privacy, *Griswold*, 381 U.S. at 484–485, or to be let alone, *Olmstead* v. *United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting), or to individual autonomy, *Carey* v. *Population Services Int'l*, 431 U.S. 678, 687 (1977).

In particular, the right to privacy does not protect commercial access to tobacco products for young people, because restricting sales of addicting tobacco products to young people ''is within the area of governmental interest in protecting public health.'' (See *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.), (right to privacy does not include access to laetrile) *cert. denied*, 449 U.S. 937 (1980); see also *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (''Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power''); *United States* v. *Horsley*, 519 F.2d 1264, 1265 (5th Cir. 1975), (holding that right of privacy does not protect possession of marijuana with intent to distribute) *cert. denied*, 424 U.S. 944 (1976); *United States* v. *Kiffer*, 477 F.2d 349, 352 (2d Cir.) (same), *cert. denied*, 414 U.S. 831 (1973).) The agency therefore concludes that this rule does not abridge an unenumerated, fundamental right reserved to the people by the Ninth Amendment to the Constitution.

(5) Several comments suggested that comprehensive regulations were unnecessary. Instead, these comments advocated training programs for retailers and, more specifically, for retail sales clerks. These training programs would be based either on voluntary efforts by the affected industries or on in-house, employee training programs. A few comments argued that any regulations to restrict access to cigarettes and smokeless tobacco would be futile because young people ''would get the products anyway.''

The agency disagrees with these comments. The preamble to the 1995 proposed rule indicated that informational or training programs, alone or without any enforcement mechanisms, have limited success (60 FR 41314 at 41322). Given the health risks caused by or associated with these products and the evidence that current, voluntary restrictions on youth access are ineffective, FDA believes that it

needs to develop an effective, mandatory program under the act to restrict young people's access to cigarettes and smokeless tobacco. The agency cannot and should not abdicate its public health responsibilities in deference to voluntary efforts to inform employees or other parties on the sale and distribution of these products, given the evidence cited in the preamble to the 1995 proposed rule that such programs must be bolstered by government sanctions and measures like those in subpart B of part 897 in order to be effective.

(6) Other comments, particularly those submitted by a few State legislators, claimed that States should be free to allocate their resources as they wished so that, if a State decided not to address a particular issue, such as access to tobacco products, that decision would be within the State's purview.

In contrast, comments submitted by State and local public health officials were unanimous in recommending strong Federal leadership in reducing young people's access to cigarettes and smokeless tobacco.

The agency believes that the comments opposing the rule misinterpret the rule's scope and application. The rule does not require States to enforce any provision, nor does it require States to allocate resources in any manner. FDA will enforce the rule as it does any other rule, by using FDA's own resources or, where appropriate and with cooperation from State officials, by ''commissioning'' State officials to perform specific functions on the agency's behalf. FDA is authorized, under section 702(a) of the act (21 U.S.C. 372), to conduct examinations and investigations through any health, food, or drug officer or employee of any State, territory, or political subdivision commissioned as an officer of DHHS. In most cases, a commissioned State or local government official is authorized to perform one or more of the following functions: (1) Conduct examinations, inspections, and investigations under the act; (2) collect and obtain samples; (3) copy and verify records; and (4) receive and review official FDA documents.[40] The scope of the official's authority depends on his or her qualifications, and the commissioning process involves active and voluntary participation by States in identifying suitable candidates for commissioning and establishing the scope of the commissioned official's duties.

(7) A few comments claimed that the rule would create friction between States and the Federal Government because, according to these comments, FDA would be interfering in State affairs. Some comments also claimed that the rule would make State efforts less effective because State regulatory or police agencies would defer to FDA.

In contrast, as noted above, several State attorneys general expressed a different view, stating that the rule would strengthen State efforts to reduce cigarette and smokeless tobacco use among young people.

The agency respectfully disagrees with those comments that claim FDA will be interfering in State affairs or that the rule will create friction or undermine the effectiveness of State officials. The agency has a history of cooperative relations with State regulatory officials. For example, as mentioned earlier, section 702(a) of the act authorizes FDA to commission State officials to perform specific functions on FDA's behalf. FDA also works with State officials in implementing statutes such as the Prescription Drug Marketing Act of 1987, the Nutrition Labeling and Education Act of 1990, and the Mammography Quality Standards Act of 1992. Given this history of cooperation between FDA and State regulatory agencies, FDA does not agree that the rule will create friction between FDA and State authorities or undermine the effectiveness of State officials.

(8) Many comments argued that the 1995 proposed rule would restrict an adult's ability to purchase or select cigarettes and smokeless tobacco. Several asserted that regulations would be ineffective because young people would obtain cigarettes and smokeless tobacco anyway. Hence, these comments would eliminate all provisions intended to reduce a young person's access to these products.

In contrast, many comments supported the rule, stating that it would reduce a young person's easy access to and opportunity for early experimentation with cigarettes and smokeless tobacco, help reduce the use of those products by young people, and prevent young people from suffering adverse health effects associated with using these products.

The agency agrees that the rule may have an incidental effect on an adult's ability to purchase cigarettes or smokeless tobacco, but FDA emphasizes that the rule's benefits far outweigh any inconvenience to adults. FDA has narrowly focused the rule to address those activities and practices that are especially appealing to, or used by, young people and to preserve, to the fullest extent practicable, an adult's ability to purchase these products. Any inconvenience to adults should be slight. For example, although the final rule eliminates self-service displays for cigarette packages in facilities that are accessible to young people, the limited amount of time spent in requesting and receiving a cigarette pack from a retail clerk should not result in hardship on adults. The agency has also amended the rule, as discussed in section IV.E. of this document to retain specific modes of sale that are restricted to—or used almost exclusively by—adults. These amendments respond to comments from adult consumers and retailers that young people cannot or do not use certain modes of sale and so those modes of sale should remain available to adults.

(9) Several comments argued that the 1995 proposed rule ''intruded'' on private life or ''discriminated'' against adult cigarette and smokeless tobacco users.

In contrast, other comments agreed that FDA has jurisdiction over cigarettes and smokeless tobacco and that the rule was an appropriate exercise of FDA's authority and properly focused on curtailing access by young people. Several comments suggested amending the rule to add restrictions for adults, to ban smoking, or to provide information to help all smokers to stop smoking.

As stated earlier, the agency has drafted the rule as narrowly as possible to restrict the sale and distribution of these products to children and adolescents, while preserving adults' ability to purchase the products.

As for extending the rule to include adults or to ban smoking, FDA declines to adopt the comments' suggestion. As discussed in section III.A. of this document, the President, and the agency in its preamble to the 1995 proposed rule, have stated that removing cigarettes and smokeless tobacco from the market would not be in the best interests of the public health. The agency adheres to this position.

(10) Many comments urged FDA to refrain from rulemaking and instead rely on voluntary, manufacturer-developed or retailer-developed programs, such as ''Action Against Access,'' ''It's the Law,'' and ''We Card,'' to prevent sales to young people. Some would require retailers and their employees to be trained to comply with existing State and local laws. Several large retail

[40] FDA Regulatory Procedures Manual, DHHS, PHS, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy, Chapter 3, p. 45, August 1995.

chains described the programs they already have in place.

Other comments expressed skepticism about such programs and, therefore, strongly supported FDA's rulemaking activities.

The agency declines to rely solely on voluntary, manufacturer- or retailer-developed programs to prevent sales to young people. The agency is regulating cigarettes and smokeless tobacco as devices under the act. Voluntary programs cannot serve as a substitute for such regulation and do not provide many of the safeguards that the act provides.

As for retailer programs to train employees not to sell cigarette and smokeless tobacco to young people, FDA believes that such training efforts will help retailers comply with their obligations under § 897.14. However, retailer training programs, alone, will not be as effective as the rule's comprehensive approach because such training would not affect certain activities (such as free samples and advertising) that are used by or appeal to young people.

Similarly, voluntary, manufacturer-developed programs are not sufficient to prevent sales to young people. Such programs purport to deter young people from using cigarettes or smokeless tobacco until they reach legal age, but often omit retail activities or impose no sanctions if a voluntary code or provision is violated. For example, one comment supported the rule, in part, because a retailer gave the author, when he was 15 years old, and other children free cigarettes. A manufacturer-developed program might not be effective at curtailing such practices by retailers, whereas the rule bars distribution of free samples by manufacturers, distributors, and retailers.

(11) One comment suggested amending the rule to include advertisers.

FDA declines to amend the rule as suggested by the comment. The agency's authority attaches to the product and those responsible for its manufacture, distribution, or sale in interstate commerce. Advertisers do not have control over the products and presumably act at the direction of manufacturers, distributors, and retailers. If an advertisement violated the requirements of this part, the agency would hold the appropriate manufacturer, distributor, or retailer responsible for the violative advertisement.

(12) One comment argued that cigarettes should be sold by prescription only. Other comments opposing the rule predicted that the agency would require prescriptions.

The agency declines to amend the rule to require prescriptions. Such a requirement would unduly affect adults and retailers and, FDA expects that the more narrowly tailored provisions in subpart B of part 897 will adequately restrict young people's access to these products.

(13) One comment criticized the 1995 proposed rule for not restricting where cigarettes and smokeless tobacco may be sold. The comment said that pharmacies and health care facilities often sell these products and that such sales undermine the credibility of health warnings related to these products. The comment suggested that FDA prohibit ''inappropriate places'' from selling these products.

FDA declines to amend the rule as suggested by the comment. The agency has no information or criteria that would permit it to determine whether certain places or types of establishments are not ''appropriate'' for selling cigarettes and smokeless tobacco.

B. General Responsibilities of Manufacturers, Distributors, and Retailers (§ 897.10)

Proposed § 897.10 would have required each manufacturer, distributor, and retailer to be responsible for ensuring that the cigarettes or smokeless tobacco that it ''manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale'' comply with the requirements in part 897. FDA proposed this provision setting forth these general responsibilities as part of the agency's comprehensive program to reduce young people's access to cigarettes and smokeless tobacco. Through this provision FDA intended to ensure that these products, from the time of their manufacture to the time of their purchase, comply with part 897 and that manufacturers, distributors, and retailers appreciate their roles, and carry out their legal responsibilities to reduce the accessibility and appeal of these products to young people. The final rule retains § 897.10 without any significant changes.

(14) Many comments interpreted proposed § 897.10 as imposing strict liability on manufacturers, distributors, and retailers. Generally, these comments interpreted the 1995 proposed rule as making a party responsible for violations committed by another party, even if the former was unaware that the violation had been committed by the latter. Some comments asserted that the agency cannot impose such vicarious liability, under these comments' interpretation of *United States* v. *Dotterweich*, 320 U.S. 277 (1943), and *United States* v. *Park*, 421 U.S. 658 (1975). One comment acknowledged that proposed § 897.10, when read literally, would not hold parties responsible for acts committed by other parties, but nevertheless claimed that, despite such language, FDA would hold manufacturers, distributors, and retailers liable for any action committed by any party.

The agency believes that the comments have misinterpreted § 897.10. Section 897.10 holds manufacturers, distributors, and retailers responsible for their own actions; it does not require any party to ensure that another party complied with the regulations, nor does it hold a party responsible criminally or civilly for actions that it did not commit or about which it had no responsibility under the act and no knowledge. This is the most logical and straightforward interpretation of § 897.10, and, as stated earlier, the provision states that ''each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes and smokeless tobacco *it* manufactures, labels, advertises, packages * * * comply with all *applicable* requirements under this part'' (emphasis added). The word ''it'' refers to the individual manufacturer, distributor, or retailer, while the word ''applicable'' signifies that a party, depending on the circumstances, is subject only to those requirements for which that party is responsible. This issue is discussed in greater detail later in this section of the document.

In determining which party may be responsible for a regulatory violation, FDA will examine where and when the violation occurred. For example, § 897.14(d), among other things, prohibits retailers from opening any cigarette package and selling individual cigarettes. If a retailer, on its own initiative, opened a package and sold single cigarettes, without the knowledge of a manufacturer or distributor, only the retailer would be responsible because only the retailer engaged in actions that violated the requirements in this part. However, if the manufacturer or distributor supplied single cigarettes to the retailer—contrary to § 897.16(b) which establishes a minimum package size for cigarettes—and the retailer sold the single cigarettes, or if the manufacturer or distributor knew or had reason to know that the retailer sold

single cigarettes and continued to provide cigarettes to the retailer, the manufacturer or distributor, as well as the retailer, would be subject to regulatory action. The manufacturer or distributor would have violated § 897.16(b) and assisted in violating § 897.14(d), while the retailer would be in violation of § 897.14(d). In sum, each manufacturer, distributor, and retailer is responsible for ensuring that *its* products (whether it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds them for sale) comply with all requirements *applicable* to it and its products. As such, § 897.10 does not create the problems that the comments suggested it does.

(15) Several comments objected to proposed § 897.10 because it would have each manufacturer, distributor, and retailer responsible for ensuring compliance with the regulatory requirements in part 897. These comments interpreted the provision as having the affected industries, rather than Federal or State Governments, determine compliance. One comment also asserted that the imposition of such responsibility on private persons is a violation of the Due Process Clause of the Fifth Amendment, which prevents unreasonable delegations of governmental authority. Several comments added that manufacturers, distributors, and retailers should not ''spy'' on each other to ensure compliance. One comment said that the rule would create a ''hidden enforcement tax.''

FDA believes that the comments objecting to § 897.10 have misinterpreted its application. Section 897.10 does not make manufacturers, distributors, or retailers solely responsible for ensuring compliance with the regulations nor does it alter or affect any Federal or State enforcement mechanism. Section 897.10 is intended to remind manufacturers, distributors, and retailers that they are responsible for complying with the regulations that are applicable to them. FDA remains primarily responsible, as it does for most FDA regulations, for determining whether parties comply with the regulations. States, of course, remain free to enforce applicable State laws relating to these products.

(16) One comment asserted that proposed § 897.10 would impose vicarious liability in violation of the Eighth Amendment's Excessive Fines Clause.

As previously discussed, § 897.10 does not impose the sort of vicarious liability on manufacturers or distributors that the comments suggested it does. The Excessive Fines Clause of the Eighth Amendment states that ''excessive fines [shall not be] imposed.'' Here, neither § 897.10 nor any other provision of the final rule imposes an excessive fine or any fine at all. Moreover, whether a fine is excessive in a particular case requires a close analysis of the facts of that case. (See, e.g., *United States* v. *One Parcel Property Located at 427 and 429 Hall Street, Montgomery, Montgomery County, Alabama*, 74 F.3d 1165, 1170–73 (11th Cir. 1996) (adopting and applying proportionality test to *in rem* civil forfeiture); *United States* v. *Chandler*, 36 F.3d 358, 365–66 (4th Cir. 1994) (adopting and applying three-part instrumentality test to *in rem* civil forfeiture) *cert. denied*, 115 S.Ct. 1792 (1995).)

(17) A few comments implied that manufacturers should be excluded from § 897.10, stating that retailers, rather than manufacturers, should be responsible for preventing sales to young people.

The agency declines to amend the rule to exclude manufacturers. The preamble to the 1995 proposed rule demonstrated how certain practices by manufacturers, such as the distribution of free samples, offer young people easy and inexpensive access to cigarettes and smokeless tobacco. (See 60 FR 41314 at 41326 (free samples).) FDA received several comments that reinforced these views, such as comments from a 12-year old recounting how his classmate acquired free cigarettes from a manufacturer, and a mother whose 14-year old daughter and friends attributed their cigarette use to free samples obtained from manufacturers. Thus, manufacturers play a critical role in making cigarettes and smokeless tobacco accessible and appealing to young people.

In addition, because cigarettes and smokeless tobacco are products subject to the act, regulation of these products properly follows them from the time of their manufacture to their sale to the consumer. Focusing solely on the sale of these products to consumers would deprive the agency of any ability to address problems that may exist at the manufacturer or distributor level. For example, if products were incorrectly packaged or labeled, a rule that concentrated solely on retail sales might permit FDA to restrict sales of those products, but might not permit FDA to require the manufacturer to package or label those products correctly.

(18) Two comments would amend the rule to exempt manufacturers that had 1 or 2 percent of the cigarette or smokeless tobacco product market. One comment came from an association of specialty tobacco companies that either manufacture or import specialty cigarettes and other tobacco products. The comment claimed that specialty cigarettes account for a very small fraction (approximately 400 million cigarettes) of the total cigarettes market, are sold at higher retail prices compared to domestic cigarettes (from $1.75 for 10 Indonesian cigarettes to $4.00 for 20 German cigarettes), and are sold in shops that young people normally do not frequent. The comment also stated that the rule would have an adverse effect on foreign products (particularly products in packages containing less than 20 cigarettes), that the companies had little control over foreign manufacturers, and that companies would go out of business or be adversely affected by the rule. The comment sought an exemption either for firms or brands that have 1 percent or less of the total cigarette market in the United States. The comment explained that an exemption would be equitable because, the comment asserted, there is no evidence that speciality cigarettes contribute to underage smoking, and would also be consistent with an exemption granted by the Federal Trade Commission (FTC) for rotating cigarette label warnings and regulations by the U.S. Department of Agriculture (USDA) defining a ''domestic manufacturer of cigarettes'' for assessing payments under the Agricultural Adjustment Act of 1938.

The other comment came from a firm whose sales focused primarily on smokeless tobacco, with the remainder devoted to cigars and ''smoking tobaccos.'' The company said that it had approximately 1 percent of the smokeless tobacco market and is the sixth largest smokeless tobacco product manufacturer. The comment sought an exemption for companies with market shares under 2 percent because it claimed the rule would ''sound the death knell'' for small, family-owned businesses.

Both comments indicated that 80 to 90 percent of their sales occurred through the mail.

The agency declines to accept the comments' suggestions to create an exemption based solely on market share. The agency believes that subjecting similar or identical products to the same statutory and regulatory standards is both practical and fair to manufacturers

and consumers. A consumer should be able to expect that similar or identical products made by different manufacturers will be regulated in the same fashion. Similarly, manufacturers will not be unfairly advantaged or disadvantaged if they are all subject to the same statutory and regulatory requirements. For example, the final rule prohibits the distribution of free samples. This restriction applies regardless of a manufacturer's market share and, aside from eliminating a free source of cigarettes and smokeless tobacco that people use, also treats manufacturers equally.

FDA is not persuaded by one comment's suggestion that an exemption would be consistent with actions taken by other agencies. FTC's exemption is based on statutory language at 15 U.S.C. 1333(c)(2)(A)(i) and is limited to changes in the label rotation sequence; in other words, the exemption does not relieve the manufacturer from placing warning statements on its packages. USDA's regulation pertaining to ''domestic'' manufacturers is based on statutory language at 7 U.S.C. 1301(b)(17) as part of the Agricultural Adjustment Act of 1938 that was designed, among other things, to create an incentive for domestic manufacturers to use domestic tobacco leaf. Thus, neither the FTC nor USDA statutes or regulations were intended to relieve foreign products from substantive requirements or to regulate foreign manufacturers.

As for the comments' assertions that their products are either not used by or accessible to young people, the agency has amended the rule to permit specific modes of sale, including mail order sales, that young people cannot or do not use. The agency did not amend the rule, however, to exclude cigarettes and smokeless tobacco or brands that young people do not appear to use or purchase. It would be inappropriate to exempt a particular brand or specialty product simply because a manufacturer claims young people do not purchase that product. (The agency also notes that the $1.75 price charged for 10 Indonesian cigarettes is lower than the price charged for some domestic brands and creating an exemption for a low cost cigarette product in a ''kiddie pack'' size would be contrary to the rule's purpose.)

Additionally, FDA traditionally classifies, as a group, device products that are sufficiently similar so that they can be considered the same type of device for purposes of applying the regulatory controls in the act (see § 860.3(i) (21 CFR 860.3(i)) (definition of ''generic type of device''), using the cumulative evidence from several manufacturers. Reclassification of one product of a particular type results in the reclassification of the entire group. (See 42 FR 46028, September 13, 1977; and 43 FR 32988 July 28, 1978.) The alternative would require FDA to classify individually each manufacturer's device, and to undertake the classification process whenever a new manufacturer marketed a product within an already identified device type. Thus, FDA applies the same regulatory requirements to all devices within an identified device type that are substantially equivalent to one another. This approach is necessary to provide similar regulatory treatment for essentially identical products of different manufacturers and distributors (42 FR 46028 at 46031; and 43 FR 32988 at 32989).

Additionally, assuming that the rule effectively restricts a young person's access to cigarettes and smokeless tobacco, it is reasonable to assume that a young person would turn to alternative products, such as foreign cigarettes that the comment would exempt. Consequently, the agency declines to exempt products with small market shares from the rule.

(19) FDA received several comments from wholesalers or distributors arguing that they should be exempt from the 1995 proposed rule, particularly proposed § 897.10, because they are unable to affect the actions of manufacturers and retailers. Several comments asserted that wholesalers and distributors are ''merely a conduit'' for transferring products from manufacturers to retailers and have small staffs that would be unable to comply with all requirements in part 897. According to these comments, a wholesaler or distributor would either have to hire additional staff to ensure that products complied with all applicable requirements or be without sufficient staff to ensure that all products supplied to all retailers complied with the regulations. Several comments added that requiring wholesalers and distributors to maintain records, submit reports to FDA, and be subject to inspection by FDA would waste the wholesaler's or distributor's resources and provide FDA with little or no useful information. A minority expressed confusion as to their obligations if they relabel cigarettes or smokeless tobacco.

The agency believes that the comments misinterpret § 897.10. The provision states that a distributor would be responsible for ensuring that the cigarettes or smokeless tobacco that *it* manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale complies with all *applicable* requirements. For example, the reporting requirement in proposed § 897.40 was directed at manufacturers. Consequently, distributors would not have been required to submit reports to FDA under § 897.40. (Moreover, as discussed in section VIII. of this document, FDA has deleted § 897.40 and exempted distributors from the registration and listing requirements in part 807. Distributors are, however, subject to other reporting requirements, such as medical device distributor reports under part 804.) However, if a distributor acts in a manner that is outside the definition of distributor in § 897.3, it may alter its regulatory status and become subject to other provisions in this part. For example, a distributor who relabels cigarettes would, for those relabeled products, become a ''manufacturer'' under this rule and be subject to those provisions pertaining to manufacturers. Section 897.3 defines a manufacturer, in part, as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels finished cigarettes or smokeless tobacco.

(20) Several comments would exempt distributors from the rule because, the comments claimed, the 1995 proposed rule set forth little or no evidence to justify regulating distributors.

FDA declines to exempt distributors from the rule. The agency reiterates that it is regulating cigarettes and smokeless tobacco under its drug and device authority, and that, as it does for other FDA regulated products, FDA's rule follows the products from the time of their manufacture to the time of their sale. Wholesale or distribution operations must be included in any effective regulatory system because products can be contaminated, diverted into illegal channels, or otherwise adulterated or misbranded at the wholesale or distribution level just as they can at the manufacturing and retail levels.

(21) Many comments asserted that, rather than impose responsibilities on manufacturers and distributors, FDA should limit the rule to requiring that retailers verify the age of persons purchasing cigarettes and smokeless tobacco. These comments claimed that no other regulatory provisions would be necessary if retailers, or their sales clerks, verified the purchaser's age.

FDA declines to exclude manufacturers and distributors from the rule. As stated earlier in section IV.B. of this document, cigarettes and smokeless tobacco are products subject to regulation under the act, and, as a result, the rule follows the products from the time of their manufacture, through storage and distribution, to product sale at the consumer level. Excluding manufacturers and distributors would compromise FDA's ability to ensure that these products are not accessible or appealing to young people. Manufacturers engage in activities, such as advertising, labeling, and distributing samples, that make cigarettes and smokeless tobacco accessible and/or appealing to young people. Distributors channel products from manufacturers to retailers, and so the rule includes distributors to ensure, among other things, that the products do not become adulterated or misbranded while held by distributors.

(22) FDA received many comments from retailers stating that FDA regulation was unnecessary because retailers train their staffs to request proof of age or have taken other steps to prevent sales to young people.

The preamble to the 1995 proposed rule provided reasons for not relying on retailer training programs alone. The preamble to the 1995 proposed rule cited a report by 26 State attorneys general stating that industry training films and retailers' programs have not, on their own, prevented illegal sales to young people and that, in some retail sectors, high employee turnover rates complicated training efforts (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also cited studies showing that significant numbers of young people are not asked to verify their age when purchasing cigarettes or smokeless tobacco and that, in some cases, retail clerks even encouraged the young person's purchase by suggesting cheaper brands or offering to make up the difference in the purchase price if the young person lacked sufficient funds (60 FR 41314 at 41323). FDA received some comments that further illustrated the ease with which young people can purchase these products; for example, one comment reflected on the author's own practice, at age 11, of purchasing cigarettes by saying ''They are for my Mom.'' Thus, while training retail clerks to request proof of age should help curtail a young person's access to cigarettes and smokeless tobacco, the reports and studies cited in the 1995 proposed rule, as well as the personal experiences reflected in some comments, suggest that additional measures are necessary to reduce a young person's access to these products.

(23) Several comments from retailers claimed that the 1995 proposed rule violated their ''right'' to sell products or arrange their stores in any manner they wished. Many comments added that, if retailers are subject to the rule, many retailers will lose sales and fees associated with cigarettes and smokeless tobacco and could be forced to fire staff. One comment further stated that this would actually harm young people because the retailer would fire its newest staff, and such staff employees are usually young people. Conversely, some comments claimed that, in order to comply with the rule, retailers would be obliged to hire additional staff.

In contrast, FDA received two comments denying that retailers would lose slotting or promotional fees. (Some manufacturers pay retailers to display their products (often referred to as ''slotting fees'') in a specific fashion or to display signs or other materials provided by the manufacturer.) One comment, based on experience in an area in northern California where self-service displays were prohibited, stated that retailers did not suffer significant economic losses after the displays were banned. Another comment opined that manufacturers would still have an incentive to offer slotting fees or allowances to retailers to ensure advantageous placement of their products behind the counter.

FDA disagrees with the comments asserting an unrestricted ''right'' to sell products. Section 520(e) of the act (21 U.S.C. 360j(e)) states, in part, that the agency may require that a device be restricted to sale, distribution, or use upon such conditions as the agency may prescribe by regulation. Because FDA has determined that these products should be regulated as restricted devices, the act authorizes FDA to impose controls on their sale and distribution. The agency further notes that, in addition to restrictions authorized under the act, other consumer products are sold subject to various restrictions. For example, under 23 U.S.C. 158(a)(1), the ''national minimum drinking age'' is 21 years, and the Secretary of Transportation is authorized to withhold certain highway funds from States that have a lower minimum age. Federal law expressly prevents licensed importers, manufacturers, dealers, and collectors from selling firearms and ammunition to any individual that the licensee knows or has reasonable cause to believe to be under 18 years old (except in specific, limited cases), or, if the firearm is not a shotgun or rifle, prohibits sales to individuals under 21 years of age (18 U.S.C. 922(b)).

Thus, there is no unfettered or unrestricted ''right'' to sell consumer products. Instead, products are often sold subject to conditions or restrictions, including those based on age, that are designed to protect the integrity of the product, to protect users or other members of the public, or to prevent the product from reaching certain groups of people.

FDA also disagrees with those comments predicting that the rule will result in lower sales and fees and compel retailers to lay off staff. Insofar as retailers are concerned, the rule does not affect sales to adults. It is intended to eliminate illegal sales to young people. Thus, for a retailer to assert that the rule will reduce its sales revenue so much as to require staff reductions, illegal sales would necessarily have to play a significant role in funding staff positions.

With respect to fees, the agency cannot determine whether manufacturers will discontinue paying slotting fees or other allowances to retailers as a result of the rule. The preamble to the 1995 proposed rule did estimate that industry promotional allowances totaled approximately $1.6 billion in 1993, or $2,600 per retailer if the sum is evenly distributed among the estimated 600,000 retail outlets (60 FR 41314 at 41369). FDA does note, however, that some comments supported the agency's position that retailers will not suffer significant economic losses. One study cited in the preamble to the 1995 proposed rule stated that, ''in the absence of advertising and promotion outlets * * * the cigarette industry may be expected to provide greater incentives to retailers to provide more and better shelf space for their brands in order to provide availability to the buyer in the store'' (60 FR 41314 at 41369). Thus, while some manufacturers might stop paying slotting fees, others might continue paying those fees or even increase the fees to obtain favorable placement of their products behind the counter.

Furthermore, as described in greater detail in section IV.E.4.b. of this document, FDA has amended the rule to permit self-service displays (or, more specifically, merchandisers) in facilities that are inaccessible to young people.

As for those comments stating that retailers would have to hire additional staff, it is possible that some retailers

who have relied on modes of sale that the rule will now prohibit or restrict may need to hire additional staff. For example, if a retailer derived a substantial portion of its revenue from vending machines and those machines would not be available under the rule, the retailer might decide to hire staff in order to continue selling cigarettes or smokeless tobacco. However, the comments did not provide sufficient information to enable FDA to determine the number of retailers who might be affected or the extent to which they might be affected.

(24) A few comments challenged the validity of the 1995 proposed rule because it did not impose responsibilities on young people who purchase cigarettes and smokeless tobacco. These comments claimed that omitting young people from the rule, while requiring retailers to comply, was unfair, arbitrary, and capricious. One comment stated, ''any effective public policy to restrict sales of tobacco products to minors must go beyond the discouragement of promotion, advertising and merchandising to minors. It must be accompanied by realistic penalties for minors who purchase and possess cigarettes and for adults who purchase for them.''

It would be inappropriate for FDA to amend the rule to impose penalties or sanctions on young people who purchase or possess cigarettes or smokeless tobacco or adults who purchase such products for young people. The main focus of the act is on the introduction, shipment, holding, and sale of goods in interstate commerce. Thus, the actions of minors who purchase cigarettes and smokeless tobacco are appropriately a matter for State or local law.

(25) One comment stated that FDA should prohibit young people under 18 years of age from selling tobacco products.

The agency declines to amend the rule to place age restrictions on those who sell these products. FDA has little evidence to suggest that manufacturers', distributors', or retailers' young employees play a significant role in making cigarettes and smokeless tobacco accessible or appealing to young people. Although some evidence indicates that, in certain settings, a young employee might be less likely to check age or to challenge his or her peers (as in situations where the young employee distributed free samples (60 FR 41314 at 41326)), other provisions in this subpart, such as the elimination of free samples, should reduce the need to place age restrictions on employees.

The agency does note, however, that in response to comments requesting that vending machines and self-service displays be permitted in ''adult-only'' facilities, FDA has amended the final rule to allow vending machines and self-service displays in facilities that are totally inaccessible to people under 18 and employ no persons below age 18. This is to ensure that an ''adults-only'' facility is truly restricted to adults rather than to create an age restriction on sellers. These changes to the rule are described in greater detail elsewhere in this document.

The agency is aware that several local governments have statutes or regulations that establish minimum age requirements for persons who sell tobacco products. Because this rule does not contain a minimum age requirement for persons who sell these products, those statutes or regulations are not preempted. The rule's preemptive effect on other State or local statutes or regulations and federalism issues are discussed elsewhere in this document.

(26) Several comments suggested that, instead of issuing regulations, the Federal Government should transfer funds to States for use in preventing cigarette and smokeless tobacco sales to young people.

FDA must decline to accept the comments' suggestion. Federal funding of State prevention efforts is beyond the scope of the rule. The agency does intend to work with State officials and cooperate in enforcement activities where appropriate and to the extent that its resources permit.

(27) Several comments suggested that FDA amend the rule so that the restrictions on the sale and distribution of cigarettes and smokeless tobacco do not apply to locations where young people do not enter or where entry is restricted, such as bars, liquor stores, factories, and prisons.

After consideration of these comments, the agency has amended the rule to allow certain retail practices to continue because those practices are not used by young people or are inaccessible to them. For example, the final rule permits mail-order sales to occur because the evidence does not establish that young people use mail-order sales to acquire these products. The final rule also permits vending machines and self-service displays (merchandisers only) to be used in locations where young people cannot enter, such as locations where proof of age is required in order to enter the premises or facilities that employ only adults. These changes are described in detail in the discussion of § 897.16 and elsewhere in this document.

C. Additional Responsibilities of Manufacturers (§ 897.12)

1. Removal of Manufacturer-Supplied or Manufacturer-Owned Items That Do Not Comply With the Regulations

Proposed § 897.12(a) would have required manufacturers, in addition to their other obligations under part 897, to remove, from each point of sale, ''all self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items'' that do not comply with the requirements in part 897. In response to comments, the agency has amended the final rule to require the manufacturer to remove only those violative items that the manufacturer owns.

(28) Many comments, including comments from manufacturers' sales representatives and retailers, strongly objected to this provision, particularly as it would apply to self-service displays. In general, the comments claimed that retailers, rather than manufacturers, own the self-service displays. The comments also expressed concern that manufacturers' representatives or retailers' employees might be physically harmed if a manufacturer's representative attempted to remove a self-service display from a retailer. Several comments also interpreted proposed § 897.12(a) as requiring a manufacturer's sales representative to remove self-service displays supplied by another manufacturer; these comments said removing a competitor's self-service display would be unethical and could result in the sales representative being barred from reentering the retail establishment in the future.

In contrast, a few comments supported proposed § 897.12(a) because manufacturers provide the displays to retailers and visit retailers often. One comment added that the burden of removing displays should not rest on retailers alone, but added that retailers should remain ultimately responsible for displays they use or have on site. This comment suggested that retailers be responsible for removing displays if the manufacturer fails to do so.

The agency agrees, in part, with the comments critical of the proposed provision and has amended § 897.12 to clarify that a manufacturer is responsible for removing all self-service displays (which the final rule also clarifies as referring to merchandisers),

advertising, labeling, and other items that it owns that do not comply with the requirements in part 897. FDA has also amended § 897.14 to clarify the obligation of retailers with respect to all other violative items in the retailer's establishment. These changes should eliminate potential conflicts between manufacturers' sales representatives and retailers.

Additionally, § 897.12 requires a manufacturer to be responsible only for the removal of the items it owns. The agency does not expect manufacturers to remove items owned by another manufacturer, but encourages manufacturers to inform another manufacturer and FDA if another manufacturer's items violate the requirements in part 897. However, the agency advises manufacturers who know or have reason to know that a distributor or retailer is misbranding that manufacturer's products, or causing its products to violate these regulations or the act, to take action, such as discontinuing sales, incentives, and supplies, to halt the violation. Manufacturers might be held liable for subsequent violations by the distributor or retailer, if the manufacturer knew or should have known about the violation and continued to supply its product to such parties.

Liability, both criminal and civil, under the act is very broad. Section 301 of the act (21 U.S.C. 331) prohibits certain acts ''and the causing thereof.'' *United States* v. *Dotterweich*, 320 U.S. 277 (1943), and *United States* v. *Park*, 421 U.S. 658 (1975) elaborate on the meaning of ''causing'' in section 301 of the act (see *Park*, 421 U.S. at 673). These cases stand for the proposition that a corporate official can be held criminally liable as having caused the corporation's violations of the act of which he had no knowledge, so long as he stood in a ''responsible relationship'' to the violations (*Id*. at 672).

Under the act, ''all who * * * have * * * a responsible share in the furtherance of the transaction which the statute outlaws'' have caused the violation and are subject to civil and criminal liability (*Dotterweich*, 320 U.S. at 284). Indeed, a corporate employee and the corporation itself can have a responsible share in the furtherance of a violation of the act committed by another corporation or a person who is not an employee of the corporation. (See, e.g., *United States* v. *Parfait Powder Puff Co.*, 163 F.2d 1008, 1009–10 (7th Cir. 1947) (holding defendant corporation criminally liable for violations committed without its knowledge by second corporation that defendant had contracted with to manufacture, package, and distribute its cosmetic product), *cert. denied*, 332 U.S. 851 (1948); *United States* v. *Articles of Drug*, 601 F. Supp. 392 (D. Neb. 1984) (enjoining drug distributor that induced its customers to pass off its drugs as controlled substances), *aff'd* in part, *rev'd* in part on other grounds, 825 F.2d 1238 (8th Cir. 1987); *cf. Inwood Lab., Inc.* v. *Ives Lab., Inc.*, 456 U.S. 844, 853–54 (1982) (manufacturer or distributor who ''intentionally induces another'' to violate trademark law or who ''continues to supply its product to one whom it knows or has reason to know'' will violate trademark law is itself responsible for violation).) And it is a ''settled doctrine[] of criminal law'' (*Park*, 421 U.S. at 669) that a person who knows or has reason to know that goods that he sells will be used unlawfully may be criminally liable as aider and abettor under 18 U.S.C. 2; *Bacon* v. *United States*, 127 F.2d 985, 987 (10th Cir. 1942) (discussing former 18 U.S.C. 550, precursor to 18 U.S.C. 2(a))).

For example, a manufacturer or distributor that continues to supply its product to a retailer whom it knows or has reason to know sells cigarettes or smokeless tobacco to young people (or who breaks open packages and sells single cigarettes) might be liable for subsequent violations by that retailer. Likewise, a manufacturer who paid a retailer a fee for the retailer to use an illegal self-service display in a store might be liable for the retailer's violation.

These examples are, however, only by way of illustration because, as the Supreme Court stated in *Dotterweich*, ''[t]o attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress * * * would be mischievous futility'' (320 U.S. at 285). It added that, ''[i]n such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted'' (*Id*.).

(29) One comment challenged FDA's authority to require manufacturers to remove items that fail to comply with the regulations. The comment explained that FDA, rather than manufacturers, is responsible for compliance activities and a manufacturer's representative is not deputized or authorized to act on the agency's behalf. The comment added that sales representatives are not trained to perform investigative or law enforcement functions and, unlike Government employees, would not enjoy the same legal protections accorded to the agency's inspectors. The comment also argued that FDA lacks authority to require manufacturers, or any other party, to remove any materials that would violate the regulations. The comment asserted that the agency has no general recall authority and that the recall authority in the act for devices requires the agency to find that a reasonable probability of serious adverse health consequences or death exists and, when exercising that recall authority, to provide an opportunity for a hearing. Thus, according to the comment, the 1995 proposed rule is deficient because it makes no findings and fails to provide for a hearing.

The agency believes that the comment misinterprets the provision. Section 897.12 would not ''deputize'' manufacturers' representatives nor confer any official responsibility on them. FDA intends to enforce the act and regulations itself and, where appropriate, will consider commissioning State officials, under its authority in section 702(a) of the act, to perform specific functions on FDA's behalf. Section 702(a) of the act does not extend to commissioning private parties, and the agency has no intention of commissioning manufacturers' representatives.

FDA also disagrees with the comment's claim that FDA has no authority to require manufacturers to remove materials that violate FDA regulations. FDA is issuing this provision, as well as part 897 generally, under its authority under section 520(e) of the act, which expressly declares, in part, that the agency may, by regulation, require that a device be restricted to sale, distribution, or use ''upon such other conditions as the Secretary may prescribe in such regulation.'' Section 897.12, as amended, is a logical and necessary complement to the restrictions on the devices' sale, distribution, and use because it requires the manufacturer to assume responsibility for removing items that it owns that do not comply with the restrictions. Furthermore, as the Supreme Court stated in *United States* v. *Park*, 421 U.S. 658, 672 (1975), ''the act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.''

The comment's argument with respect to the agency's recall authority is also misplaced. Section 897.12 applies in situations where a manufacturer knows,

either acting on its own or on the basis of information supplied to it, that one of its items does not comply with the regulations. Knowing that the item does not comply with the requirements in part 897, the manufacturer is then obligated to remove the violative item. Notice of an opportunity for a hearing or other due process considerations associated with recalls under section 518 of the act (21 U.S.C. 360h) are inapplicable because the manufacturer, rather than the government, would be the principal party during this process, using information it has to act on its own items. In any case, section 518 of the act applies to the recall of a device, not its advertising.

FDA fully expects manufacturers to comply with § 897.12. For example, if the manufacturer provided advertising that used colors and photographs, contrary to § 897.32, which requires black and white text only, the manufacturer is deemed to know that the advertising does not comply with § 897.32 and should remove that advertising. In this situation, where the manufacturer's advertising clearly does not comply with the regulations, requiring FDA to provide notice and an opportunity for a hearing (as the comment would apparently require) would simply waste FDA's and the manufacturer's resources.

FDA will take regulatory action against manufacturers who fail to comply with this provision or any other applicable provision. The nature of the regulatory action will depend, in large part, on the violation, but could range from issuance of a warning letter, to an injunction under section 302 of the act (21 U.S.C. 332), the imposition of civil penalties, criminal fines, and/or imprisonment under section 303 of the act (21 U.S.C. 333), and seizures under section 304 of the act (21 U.S.C. 334).

2. Visual Inspections by a Manufacturer's Representative at Each Point of Sale

Proposed § 897.12(b) would have required a manufacturer's representatives to visually inspect each point of sale that they visit during the normal course of business to ensure that cigarettes and smokeless tobacco are ''labeled, advertised, and distributed in accordance with this part.'' The preamble to the 1995 proposed rule indicated that manufacturers keep extremely detailed records about each retailer and that some records noted whether the retailer should be visited weekly, biweekly, etc. and noted the types of displays in the retailer's establishment (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also stated that this provision would not impose a new responsibility or burden on companies that did not visit retailers as part of their ordinary business practice and, for those manufacturers that would be expected to comply, estimated that these visual inspections would take no more than 2 to 3 minutes per visit (60 FR 41314 at 41323 and 41365). Based on the comments received in response to this proposal, the agency has deleted § 897.12(b) from the final rule.

(30) Several comments opposed proposed § 897.12(b). One comment argued that proposed § 897.12(b) is unconstitutional because it would hold manufacturers vicariously liable for the acts of others in violation of the Due Process Clause, and would violate Article I, Section 8 of the Constitution, which implicitly reserves to States the authority to raise militias. One comment asserted that the number of manufacturers' representatives varies among manufacturers and that there are too many retail establishments for those representatives to inspect. The comment added that any inspection would require more than 3 minutes to be effective, so that conducting inspections at each retailer would be labor intensive and costly. Another comment, notwithstanding the statement in the preamble to the 1995 proposed rule that the provision applied only to those firms that visit retailers in the ordinary course of business, asserted that its entire staff would be too small to visit all the retailers that it services. A small number of comments added that such responsibilities would, in effect, constitute a hidden ''tax'' on manufacturers.

Other comments, many submitted by sales representatives, objected to proposed § 897.12(b), stating that the representatives have no power over a retailer's actions and cannot take any adverse action, such as discontinuing supplies, to retailers who sell cigarettes and smokeless tobacco to young people. Some comments explained that, even if a sales representative could ask a distributor to stop supplying certain retailers, the retailer could simply switch distributors and continue to obtain products. Other comments argued that the responsibility to prevent sales to young people rests solely with the retailer.

In contrast, several comments supported proposed § 897.12(b) because sales representatives frequently visit retailers or because manufacturers deliver materials, such as self-service displays and promotional materials, to retailers. One comment even suggested amending the rule to require manufacturers to enter into contracts with retailers and distributors to comply with FDA regulations and to state that failure to comply would result in termination of the retailer's or distributor's ability to obtain the manufacturer's cigarettes or smokeless tobacco.

After consideration of the comments, the agency has removed § 897.12(b). FDA intends to examine this matter further and to develop a guidance describing how manufacturers may be able to assist retailers to comply with this subpart. Possible options might include methods suggested by the comments, such as contractual agreements between retailers and manufacturers including provisions on compliance and the consequences of noncompliance.

D. Additional Responsibilities of Retailers (§ 897.14)

Proposed § 897.14 would have established additional responsibilities for retailers, stating that ''[i]n addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes and smokeless tobacco to any person (other than a distributor or retailer)'' comply with specific, listed requirements.

FDA, on its own initiative, has amended § 897.14 to delete the parenthetical text referring to a distributor or retailer because the evidence does not establish that retailers sell these products to such parties, and if a retailer did sell these products to a distributor or retailer, the retailer would be acting as a ''distributor'' as defined in § 897.3(c).

FDA, also on its own initiative, has amended § 897.14 to add a new paragraph (a) stating that, as one of the listed requirements, ''[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age'' and has renumbered proposed § 897.14(a) through (c) accordingly. The new paragraph codifies a concept that was present throughout the 1995 proposed rule, namely that retailers are not to sell cigarettes or smokeless tobacco to young people under 18 years of age.

1. Use of Photographic Identification to Verify Age

Under proposed § 897.14(a) (now renumbered as § 897.14(b)), each retailer, or an employee of the retailer,

would have been required to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing or intending to purchase cigarettes or smokeless tobacco is younger than 18 years of age.

The preamble to the 1995 proposed rule explained that studies indicate that young people who purchase cigarettes and smokeless tobacco from stores are often not asked to verify their age. For example, one study found that 67 percent of young people, whose mean age was 15 years, were asked no questions when they attempted to purchase cigarettes. In some cases, retail clerks even encouraged purchases by young people, suggesting less expensive brands or offering to make up the difference if he or she lacked sufficient funds (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also noted that requiring proof of age to purchase cigarettes and smokeless tobacco could reduce cigarette and smokeless tobacco use among young people (60 FR 41314 at 41323). Consequently, the 1995 proposed rule would have required retailers to verify that persons who intend to purchase cigarettes or smokeless tobacco are legally entitled to do so.

The preamble to the 1995 proposed rule also indicated that a driver's license or college identification card would be acceptable forms of photographic identification, but the agency invited comment on whether the final rule should contain more specific requirements on the types of identification (60 FR 41314 at 41323).

FDA received many comments supporting a proof of age requirement. These comments came from law enforcement entities, drug abuse prevention groups, health care professionals, medical societies, public health organizations, and even some adult smokers who agreed that a proof of age requirement will reduce young people's access to cigarettes and smokeless tobacco. One comment from a coalition of State attorneys general said there ''are many teenagers who look much older than they are, who can obtain tobacco products quite easily. When they are required to show age verification, they will not be mistaken for an older age. Therefore, they will not be permitted to acquire tobacco products.'' Another comment from a State public health department reported that, based on data analyzed from the State's own experience, illegal tobacco purchases occur less than 5 percent of the time when the retailer checks a photographic identification card to verify age, as opposed to a 95 percent illegal sales rate when no photographic identification card is checked.

In response to comments and changes to § 897.16 regarding mail order and vending machine sales and self-service displays in facilities that are inaccessible to children and adolescents, the final rule excepts the proof of age requirement under these limited circumstances.

(31) Several comments objected to making retailers responsible for their employees' actions. These comments asserted that an employee's failure to verify a potential purchaser's age or an employee's error should not subject the retailer to any regulatory action. A few comments faulted the 1995 proposed rule for not holding sales clerks responsible or argued that the rule would be ineffective because it would not alter a sales clerk's behavior.

In contrast, many comments supported the requirements that hold retailers responsible for preventing illegal sales. Indeed, one comment suggested that there should be ''significant penalt[ies] for sales to persons under 18, including the loss of the opportunity to sell tobacco * * *.'' Another comment stated that the rule should contain penalties for illegal tobacco sales.

The agency declines to amend the rule to relieve retailers from responsibility. Retailers, in general, are responsible for the acts of their employees. (See *United States* v. *Park*, 421 U.S. 658, 672 (1975).) Relieving retailers from responsibility for their employees' actions would only invite abuse because retailers could continue to sell products to young people and, if caught making such sales, could blame their employees without suffering any adverse consequences themselves. To reflect its position that retailers are generally responsible for their employees' actions, FDA has amended § 897.14 to remove all references to ''an employee of the retailer.'' Thus, § 897.14 now refers to a ''retailer'' and makes no distinction for the retailer's employees.

As for the comment claiming the rule contains no penalties for illegal tobacco sales, the agency believes that the comment misunderstands how the rule will operate. In general, FDA regulations implement and interpret the agency's statutory obligations under the act, including various criminal and civil penalties. Thus, a regulation need not specify what penalties are attached to a violation because the act provides this information.

FDA has, however, amended proposed § 897.14(a) (now renumbered as § 897.14(b)) to state that, ''[e]xcept as otherwise provided in § 897.16(c)(2)(i) and in paragraph (a)(2) of this section,'' a retailer shall ensure compliance with the prohibition against sales to persons under 18 by verifying the purchaser's age. FDA made this amendment to correspond with the prohibition, in § 897.14(a), against sales to persons under 18 and because, as discussed in greater detail below, the final rule permits sales from vending machines and self-service merchandisers that are inaccessible to young people and permits mail-order sales. These modes of sale are either secure from access by young people (by requiring age verification upon entrance to the facility) or not used by them. The exception for paragraph (a)(2) complements another change to § 897.14 (discussed in greater detail below) to not require proof of age from persons over the age of 26.

FDA has also amended § 897.14(b) to delete the words ''intending to purchase.'' The requirement that retailers verify the age of persons ''purchasing the product'' sufficiently accomplishes the provision's goal of reducing illegal sales.

(32) Several comments supported the use of identification cards to verify the purchaser's age. Some comments, responding to a question in the preamble to the 1995 proposed rule asking whether the rule should specify the types of identification that would comply with a proof-of-age requirement, advocated using identification cards, passports, or other official documents establishing the bearer's age issued by States, the Federal Government, or foreign governments. One comment recommended that States develop a uniform coding system for identification cards to permit retailers to read or to scan identification cards quickly to verify a purchaser's age. Other comments advised against the use of college or school identification cards; the comments noted that colleges and schools have little incentive to design their identification cards to be sufficiently tamper-proof.

In contrast, one comment stated that the agency should not ask for comment on the type of identification card to require, arguing that the ''degree of micromanagement implied by the Agency's invitation for such comment underscores the inappropriateness of federal action in this area.''

FDA recognizes the comments' concern. However, the final rule does

not require a uniform coding system or a Federal, State, or local government identification card.

(33) FDA received several comments that addressed when a retailer should inspect a purchaser's photographic identification card. One comment interpreted the provision as requiring retailers to inspect visually the photographic identification card of every purchaser, and said that this would be unreasonable. The same comment contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; this was the standard employed in Everett, WA, which was cited in the preamble to the 1995 proposed rule.

In contrast, other comments supported age verification for all tobacco sales. Some comments from retailers indicated that some retailers check identification cards for all tobacco sales, while many comments submitted by retailers stated that they check identification cards to verify the age of purchasers who appear to be ''underage.'' Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age. Such a requirement appeared to be independently selected to ensure that the purchaser met the age requirement in the particular jurisdiction.

Contrary to the comment that interpreted the rule as requiring proof of age in all transactions, the 1995 proposed rule would have given retailers some flexibility in deciding when to demand proof of age. The preamble to the 1995 proposed rule cited studies and reports demonstrating that few retailers request proof of age from young people attempting to purchase cigarettes or smokeless tobacco (60 FR 41314 at 41323). Consequently, proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required retailers to verify that prospective purchasers are of legal age, and the preamble to the 1995 proposed rule suggested that retailers request proof of age from anyone who does not appear to be at least 26 years old (60 FR 41314 at 41323). This suggestion was similar to a recommendation made in a report by 26 State attorneys general. The agency anticipated, for example, that requiring proof of age from a senior citizen would be unnecessary, but strongly recommended requiring proof of age from an individual who appears youthful.

However, due to concerns that, despite the language in the preamble to the 1995 proposed rule, the rule would require age verification in all cases, the agency has amended the rule to except from the age verification requirement individuals who are over 26 years old. The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person's age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person ''looked'' like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

The agency notes that using the higher age of 26 as the threshold for requiring proof of age should increase the likelihood that illegal sales to young people will not occur. Using a lower age, such as 18 (which is used in some States) or 21, as the threshold for requiring proof of age may enable some young people to purchase cigarettes and smokeless tobacco, and, as a result, cause a retailer to be in violation of this subpart.

(34) Many comments, particularly comments from retailers, supported the requirement for age verification but added that the requirement should be voluntary. Others said that State law or regulations requiring age verification are adequate, and that, as a result, FDA regulation is unnecessary. Other comments claimed FDA regulation would add ''red tape and paperwork'' that would not reduce young people's access to cigarettes and smokeless tobacco and would instead ''come at great cost to taxpayers.''

On the other hand, State attorneys general and other State and local enforcement authorities commented that the Federal regulations requiring age verification by inspection of photographic identification card will complement and enhance their enforcement abilities.

FDA declines to delete an age verification requirement from the rule. The preamble to the 1995 proposed rule cited studies and reports to show that young people are often able to purchase cigarettes and smokeless tobacco without showing proof of age (60 FR 41314 at 41323). In one case, the young people were able to purchase cigarettes even when they admitted that they were under the legal age (60 FR 41314 at 41323). These studies and reports suggest that the final rule must require retailers to demand proof of age because voluntary efforts are ineffective.

As for deferring to State laws and regulations, FDA believes that State efforts to require proof of age, and retailer compliance with such efforts, should increase and become more effective due to section 1926 of the PHS Act. This provision requires States to enact and to enforce laws prohibiting manufacturers, retailers, or distributors of tobacco products from selling or distributing such products to persons under age 18 in order to receive substance abuse prevention and treatment block grants. However, State laws may differ, and so the final rule requires retailers to verify the age of purchasers. This will establish a uniform, national requirement regarding proof of age and is consistent with the assertion of Federal authority over these products under the act.

(35) Many comments pointed out that there is no penalty for parents who allow underage children to smoke.

FDA believes that the vast majority of adults and parents do not purchase tobacco products for young people. Parental actions are also beyond the scope of FDA's authority. However, it should be noted that parental consent to a young person's purchase of cigarettes and smokeless tobacco cannot override the requirements in § 897.14(a) prohibiting sales to anyone under 18 and in § 897.14(b) that each purchase is subject to age verification. Thus, under this rule, a retailer must refuse to sell cigarettes or smokeless tobacco to any young person who claims that he or she has ''permission'' to purchase such products for himself or herself or for an adult.

(36) One comment contended that the photographic identification card requirement is invalid because it exceeds FDA's authority under section 520(e) of the act because it does not purport to provide reasonable assurance of the safety and effectiveness of cigarettes.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to establish, by regulation, conditions restricting the sale, distribution, or use of a device if, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, the agency determines that there cannot be a reasonable assurance of the device's safety or effectiveness. A photographic identification card requirement is a

condition of sale for these products and a collateral measure that is necessary to the requirement that the products are not sold to anyone under the age of 18.

(37) One comment contended that proposed § 897.14(a) (now renumbered as § 897.14(b)) is precluded by section 1926 of the PHS Act. The comment stated that this law established Congress' intent to allow States to enact necessary programs to keep tobacco products out of the hands of young people as a condition for receiving block grant funding. According to the comment, there is no single best approach, and the FDA proposal prevents States from emulating the successful approach used in Woodridge, IL. The comment stated that FDA may not preempt State laws without making a showing of clear and manifest congressional intent to authorize its preemption of those State laws.

The agency disagrees with the comment. The preemption issues related to this rule (as well as the rule's relationship to the regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule) are discussed in great detail in section X. of this document.

2. Minimum Age

Proposed § 897.14(a)(now renumbered as § 897.14(b)), would have required retailers to verify that persons buying cigarettes or smokeless tobacco were not younger than 18 years of age. FDA received many comments supporting a Federal minimum age to purchase cigarettes and smokeless tobacco. Some comments suggested that enforcement of this provision would be as effective as advertising limitations in controlling underage smoking. In supporting the proposal, comments noted that while most teenage smokers do not plan to be smokers 5 years after they begin smoking, less than 10 percent of teenagers are able to quit within 5 years of starting. Moreover, like their adult counterparts, 70 percent of high school seniors who smoke would like to stop smoking completely. Some comments noted that the average age at which teenage smokers first tried their first cigarette is 13 or 14 years, and by age 18, many teens are smoking daily and smoking at a rate very near the adult rate. Health-care professionals (nurses, physicians, dentists, public health officials, etc.) as a group were very supportive of a Federal minimum age limit of at least 18.

(38) A major American medical association suggested amending § 897.14(a) (now renumbered as § 897.14(b)) to raise the minimum age of sale to 21. It noted that one State, Pennsylvania, has set 21 as the minimum age for the purchase of cigarettes, and argued that prior to enactment of the national standard of age 21 for alcohol purchase, many States had laws that allowed purchase at age 18, but subsequently changed to 21 without hardship.

Other comments advocated raising the minimum age to 19 years. Several comments explained that many high school students are 18 years old; thus, if FDA increased the minimum age to 19 years, it would be less likely that an underage high school student would be able to purchase or obtain cigarettes or smokeless tobacco, because raising the age to 19 would eliminate from the high school environment peers who are legally able to obtain nicotine-containing tobacco products. In addition, the agency received a considerable number of comments from students, teachers, and even adult smokers, urging the agency to raise the legal age to purchase cigarettes to 21, to be consistent with the legal age to purchase alcohol. Indeed, many comments assumed that the legal age was already 21 and urged the agency to retain this age limit.

In contrast, other comments supporting 18 as the minimum age for purchasing cigarettes and smokeless tobacco argued that, because most States already established 18 as the minimum age, FDA regulations did not need to establish a minimum age. A few comments, mostly from young people, asked FDA to lower the legal age for purchasing cigarettes to below 18 years of age.

In order to make its decision on the appropriate minimum age, the agency weighed a variety of factors including evidence on the onset of nicotine addiction and the history underlying the age of majority. FDA's goal is to prevent underage use of tobacco in order to preclude as many new cases of nicotine addiction as possible. The agency considered minimum ages from 18 to 21, because individuals are generally viewed as reaching adulthood in this age range. The agency faced the question: At which age in this range are most individuals able to make an informed decision to begin using a product that the overwhelming majority of individuals will not be able to stop using, even though using the product is likely to lead to severe disability and premature death?

The agency began by reviewing key data sources on the onset and course of nicotine addiction. The National Household Surveys on Drug Abuse sought to determine the age when individuals first tried a cigarette and the age when individuals first started smoking daily—an important measure of the progression toward addiction. The survey asked questions of 30 to 39 year olds who had ever smoked daily. The average age of first trying a cigarette was 14.5 years.[41] Eighty-two percent had tried a cigarette before 18, 89 percent before 19, 91 percent before 20, and 98 percent before 25.[42] Daily smoking began slightly later. Fifty-three percent began smoking daily before 18, 71 percent before 19, 77 percent before 20, and 95 percent before 25.[43]

The agency reviewed the history underlying the theory of majority and the concept of adults making informed choices. Majority is defined in Black's Law Dictionary as ''the age at which, by law, a person is capable of being legally responsible for all his or her acts * * *, and is entitled to the management of his or her own affairs and to the enjoyment of civic rights. * * *''[44] The 26th Amendment to the United States Constitution provides those 18 years and above with the right to vote. Prior to the adoption of the 26th Amendment in 1971, the age of majority in almost every State was 21. Each State has the power to set its own age of majority and since enactment of the 26th Amendment most States have lowered the age of majority from 21 to 18.

The agency reviewed the reasons why Congress chose 18 as the appropriate age to vote. According to a Senate report on lowering the voter age, the 21 year age was believed to be derived by historical accident. Eighteen-year olds bore many adult citizens' responsibilities such as the ability to marry and raise a family, and serve in the military. A lower voting age was seen as benefiting society by bringing into the American political system the idealism, concern, and energy of young people. (See ''Lowering the Voting Age to 18,'' S. Rept. 92–96, 92d Cong., 1st sess., p. 5, March 8, 1971.)

While the justifications do not necessarily support establishing a minimum age of 18 for tobacco

[41] 1994 SGR, p. 67.

[42] *Id.*, p. 65.

[43] *Id.*

[44] *Black's Law Dictionary*, edited by M. A. Black, West Publishing Co., St. Paul, MN, p. 955, 1990.

products, the agency declines to raise the minimum age for several reasons. First, as stated in the preamble to the 1995 proposed rule, all States prohibit the sale of tobacco products to persons under the age of 18; currently only four States prohibit cigarette sales to persons over 18 (60 FR 41314 at 41315). Consequently, setting a national minimum age of 18 is consistent with most States. Second, selecting 18 as the minimum age is consistent with the age Congress established under section 1926 of the PHS Act, which conditions a State's receipt of substance abuse grants on State laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under the age of 18.

FDA also declines to amend the rule to eliminate a Federal minimum age and instead rely on existing State laws. Establishing 18 as the national minimum age will strengthen State and local enforcement, as discussed earlier.

FDA also declines to amend the rule to reduce the minimum age. Reducing the minimum age would undermine existing State laws and the rule's effectiveness because it would, in essence, circumvent statutory and regulatory protections by letting more young people purchase these products. Reducing the minimum age would also be contrary to the evidence cited in the preamble to the 1995 proposed rule, which shows that half of adults start smoking daily before age 18.

FDA does plan to monitor closely the incidence of new cases of nicotine addiction. If the evidence indicates that the number of new cases of nicotine addiction does not significantly decline, consistent with the agency's stated goal of a 50 percent reduction, but rather are merely delayed a year or two, FDA will consider whether increasing the minimum age for purchase of nicotine-containing tobacco products would further the goal of the rule.

3. Restrictions Against ''Impersonal'' Modes of Sale

Proposed § 897.14(b) (now renumbered as § 897.14(c)) would have required the retailer or an employee of the retailer to provide cigarettes or smokeless tobacco to a purchaser ''without the assistance of any electronic or mechanical device (such as a vending machine or remote-operated machine).'' The preamble to the 1995 proposed rule stated that this provision would have the practical effect of making access to cigarettes and smokeless tobacco more difficult for young people (60 FR 41314 at 41324). In response to comments, the agency has amended § 897.14(c) to allow for the use of certain impersonal modes of sale, such as vending machines and self service displays (merchandisers only), in facilities which are inaccessible to individuals under the age of 18 at any time. Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to ''an employee of the retailer'' because retailers are generally responsible for their employees' actions and has revised the text to correspond more closely with § 897.16(c).

(39) Several comments objected to proposed § 897.14(b). One comment asserted that proposed § 897.14(b) (now renumbered as § 897.14(c)) was unjustified, and arbitrary and capricious because it would apply to locations where young people are not permitted to enter and, in places where they can enter, would be unnecessary if retailers required proof of age from prospective cigarette and smokeless tobacco purchasers. The comment stated that less restrictive alternatives, such as increased supervision over self-service displays, exist. The comment further argued that FDA lacked support for this provision, stating that, regardless of how tobacco products are sold over-the-counter, the key party in the transaction is the cashier. According to the comment, requiring retail clerks to comply with applicable minimum age laws should be sufficient to prevent illegal sales to young people, thereby making the proposed provision unnecessary. The comment, therefore, stated that the evidence did not support a rule that would preclude State and local governments from relying on ''less drastic controls.''

In contrast, many comments agreed that this provision would reduce a young person's access to cigarettes and smokeless tobacco because it would require potential purchasers to interact with retailers or would discourage young people from purchasing these products because they would have to interact with a retailer and provide proof of age. One comment stated that the regulations establish a code of conduct for merchants, ensuring that they take practical steps to prevent illegal sales of tobacco products to young people. One comment stated that face-to-face transactions are the only way to assure that identification of under-age customers is checked.

FDA disagrees, in part, with the comments that oppose this provision. FDA declines to amend the rule to rely on alternative measures such as increased supervision of displays or proof of age alone. The preamble to the 1995 proposed rule cited reports and studies showing that young people can easily use impersonal modes of sale despite restrictions on their placement or the installation of devices to prevent illegal sales. For example, for self-service displays, the Institute of Medicine (IOM) Report *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths* (1994) referred to surveys in two communities that found over 40 percent of daily smokers in grade school shoplifted cigarettes (60 FR 41314 at 41325). For vending machines, the preamble to the 1995 proposed rule cited several studies and reports showing that young people were able to purchase cigarettes—despite laws restricting the placement of those machines, or requiring the machines to have a locking device to prevent sales to young people (60 FR 41314 at 41324 through 41325).

FDA also found that relying solely on retailers to verify the purchaser's age had limited effect on reducing young people's access to cigarettes and smokeless tobacco; retail clerks rarely asked young people to verify their age or even assisted in completing a purchase. Some retail sectors also suffered from high employee turnover rates that undermined the effectiveness of retailer programs to prevent illegal sales (60 FR 41314 at 41323). Consequently, the agency believes that the most effective approach towards reducing young people's access to cigarettes and smokeless tobacco is a sufficiently comprehensive set of access restrictions to prohibit most impersonal modes of sale, require retailers to verify the consumer's age, and make young people's access to these products more difficult.

The agency also reminds parties that these products are restricted devices because of their potentiality for harmful effect. The final rule contains restrictions that the agency believes are necessary in order to reduce the number of children and adolescents who use and become addicted to these products. Relying solely on retail clerks to verify age, increasing supervision over displays, or deferring to other less restrictive alternatives would not, in comparison to the rule's comprehensive approach, be sufficient to achieve that goal.

With respect to locations that are entirely inaccessible to young people, however, the agency has amended

§ 897.16 to permit certain modes of sale, such as vending machines and self-service displays (merchandisers only), in facilities where young people are not present, or permitted to enter, at any time. These modes of sale do not involve hand-to-hand transactions between the retailer and the purchaser. Consequently, FDA has made a corresponding amendment to § 897.14(c) to require retailers to personally provide cigarettes or smokeless tobacco to purchasers ''[e]xcept as otherwise provided in § 897.16(c)(2)(ii) and revised the text to correspond more closely with the language in § 897.16(c)(1).'' The amendments to § 897.16 are discussed in greater detail below.

(40) A few comments questioned the need for proposed § 897.14(b) (now renumbered as § 897.14(c)). These comments said that the rule would not prompt retailers to verify a prospective purchaser's age because retailers who sell cigarettes and smokeless tobacco to minors are already in violation of State laws.

FDA disagrees with the comments' assertion. FDA's enforcement authority and the range of sanctions under the act should give retailers additional incentives to verify proof of age. Hence, FDA believes that the weight of Federal law and these regulations will prompt retailers to pay more attention to the consumer's age. By way of analogy, the United States enjoys a very high rate of compliance with prescription drug restrictions in part because a violation of the prescription requirement is actionable under Federal law. Similarly, section 1926 of the PHS Act gives States, as a condition for receiving a block grant for the prevention and treatment of substance abuse, further incentive to ensure that illegal tobacco sales to young people do not occur and that the illegal sales rate steadily decreases from 50 percent in fiscal year 1994 (or fiscal year 1995 for some States) to 20 percent 4 years later. States must also conduct annually a reasonable number of random, unannounced inspections to ensure compliance with State law (see 61 FR 1492 at 1508, January 19, 1996). Section 1926 of the PHS Act and its implementing regulations should also prompt States to devote more attention to compliance efforts to prevent illegal sales to young people and, through the requirement for random, unannounced inspections, make retailers more aware of the need to verify the consumer's age.

4. Restrictions Against the Sale of Individual Cigarettes

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee of the retailer from breaking or otherwise opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco that is smaller than the quantity in the unopened product. In response to comments and for other reasons discussed below, the agency has amended § 897.14(d) to prohibit retailers from breaking or otherwise opening ''any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use.'' Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to ''an employee of the retailer'' because the retailer is generally responsible for its employee's actions.

(41) Several comments opposed proposed § 897.14(c) (now renumbered as § 897.14(d)) in conjunction with proposed § 897.10 (which would establish general responsibilities for manufacturers, distributors, and retailers). The comments said it would be unreasonable to expect retailers to inspect all packages to assure compliance with minimum package requirement, as well as other requirements, and yet retailers would face significant penalties if they failed to comply. Other comments asked whether retailers would be held liable for opening shipping packages consisting of individual cigarette packages or cartons and selling the individual packages or cartons.

The comments misinterpreted the proposed provision. Section 897.14(d) does not require retailers to police minimum package requirements, but rather expressly states that the retailer shall not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the quantity in the unopened package. The confusion may have stemmed from the definition of ''package.'' Section 897.3(f) defines ''package'' as a ''pack, box, carton, or other container * * * in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.'' The provision, therefore, focuses on two distinct actions: (1) The retailer breaks or opens a cigarette package or smokeless tobacco product; and (2) the retailer sells or distributes a portion of the cigarette package or smokeless tobacco product to a consumer.

A literal reading of proposed §§ 897.3(f) and 897.14(d) together would prohibit a retailer from opening a carton of cigarettes to sell a single package of 20 cigarettes. The agency did not intend to prohibit retailers from opening shipped quantities or bundles of cigarette packages or cartons or smokeless tobacco in order to break that shipment down into ordinary packages, cartons, or other standard product units. The agency has amended § 897.14(d), to eliminate this unintended effect. The new language clarifies that retailers may open shipping boxes or cigarette cartons to sell a pack of cigarettes or a smokeless tobacco package. Additionally, FDA has modified the introduction to § 897.14(d), changing ''the retailer shall not'' break or open any cigarette or smokeless tobacco package to ''no retailer may'' break or open any package. This change is intended to simplify the text and does not alter a retailer's obligations under § 897.14(d).

(42) One comment from a company opposed a restriction on the sale of single cigarettes because it had made a substantial investment developing a vending machine that would sell single cigarettes that complied with applicable labeling and tax laws. The comment added that its machines are located in areas that are frequented by or limited to adults and that there is a market for adults who wish to smoke only occasionally.

The restriction against the sale of single cigarettes pertained to single cigarettes that are removed from cigarette packages or cartons and sold on an individual basis. Thus, the product described by the comment, a prepackaged single cigarette that complies with all applicable labeling and tax laws, does not appear to correspond to what is commonly known as a ''loosie.'' As for selling a packaged single cigarette in a vending machine, the final rule permits vending machines to be used in certain locations that are entirely inaccessible to young people. This comment, and corresponding amendments to the rule, are discussed in greater detail in section IV.E.4.a. of this document.

(43) A small number of comments opposed any restriction on the sale of single cigarettes, stating that such a restriction would make purchases by adults more difficult or could actually work to the detriment of adults who are trying to reduce their cigarette consumption by purchasing single cigarettes.

Most comments, however, supported a prohibition against the sale of single cigarettes. In general, they agreed that eliminating single cigarettes would make cigarette purchases more expensive for young people and, as a result, less likely. A number of State attorneys general stated that this provision, in conjunction with others, would assist States in enforcing compliance with State laws. A few comments noted reports of single cigarette sales occurring within their State or jurisdiction; one stated that ''the problem of loosies is a very old story within the inner city,'' while another even claimed seeing young people wait in line for free samples of single cigarettes.

The agency declines to amend the rule to exclude single cigarettes. The preamble to the 1995 proposed rule cited evidence that a significant number of retailers are willing to sell single cigarettes to young people and are sometimes more inclined to sell single cigarettes to young people than to adults (60 FR 41314 at 41324). The comments supporting the rule reinforce the notion that single cigarettes appeal to young people.

While FDA is sensitive to the fact that adults who wish to quit smoking may wish to purchase single cigarettes to reduce smoking, on balance, the agency believes that the benefits of eliminating single cigarette sales to young people outweighs any possible detriment to adults.

5. Additional Comments

(44) Several comments suggested that FDA license retailers and impose fines or other sanctions on retailers who sell cigarettes and smokeless tobacco to young people.

The agency declines to amend the rule to create a licensing system. FDA notes that SAMHSA confronted similar comments when it proposed rules to implement section 1926 of the PHS Act and elected not to require a licensing system (61 FR 1492 at 1495). The preamble to the SAMHSA rule indicated that States could use a licensing system to identify retail outlets and enforce State laws, with licensure fees and civil penalties funding the States' random, unannounced inspections and covering administrative and enforcement costs (61 FR 1492 at 1495). FDA concurs with the SAMHSA analysis and, because licensure would be a State matter, will refrain from establishing a licensing system for retailers.

As for fines and other sanctions, no amendment to the rule is necessary. The act already establishes fines and other sanctions for parties who violate the act. For example, any restricted device that is sold, distributed, or used in violation of regulations for that restricted device is misbranded under section 502(q) of the act (21 U.S.C. 352(q)), and section 301(a) of the act prohibits the introduction or delivery for introduction into interstate commerce of a misbranded device. (Section 709 of the act creates a presumption that all devices are in interstate commerce and section 304 allows seizure of adulterated or misbranded devices even in the absence of interstate commerce.) Among other things, section 301(b) of the act prohibits the misbranding of a device in interstate commerce, while section 301(c) of the act prohibits the receipt in interstate commerce of any misbranded device. Additionally, any person who violates section 301 of the act is subject to injunctions under section 302 of the act and civil penalties, fines and imprisonment under section 303 of the act, while section 304 of the act authorizes seizure actions against misbranded devices themselves without any need for proof of interstate commerce.

(45) One comment argued that retailers should be required to keep cigarette products from public view.

FDA declines to amend the rule as suggested by the comment. The agency believes that concealing these products from view would not significantly enhance the restrictions against access by young people and would instead unduly impair an adult's ability to determine what products and brands a retailer is selling as well as the retailer's ability to sell those products.

(46) One comment stated that § 897.14 can only be enforced by routine compliance checks using underage agents. The comment suggested that FDA negotiate with States to receive information on violations of State laws and to use that information against retailers who fail to comply with § 897.14.

FDA intends to cooperate with State governments to curtail illegal sales of cigarettes and smokeless tobacco to young people. Additionally, as stated earlier in this document, FDA is authorized to commission State officials to perform certain functions on behalf of the agency. FDA may consider commissioning State officials, where appropriate, if commissioned State officials would help ensure compliance with these regulations.

(47) One comment would amend § 897.14 to refer to ''purchasing'' and ''obtaining'' cigarettes or smokeless tobacco. The comment said this would prevent young people from attempting to obtain cigarettes or smokeless tobacco from retailers by claiming to act with a parent's permission or on behalf of a parent or adult.

The agency declines to amend the rule as suggested by the comment. As written, § 897.14 prohibits retailers from selling cigarettes or smokeless tobacco to anyone under 18 and also requires retailers to verify the purchaser's age. These provisions do not make any distinction or exception as to whether the person purchasing the products claims to be purchasing the products for an adult. In other words, even if a young person claimed to have a parent's permission or to be purchasing these products for an adult, § 897.14(a) still prohibits retailers from selling cigarettes or smokeless tobacco to that young person, and § 897.14(b) requires the retailer to verify the purchaser's age.

(48) As mentioned earlier in the discussion for § 897.10, FDA has amended the final rule to create a new § 897.14(e) to require each retailer to remove or bring into compliance all self-service displays, advertising, labeling, and other items at the retailer's establishment if those items do not comply with the requirements under this part. This amendment became necessary because comments from manufacturers and retailers claimed that retailers owned the self-service displays or that, once the manufacturer's representative gives an item to a retailer, the item becomes the retailer's property. Consequently, § 897.14(e) requires retailers to remove or otherwise bring into compliance items at the retailer's establishment if those items do not comply with this subpart. This provision essentially gives retailers three options with respect to an item that violates the requirements in this rule: (1) If the item belongs to a manufacturer, the retailer could ask the manufacturer to remove the item, consistent with the manufacturer's obligations under § 897.12; (2) the retailer could convert the item to another use or alter the item to make it comply with the regulations; or (3) the retailer could remove the item.

E. Conditions of Manufacture, Sale, and Distribution (§ 897.16)

1. Restrictions on Nontobacco Trade Names on Tobacco Products

Proposed § 897.16 would have established several important restrictions or conditions on the sale of cigarettes and smokeless tobacco. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product ''except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995.'' For example, Harley Davidson cigarettes would be ''grandfathered'' under this provision. The preamble to the 1995 proposed rule stated that the provision would be necessary to prevent the industry from circumventing the purpose behind the rule (60 FR 41314 at 41324) by benefitting from the promotion of the nontobacco items in ways that appeal to young people. FDA noted, however, that several cigarette brands already used trade names that are normally associated with nontobacco products and would exempt those brands from § 897.16. The final regulation remains essentially the same, but clarifies the agency's intent by amending the language to limit the exception to those product names ''whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.''

(49) FDA received few comments on this provision. The comments asserted that the 1995 proposed rule would effect takings compensable under the Fifth Amendment.

The agency disagrees with these comments. The final rule does not violate the Fifth Amendment. This issue is discussed in greater detail in section XI. of this document.

(50) Several comments on the use of nontobacco trade names on tobacco products would delete proposed § 897.16(a), arguing that the provision will have no effect on cigarette or smokeless tobacco use by young people, and that businesses should be free to decide how to advertise or sell their products. One comment challenged the agency's authority to regulate nontobacco trade names, stating that the act only permits the agency to take action against names that are false and misleading. According to this comment, a nontobacco trade name that appeals to young people does not become subject to the act. The comment further charged that FDA has no evidence to support a conclusion that a tobacco product bearing a nontobacco trade name would be especially appealing to young people; the comment explained that the brands mentioned by FDA in the preamble to the 1995 proposed rule—Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes—either have very small market shares or are not sold in the United States.

In contrast, one comment said § 897.16(a) is ''essential to avoid the same problems that occur with 'image' advertising.'' The comment explained that tobacco manufacturers have used nontobacco trade names on tobacco products to give the tobacco products an ''instant image.''

The point of this provision, like the restrictions on advertising, is to ensure that the restrictions on sale and distribution to children and adolescents are not undermined by how the product is presented to the public. As detailed in subpart D of part 897, FDA is restricting the way cigarette and smokeless tobacco are advertised in order to eliminate those elements that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging. The use of nontobacco trade names has particular appeal in the former regard. If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people.

For example, young people might purchase a particular nontobacco product that they perceive as symbolizing the adult sophistication or sex appeal of its users; they might also be inclined to purchase cigarettes bearing the same trade name if they perceive that the cigarettes will enhance their lifestyles in the same manner. Section 897.16(a), therefore, eliminates a potential loophole in the advertising and labeling provisions.

FDA also disagrees with the comment challenging FDA's authority. Section 897.16(a) is authorized under section 520(e) of the act which permits FDA to restrict, by regulation, the sale, distribution, or use of certain devices. Prohibiting firms from adopting nontobacco product names that appeal to young people is a restriction on the product's ''sale.'' The comment's suggestion that FDA cannot rely on section 502(a) of the act reveals a misunderstanding of FDA's position. FDA predicated its action on section 520(e) of the act and therefore it is not necessary to address the relevance of section 502(a).

FDA is not persuaded that small market shares for cigarette products bearing nontobacco trade names undermines the need for § 897.16(a). The preamble to the 1995 proposed rule demonstrated that young people use the most heavily advertised brands and that they can purchase cigarettes and smokeless tobacco easily (60 FR 41314 at 41323 through 41326, and 41332). The brands cited in the preamble, Harley-Davidson, Cartier, and Yves St. Laurent's Ritz, are not among the most heavily advertised brands, and, according to the comment, two (Cartier and Ritz) are not sold in the United States. Thus, there is no reason to expect these brands to be especially appealing to or purchased by young people in the United States today. However, if the other provisions in this rule are effective, some manufacturers might try altering their advertising or marketing strategy in order to generate product appeal; § 897.16(a) thus eliminates this potentially significant avenue for making a product appeal to young people.

(51) A few comments noted that the provision did not elaborate on what constitutes a ''trade or brand name for a nontobacco product.'' One comment interpreted the terms as including any nontobacco product trade name used anywhere in the world and, as a result, argued that the provision would impose an impossible burden on manufacturers to conduct trademark searches. The comment added that manufacturers would not be able to conduct trade or brand names searches with certainty (because the 1995 proposed rule did not confine itself to registered trademarks) and manufacturers would be subject to regulatory action even if they unknowingly used a trade or brand name for a nontobacco product.

In contrast, another comment noted that a brand name directory published by the Tobacco Merchants Association of the United States lists numerous brand names for both nontobacco and tobacco products. The comment suggested that there are a greater number of cigarette products whose brand names were the same as brand names for nontobacco products than the three brands that FDA identified in the preamble to the 1995 proposed rule. The comment suggested that FDA amend the rule to limit eligible brand name ''tie-ins'' to those relating to both tobacco products and to nontobacco products

sold in the United States as of January 1, 1995.

FDA agrees, in part, with the comments. It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality or whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere. FDA intended that proposed § 897.16(a) would apply to trade names in use in the United States, and that the exception for nontobacco product trade names would apply only to product trade names that were in use on both tobacco and nontobacco products as of January 1, 1995. Consequently, to clarify the rule, FDA has amended § 897.16(a) to restrict manufacturers to use of those product names that were used on both nontobacco and tobacco products in the United States as of January 1, 1995.

(52) One comment would amend § 897.16(a) to state that, in addition to being on the market as of January 1, 1995, the cigarette brand had to have generated sales of at least 500 million cigarettes or 500 million grams of cigarette or smokeless tobacco in 1994. The comment explained that this amendment would eliminate a ''loophole'' because a product with ''nominal sales volume could open up large marketing holes for all sorts of product names.''

FDA declines to amend the provision as suggested by the comment. The final rule, as amended, prohibits manufacturers from using a nontobacco product trade or brand name as the trade or brand name for a cigarette or smokeless tobacco product. The sole exception is for tobacco products whose trade or brand name was on both nontobacco and tobacco products sold in the United States as of January 1, 1995. FDA will construe this exception narrowly such that the trade or brand name on the nontobacco product must be the same. For example, if the trade name for a nontobacco product was ''Old Time Country Store,'' a cigarette product called ''Old Time'' would not qualify for the exception because the name is not identical to that for the nontobacco product.

(53) FDA, on its own initiative, has amended § 897.16(a) to replace the word ''may'' with ''shall.'' This amendment is intended to reinforce the notion that, except as otherwise provided in § 897.16(a), manufacturers are prohibited from using a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product.

2. Minimum Package Size

Proposed § 897.16(b) would have made 20 cigarettes the minimum package size for cigarettes. The preamble to the 1995 proposed rule explained that FDA selected 20 as the minimum number of cigarettes because most cigarette packs in the United States contain 20 cigarettes and that establishing a minimum package size would preclude firms from manufacturing so-called ''kiddie packs.'' The preamble to the 1995 proposed rule explained that ''kiddie packs'' usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-sized packs. The preamble to the 1995 proposed rule also noted that, based on studies or reports in other countries, significant numbers of children purchase ''kiddie packs'' (60 FR 41314 at 41324). Thus, by establishing a minimum package size, the 1995 proposed rule would have essentially eliminated the manufacture, distribution, and sale of ''kiddie packs.'' The final rule provides a narrow exception to the minimum package size in response to a comment on vending machines that sell certain packaged, single cigarettes.

(54) Several comments opposed creating any minimum package size. A minority disputed that the rule would be effective, stating that young people will get cigarettes anyway or will simply begin purchasing full-sized packs. One comment, submitted on behalf of specialty tobacco companies, suggested exempting specialty tobacco products from the rule. The comment explained that many specialty tobacco products are produced in package sizes smaller than 20 cigarettes, ranging from 8 to 18 cigarettes, but that young people do not purchase specialty tobacco products. Consequently, the comment sought an exemption for specialty tobacco products or for products with a very small market share. One comment asserted that small package sizes reduce smoking by adults while another comment would amend the rule to lower the minimum size to 10 cigarettes; neither comment offered any evidence to support their assertions.

In contrast, many comments supported proposed § 897.16(b). The comments indicated that eliminating ''kiddie packs'' is ''essential to protect youth'' and described ''kiddie packs'' as an ''obvious come-on that would appeal to kids.'' Other comments said the provision would reduce underage purchases because children would not be able to afford full-sized packs as easily or as quickly as they might afford ''kiddie packs.''

The final rule retains 20 cigarettes as the minimum package size. The agency disagrees that this provision will be ineffective. The provisions in this subpart are designed to: (1) Make young people's access to cigarettes and smokeless tobacco more difficult by restricting specific modes of access to these products that young people use, and (2) make purchases by young people more difficult (by requiring proof of age, and other methods) and more expensive (by eliminating free samples and ''kiddie packs'').

Additionally, while some tobacco products, specifically the specialty tobacco products, may have been sold in smaller sizes, the benefits of eliminating ''kiddie packs,'' namely eliminating a product size that is relatively inexpensive and appealing to young people, outweigh any inconvenience to adults.

FDA also declines to create an exemption based on market share or claims that young people do not use a particular type of cigarette; such exemptions would not treat manufacturers equally, would depart from FDA's traditional approach of regulating devices as a class (see section IV.B. of this document), and would be impractical because a firm's compliance with the rule could vary depending on fluctuations in market share and use by young people. Moreover, even a small percentage of a market, such as 1 or 2 percent, could translate into a large number of Americans; for example, 2 percent of the approximately 50 million Americans who smoke would represent 1 million people. Two percent of the approximately 3 million children under age 18 who are regular smokers would represent 60,000 young people.

Furthermore, FDA declines to make 10 cigarettes the minimum package size. The comment did not offer any justification for the lower figure, and the agency believes that a smaller package size would be counterproductive because a 10-cigarette minimum size would be tantamount to making a ''kiddie pack'' the minimum package size for cigarettes.

(55) One comment supported the provision, but suggested that FDA amend the rule to prevent the development of ''mini'' cigarettes or ''short smokes.'' The comment said such products contain less tobacco so that they can be sold at a lower price.