TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated[1,2]	10.0	5,201	18.0	4,614	17.1
People[1,2]	9.8	3,020	7.8	2,465	8.0
TV Guide[1,2]	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade[2]	3.7	n/a	n/a	6,059	6.9
Cosmopolitan[1]	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly[2]	2.9	n/a	n/a	674	15.3
Better Homes & Gardens[1]	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour[1,2]	2.0	2,216	17.1	1,540	17.4
Rolling Stone[1,2]	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver[1]	1.6	1,465	18.3	n/a	n/a
Life[1]	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life[1]	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track[1]	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle[1,2]	1.0	1,369	19.7	959	18.5
Vogue[1,2]	1.0	2,237	18.0	1,300	17.4
Hot Rod[1]	0.8	2,295	28.0	n/a	n/a
Ebony[1]	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly[1]	0.7	1,037	15.1	n/a	n/a
Motor Trend[1]	0.7	1,393	22.1	n/a	n/a
Premiere[1]	0.7	617	25.8	n/a	n/a
Sport[1,2]	0.7	2,274	33.8	1,132	24.0
Elle[1]	0.6	819	17.8	409	14.4
Essence[1]	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet[1]	0.4	1,724	16.7	1,169	12.2
Popular Science[1,2]	0.4	1,906	20.8	874	16.1
Self[1]	0.4	786	16.2	n/a	n/a
Harper's Bazaar[1]	0.3	718	18.2	n/a	n/a
The Sporting News[1,2]	0.3	1,394	27.8	666	15.7
Cable Guide[1]	0.2	3,358	22.6	n/a	n/a
Ski[1,2]	0.0	827	26.4	584	24.9

[1]MediaMark youth readership exceeds regulatory threshold.
[2]Simmons youth readership exceeds regulatory threshold.
Source: Barents Group LLC Tables IV–1 and A–2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, ''The Ad Age 300,'' *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.

Because FDA does not know how tobacco manufacturers will adapt their marketing strategies to the new regulatory thresholds, it is difficult to predict the number of new readership surveys that may be initiated. It seems likely, however, that tobacco companies will both increase the frequency of advertising in ''adult'' magazines that already carry tobacco advertisements and find suitable ''adult'' magazines to replace many of the other magazines.

One plausible scenario is that approximately one-half, or 50, of the magazines with current tobacco ads would not qualify as ''adult'' publications, because they exceed the youth readership threshold; and that the tobacco industry would choose to advertise in 50 other ''adult'' publications that do not currently carry tobacco ads. To identify these 50 additional ''adult'' magazines, the industry might need to collect new youth readership data for up to 100 magazines. In addition, as noted above, of the original 100 magazines with current tobacco advertising, youth readership data is now available for at least 40. Thus, the tobacco industry may initially need to obtain new youth readership data for the remaining 60 magazines. In total, therefore, the tobacco industry might opt to obtain youth readership data for an additional 160 publications in the first year that the rule becomes effective. In subsequent years, this number might fall to about 100 surveys, as the industry would concentrate its survey efforts on publications very likely to qualify.

If a marketing research firm collects youth readership data, the cost may depend on the particular characteristics of the magazines being surveyed. The tobacco industry could choose, however, to hire a survey firm to develop and administer a questionnaire solely to gather readership data for magazines with tobacco advertising. While FDA is uncertain about which approach the industry would take, the agency estimates that such new surveys might cost approximately $2 million in one-time costs and $1 million in annual costs, based on an average cost of about $650 and $350 per sample household.

11. Records and Reports

Manufacturers will need to comply with device regulations governing submissions of representative labels and advertising, medical device reporting (MDR's), establishment registration and product listing, and current good manufacturing practices (CGMP's).

a. *Labels and advertising.* The rule requires that each manufacturer annually submit to FDA copies of representative samples of labels and advertising. While the agency expects about 1,000 product labels, FDA has no direct evidence on the number of advertisements that will be submitted. An approximate estimate, however, can be derived from the number of advertising samples submitted by the pharmaceutical industry. First, FDA calculated that of the $6.1 billion in advertising and promotional outlays reported to the FTC by the tobacco industry, only about $1.2 billion is spent on printed advertisements. (Derived by subtracting categories for ''Coupons/Value Added,'' ''Promotional Allowances,'' ''Specialties Items,'' and ''Free Samples'' from the total $6.1 billion).

The pharmaceutical industry spends an estimated 22.5 percent of sales on marketing, of which about one-quarter may be allocated to advertising ethical pharmaceuticals.[337] The approximately $50 million in annual sales of pharmaceutical manufacturers, therefore, implies a $2.5 billion annual advertising budget. FDA estimates that it currently receives about 25,000 pieces of pharmaceutical advertising per year. As the pharmaceutical budget is roughly twice the size of the $1.2 billion tobacco industry figure derived above, the agency might receive half as many documents. Alternatively, reduced promotional activities may prompt an increase in the number of printed advertisements prepared by tobacco companies, although the Barents Group assumed this number would decline. Therefore, FDA projects that it will receive the same number of advertisements for tobacco products as it currently receives for pharmaceutical products, or about 25,000 per year, plus about 1,000 labels.

Estimates of the time burden of these paperwork submissions ranged from 20 minutes (The Barents Group) to 1 hour and estimates of the hourly cost ranged from $25.00 (Tobacco Institute) to $45.26 (the Barents Group). Using the high end of both ranges provides an upper bound cost estimate of $1.2 million. This figure is significantly lower than either the original FDA estimate, or the Barents Group estimate of $55 to $57 million, largely because the final rule imposes no specific paperwork requirements on retail establishments.

b. *MDR's.* The final rule will require MDR's for serious unexpected incidents. FDA assumes that 31 manufacturing companies[338] and 1,365 distributors[339] will bear total one-time costs of $21,000 and $231,000, respectively, for establishing and documenting procedures for MDR reporting. These costs include 32 hours of effort per manufacturing firm and 8 hours per distributor. Based on estimates previously developed for the Medical Device User Facility and Manufacturer Reporting Final Rule, these activities were distributed over wage rates averaging $21.17. Annual costs for MDR reporting requirements are more difficult to predict, because they depend on the number of adverse event reports that will be submitted. FDA projects, however, that followup investigation and reporting of a single event takes about 8 hours of labor and costs about $218. Thus, if 50 adverse event reports were filed annually, the annual cost would be about $11,000. In addition, if each manufacturing company submits a single baseline report and annual updates, these costs would be about $2,100 annually, based on unit costs of $54 and $14 per report, respectively. Annual certification is necessary, but is typically a formality in terms of data collection and reporting and is estimated to cost about $800 for all manufacturers and $35,000 for all distributors assuming 1 hour of professional and clerical time at $25.80 per hour.

c. *Registration and listing.* Registration and listing duties are estimated to take 41 manufacturing establishments 2 hours each to prepare at a unit cost of $42, totaling about $1,700 per year for the industry.

d. *CGMP's.* The Tobacco Institute asserted that cigarette manufacturers would need substantial time to comply with CGMP's as the industry ''would need to adopt major new systems * * * [and] make major changes to their procedures just to accommodate the recordkeeping required.'' Conversely, the economics study prepared by the Barents Group for the Tobacco Institute showed no additional costs for this requirement. FDA agrees that these costs

[337] U.S. Congress, Office of Technology Assessment, ''Pharmaceutical R&D: Costs, Risks and Rewards,'' OTA-H-522 Washington, DC: U.S. Government Printing Office, pp. 303–304, February 1993.

[338] 1992 U.S. Census of Manufactures, Industry Series, Tobacco Products, Table 1a. A few U.S. agents designated to represent foreign manufacturers would also need to file forms, but these costs should be minimal.

[339] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States (unpublished data).

should be minimal for facilities with good quality assurance programs. Its CGMP's do not specify a specific format, but encompass a wide variety of broad requirements for documenting operating procedures. Contrary to the Tobacco Institute's claim that ''even a well-run cigarette manufacturing facility would need to adopt major new systems,'' CGMP's are, in fact, based on the activities of well-run operations. Moreover, device CGMP's are currently under revision to bring them even closer to ISO 9001, the generally recognized international standard for quality assurance systems. Thus, while FDA has little experience with day-to-day tobacco manufacturing procedures, the agency does not anticipate the need for substantial quality system redesign. Wholesalers and distributors also submitted comments contending that the CGMP's would create added paperwork burdens, but the agency has exempted these sectors from the CGMP requirements.

12. Government Enforcement

FDA estimates of internal costs for administering and enforcing this regulation are extremely uncertain, as they will depend on the working relationships to be established with State tobacco control programs. As a best estimate, however, FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of $100,000 per FTE places the dollar cost at between $3 and $5 million per year. SAMHSA has estimated that State programs will need between $25 and $50 million annually to administer and enforce appropriate State operations.

13. Comparison of Benefits to Costs

FDA expects the net societal benefits of the rule to far exceed the regulatory costs. Based on the analysis presented above, the estimated one-time costs of the combined FDA and SAMHSA rules are $174 to $187 million and the estimated annual costs are $149 to $185 million. Taking the midpoint of the ranges and annualizing the one-time costs at 3 and 7 percent, respectively, yields total annualized costs of $172 million and $180 million. In contrast, the agency's best estimate of the monetized regulatory benefits that would follow a 50 percent reduction in underage tobacco use ranges from $28.1 to $43.2 billion at a 3 percent discount rate and from $9.2 to $10.4 billion at a 7 percent discount rate. Thus, as shown in Table 12, the *net* benefits (benefits minus costs) of a total effectiveness rate of 25 percent range from $27.9 to $43 billion at a 3 percent discount rate and from $9.0 to $10.2 billion at a 7 percent rate. Table 13 indicates that those figures imply a cost per life-year saved of from $800 to $4,700 and a cost per death avoided of from $11,000 to $52,000. As noted earlier, these benefits are exclusive of the substantial health improvements expected to result from the reduced consumption of smokeless tobacco.

The substantial differential between these estimated costs and benefits withstands rigorous sensitivity analysis (see Table 12). For example, SAMHSA estimated that its rule would reduce underage tobacco use by from one-third to one-tenth. The approximate midpoint of that estimate (20 percent) constitutes about 40 percent of the regulatory benefit of reducing underage tobacco use by one-half. If, for illustrative purposes, these results, as well as a proportional fraction of the relevant costs,[340] are attributed to SAMHSA, the *incremental* net benefits of the FDA rule still range from $16.8 to $25.8 billion at a 3 percent discount rate, and from $5.4 to $6.2 billion at a 7 percent discount rate.

Moreover, FDA assumed that reaching the ''Healthy People 2000'' goal would deter about one-quarter of the 1 million youth under age 18 who currently begin to smoke each year from ever smoking as an adult. Thus, this goal implies a 25 percent overall effectiveness rate. If, however, these rules prevent smoking as an adult for even 5 percent of the teenagers who would otherwise become adult smokers, they would produce estimated annual net benefits of from $5.4 billion to $8.5 billion at a 3 percent discount rate and from $1.7 billion to $1.9 billion at a 7 percent discount rate. Even if this latter scenario attributed 40 percent of the benefits and relevant costs to SAMHSA, the annual *net* benefits of the FDA rule would still range from $3.3 billion to $5.1 billion at a 3 percent discount rate and from $1.0 billion to $1.2 billion at a 7-percent discount rate. This last example implies a cost per life-year saved of $3,500 to $21,100 and a cost per death avoided of $47,000 to $234,246. These figures are well within the range of values for health interventions typically considered cost-effective.

TABLE 12.—NET BENEFITS

($ Billions)

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Low	High	Low	High	Low	High	Low	High	Low	High
3%	27.9	43.0	16.7	25.7	11.1	17.1	5.4	8.5	2.6	4.1
7%	9.0	10.2	5.3	6.1	3.5	4.0	1.7	1.9	0.74	0.86
Illustrative Incremental Net Benefits[1]										
3%	16.8	25.8	10.0	15.5	6.7	10.3	3.3	5.1	1.6	2.5
7%	5.4	6.2	3.2	3.7	2.1	2.4	1.0	1.2	0.45	0.53

[1] Attributes 40% of benefits and associated costs to SAMHSA

[340] Costs include 100 percent of SAMHSA's state enforcement costs, plus 40 percent of retail training costs, vending machine costs, and retail and consumer I.D. check costs.

TABLE 13.—COST EFFECTIVENESS

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)
3%	815	10,862	1,358	18,103	2,038	27,155	4,075	54,310	8,151	108,621
7%	4,722	52,423	7,870	87,372	11,804	131,059	23,609	262,117	47,218	524,235
Illustrative Incremental Cost-effectiveness[1]										
3%	706	9,413	1,177	15,689	1,766	23,533	3,532	47,067	7,064	94,134
7%	4,220	46,849	7,033	78,082	10,549	117,123	21,098	234,246	42,197	468,492

[1] Attributes 40% of benefits and associated costs to SAMHSA

E. Distributional Effects

These regulations will impose a variety of sector-specific distributional effects. Those sectors affiliated with tobacco and tobacco products will lose sales revenues and these losses will grow over time. Businesses engaged in the provision of tobacco product advertising may also face reduced revenues. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers and Distributors

For its calculation of regulatory benefits, FDA estimates that implementation of the regulations may reduce the cigarette consumption of underage smokers by one-half within 7 years. As discussed earlier in this section, based on data presented in Cummings, et al., FDA finds that teenage smokers under the age of 18 consumed about 316 million packs of cigarettes in 1994. A 50-percent cut in sales would drop the number of packs sold by 158 million. Moreover, FDA has assumed that at least one-half of those 500,000 teenagers who would be deterred from starting to smoke each year would refrain from smoking as adults, decreasing the number of adult smokers by 250,000 per year. Because each adult smoker consumes about 500 packs per year, about 124 million fewer packs would be sold per year.

Thus, achieving the agency's goal would reduce cigarette consumption by 158 million packs in the first year (while only teenagers are affected), 158 million plus 124 million packs in the second year, 158 million plus 2 times 124 million packs in the third year, and so on. Since 1994 cigarette shipments totaled 36.3 billion packs,[341] cigarette consumption would fall by about 0.4 percent in the first year, 1.8 percent in the fifth year, and 3.5 percent in the tenth year following implementation. (In fact, these reductions may take even longer, because it may be several years before the 50-percent effectiveness level is achieved, and because young adults smoke fewer packs than older adults).

Hence, annual tobacco revenues will decline slowly over time. The U.S. Bureau of the Census estimates 1994 revenues for cigarette and smokeless tobacco manufacturers at about $25.9 billion.[342] Assuming comparable reductions in smokeless tobacco, these calculations imply that tobacco manufacturer revenues will fall by $128 million in the first year (0.5 percent), $501 million in the fifth year (1.9 percent), and $966 million in the tenth year (3.7 percent). While these reductions are significant, the gradual phasing of the impacts will significantly dissipate any associated economic disruption.

In a 1992 report prepared for the Tobacco Institute, Price Waterhouse estimated that the tobacco manufacturing, warehousing and wholesale trade sectors employed about 107,000 full-time workers.[343] Thus, a constant production-to-employment ratio projects that a 3.7-percent reduction in sales over a 10-year period would result in the displacement of about 4,000 jobs, or 400 jobs annually among manufacturers, warehousers, and wholesalers. Alternatively, a University of Virginia study concluded that ''the Price Waterhouse study for the Tobacco Institute provides estimates of tobacco's impact that are high compared to other measures.''[344] That study referenced a recent U.S. Department of Agriculture analysis by Gale that found that manufacturing and wholesale trade activities employ only 83,000 full-time equivalent workers.[345] If true, this finding reduces these job loss estimates to about 3,000 jobs, or 300 annually.

The smaller job loss estimate is generally confirmed by a recent study by Warner, et al., who applied a computer simulation model to forecast the regional impact of reductions in tobacco use.[346] The authors used ''a state-of-the-art macroeconomic model to simulate what would happen if consumers reduced their tobacco expenditures, with the same level of spending redistributed to other goods and services * * *.'' One scenario assumed that tobacco control activities would reduce the expected rate of tobacco purchases by 2.06 percent per year, or roughly 5 times the estimated effect of the FDA rule. While this scenario does not present direct impacts to the tobacco industry alone, it forecasts job losses after 8 years of 6,401 for all U.S. wholesalers and 5,957 for Southeast Tobacco Region

[341] ''Tobacco Situation and Outlook Report,'' U.S.D.A., Economic Research Service, p. 4, April 1995.

[342] ''1994 Annual Survey of Manufactures: Value of Product Shipments,'' U.S. Department of Commerce , Bureau of the Census, Table 1, p. 210. ASM does not report data below the 5-digit SIC Code Level. FDA assumed chewing tobacco represented the same percentage of SIC Code 2131 (Chewing and Smoking Tobacco) in 1994 as it did in 1992 when it was classified at a 6-digit SIC code in the Census of Manufacturers.

[343] ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, p. ES–3, October 1992.

[344] Knapp, J. L., ''Tobacco in Virginia,'' Weldon Cooper Center for Public Service, University of Virginia, p. 5, December 1995.

[345] Gale, F., ''What Tobacco Farming Means to Local Economies,'' U.S. Department of Agriculture, Economic Research Service, Agriculture Economic Report Number 694, p. 5, September 1994.

[346] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, ''Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States,'' *JAMA*, pp. 1241–1246, April 24, 1996.

manufacturers. Accounting for the multiple of 5, comparable job losses attributable to the FDA rule would total about 2,600 after 8 years, or about 325 annually.

The Barents Group did not address the long-term gradual decline in tobacco use projected by FDA. Nevertheless, it claimed that the agency underestimated the economic impact on industry by failing to account for the lost sales to adults that would result from the proposed ban on vending machines and self-service displays and the required checking of customer I.D.'s. The Barents Group argued that the added consumer inconvenience imposed by these provisions was tantamount to an increase in the effective price of tobacco products, which would rapidly decrease the consumption of tobacco by adults. Relying on ''hypothetical scenarios'' that assume demand declines of 5 and 10 percent, the Barents Group forecast that the tobacco manufacturing industry would lose from 1,800 to 3,700 jobs due to this increased consumer inconvenience.

FDA believes these Barents projections are substantially overstated. Impacts associated with cigarette consumption declines of 5 to 10 percent cannot possibly be attributed to the loss of vending machines, because vending machine purchases make up less than 1 percent of all cigarette purchases. Further, according to NAMA, there are only 141,000 cigarette vending machines currently in use (and that number is falling rapidly), and the cost analysis prepared by the Barents Group predicted that 100,000 of these machines would be replaced by new OTC establishments. Thus, the Barents Group's own analysis eliminates any added consumer inconvenience from three-quarters of the existing inventory of machines. Moreover, the near-term impact on adult tobacco consumption will be further moderated both because the final rule allows vending machines in ''adult'' facilities, and because the added inconvenience cost will be partially offset by the lower price of the OTC product. These factors together make it extremely unlikely that fewer vending machines will lead to a substantial near-term fall in tobacco industry sales revenues.

The likelihood that tobacco sales will decline significantly due to inconvenience imposed on adult customers by the self-service restriction is similarly remote. While some purchasers would need more time to complete a transaction, other purchasers would save time by no longer having to search and retrieve a desired product. In the absence of empirical evidence, the result is indeterminate; but FDA has seen no convincing evidence or arguments to demonstrate that any delays caused by the self-service restriction will significantly curtail adult tobacco use.

Finally, although FDA calculated above that increased delays due to I.D. checking could cost young adult consumers under the age of 26 up to $50 million per year, even this cost would not lead to significant consumption declines. As described, the increased checkout waiting time for young purchasers was estimated to average about 8.3 seconds, which translates to a cost of about 2.3 cents per transaction, or 1.35 percent of the cost of a pack of cigarettes. According to the Barents Group, representative estimates of demand elasticities for cigarettes range from -0.6 to -1.0. Young adults under the age of 26, however, purchase only about 10 percent of all tobacco products. Thus, the fall in total tobacco sales would be, at most, 0.1 percent, not the 5 to 10 percent assumed by the Barents Group. Moreover, even the 0.1 percent figure is an overestimate, because those consumers irritated by the delay will increase the volume of tobacco products purchased per transaction. As a result, the number of cartons sold will rise, but the decline in tobacco product sales revenues attributable to the inconvenience effects of I.D. checks will be negligible.

2. Tobacco Growers

As explained above, total cigarette and chewing tobacco consumption is expected to decrease by 0.5 percent in the first year, 1.9 percent by the fifth year, and 3.7 percent by the tenth year, following compliance with the regulation. Price Waterhouse estimated that, on a full-time equivalent basis, about 153,000 farmers grew tobacco in 1990. Based on these figures, constant production-to-employment ratios imply employment losses among tobacco growers of about 5,700 after 10 years, or about 570 annually. Alternatively, the Gale study for the U.S. Department of Agriculture (USDA)[347] estimated the number of full-time equivalent tobacco farmers to be only 65,400, which would reduce the job loss estimate to about 2,500 by the tenth year, or 250 annually.

This latter figure also closely fits the findings of Warner, et al., who, as described above, used a ''state-of-the-art'' macroeconomic simulation model to project the employment effects of declining tobacco consumption.[348] Assuming domestic tobacco consumption decreases of 2.06 percent per year, Warner, et al. predicted about 7,500 job losses within an 8-year period for ''Southeast Tobacco Region'' farmers. As this fall in tobacco use is roughly five times that projected by FDA, the analogous job loss estimate would be about 1,500 over the 8-year period, or about 190 per year.

According to the USDA study by Gale, ''[f]or most farms, tobacco growing is a part-time, seasonal enterprise, and production per farm is usually small. About two-thirds of tobacco farmers work off-farm.''[349] Citing 1987 Census of Agriculture data, Gale notes that only 65 percent of the farms growing tobacco in the United States reported earning more than half of their receipts from tobacco, and of those farms, approximately 80 percent had total farm sales under $20,000. He explains that the availability of alternative land uses will dictate the economic results:

> The key factor in adjustment to a smaller tobacco industry is the alternative uses available for land, labor, and capital used in tobacco production * * * For the most part, concern is focused on rural areas where tobacco is grown because this stage of production has the most specialized resources with fewer attractive alternative uses. In many areas, small farms that are unviable without tobacco profits would cease production and their land would be absorbed into larger neighboring farms or converted to other uses * * * In marginal farming areas * * * much of the land devoted to tobacco would be converted to residential, commercial, industrial, or forestry uses, in which case it would still generate income for the local economy * * * This land is already being converted to nonfarm uses in rapidly growing areas like southern Maryland and Raleigh-Durham, North Carolina.[350]

FDA notes that the economic consequences of these trends will be substantially mitigated by the very moderate pace of the projected changes.

3. Vending Machine Operators

The final regulation prohibits all vending machine sales of regulated tobacco products except for those machines located in a facility where

[347] Gale, F., ''What Tobacco Farming Means to Local Economics,'' USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 5, September 1994.

[348] Warner, K. E., G. A. Fulton, and D. R. Grimes, ''Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States,'' *JAMA*, pp. 1241–1246, April 24, 1996.

[349] Gale, F., ''What Tobacco Farming Means to Local Economies,'' USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 1, September 1994.

[350] *Id.*, p. iii.

persons under the age of 18 are not present at any time. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. According to the NAMA:

[t]he 1986 cigarette location survey mirrored an industry with about 700,000 cigarette vending machines on location. In 1994, the vending industry was estimated to have between 141,000 and 400,000 cigarette machines. This represents a decline in the number of cigarette vending machines on location of between 43 percent and 80 percent.

The U.S. Department of Commerce [351] reports that 1992 sales of tobacco products by automatic merchandising machine operators were about $452 million, or 7.1 percent of that sector's total sales, but a NAMA fact sheet shows this rate continuing to fall, dropping from 8.5 percent in 1990 to 2.7 percent in 1994. One trade magazine explains that, ''[c]igarette vending, once an industry mainstay, is now a niche business increasingly conducted by specialized enterprises.'' [352]

Referring to 1992 Census data, NAMA declared that over 3,000 vending machine operators supply cigarettes, not including the bars, restaurants, hotels, and bowling alleys that own their own machines. On average, these mostly small firms receive 10 percent of their revenues from cigarette sales, although some firms are even more dependent. While some vending machines can be converted to sell other products, one large cigarette machine manufacturer maintained that more than 85 percent of the existing machines can be converted only for new products with packaging similar in dimension and form to cigarette packages.

While vending operators will need to develop new markets to replace the already dwindling sales revenues from cigarette vending machines, the overall economic impact will be mitigated somewhat by FDA's decision to exempt ''adult only'' locations from the ban. According to a 1995 NAMA survey, 58 percent of cigarette vending machines are located in bars and cocktail lounges, 11 percent in factory/plant locations, and 3 percent in business offices. [353] Those locations that do not permit the entry of youngsters under the age of 18 will be exempted from the cigarette vending machine restriction.

4. Advertising Sector

In annual reports to FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of $6.0 billion and $119 million, respectively (see Table 14). About $2.6 billion (43 percent) of these outlays went to consumers as financial incentives to induce further sales (e.g., coupons, cents-off, buy-one-get one free, free samples), and $1.6 billion (26 percent) to retailers to enhance the sale of their product. The remaining $1.9 billion (31 percent) were related to consumer advertising activities that will be significantly modified by the ''text only'' restrictions.

TABLE 14.—TOBACCO ADVERTISING/PROMOTIONAL EXPENDITURES 1993 (Millions of Dollars)[1]

Promotion Type	Cigarettes	Smokeless	Total
Coupons/Value Added	2,559	32	2,591
Promotional Allowances	1,558	13	1,571
Point of Sale	401	13	414
Specialties Items	756	4	760
Outdoor	231	1	232
Magazines	235	7	242
Public Entertainment	84	23	107
Free Samples	40	16	56
Transit	39	0	39
Newspapers	36	1	37
Direct Mail	31	1	32
Endorsements	0	0	0
All Others	64	7	71
Total	**6,035**	**119**	**6,154**

[1] Totals may not add due to rounding.
Source: U.S. Federal Trade Commission

FDA cannot project the ultimate industry response to these advertising restrictions. On the one hand, the effectiveness of many advertisements will fall. On the other hand, many alternative marketing promotional activities will be prohibited or constrained even more stringently, raising the relative desirability of the remaining advertising options. Moreover, as described above, FDA may require new informational programs that would generate a substantial increase in advertising industry revenues. Nevertheless, if tobacco outlays fall, there will be short-term dislocations as industry resources are redirected to other uses. One firm that depends heavily on tobacco advertising warned of severe economic burdens, pointing to income and job losses for many of its employees and suppliers. Most advertising suppliers, however, are not overly specialized with respect to particular consumer products and would redirect resources to other advertising purchasers, albeit at some revenue loss. While FDA is aware that such demand shifts cause short-term disruption, the U.S. economy creates and discards thousands of products each day. For most advertising media, the ability to respond rapidly to

[351] U.S. Department of Commerce, ''Merchandise Line Sales,'' *1992 Census of Retail Trade*, RC92–S–3RV, pp. 3–27, 3–31.

[352] *Vending Times*, Census of the Industry Issue, p. 36–D, 1995.

[353] National Automatic Merchandising Association, Cigarette Vending Machine Location Study, conducted August 31, 1995.

changing markets is a mainstay of economic survival.

a. *Print media.* The final regulation requires that advertising of cigarettes or smokeless tobacco be restricted to black text on a white background in those publications where youthful readers constitute more than 15 percent of total readership or number more than 2 million. FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but foresees a possible fall in the $242 million worth of magazine advertising and the $37 million worth of newspaper advertising that tobacco manufacturers reported to the FTC in 1993. These advertising revenues comprised about 1.1 percent and 0.1 percent of the 1992 value of shipments for periodicals and newspapers, respectively.[354] The Barents Group identified 32 leading magazines with tobacco advertising in 1994 that have youth readership levels exceeding the regulatory threshold and found that these publications received, on average, 7.3 percent of their total advertising revenues from tobacco in 1994. They also predicted, based on the sharp downward trend of these advertising outlays, a 21-percent drop in magazine advertising and a 45-percent drop in newspaper advertising for tobacco products by 1996, irrespective of the FDA regulation.

The impact of these restrictions on the various advertising media and agencies is difficult to determine. The Barents Group contended that FDA had argued in its original analysis that ''regulations for print media will have little or no adverse impact.'' In fact, FDA made no such projection, although the agency did present several historical examples of advertising bans (e.g., the broadcast ban on tobacco products) where advertising revenues rebounded in spite of new legal restrictions. The Barents Group also faulted FDA for not comparing actual revenues after the broadcast ban to revenues ''that *would have* been expected in the absence of the ban.'' FDA, however, does not believe that this ''counter factual'' logic for estimating costs precludes the agency from suggesting that income and employment would not necessarily fall in the wake of new advertising restrictions.

Several comments declared that advertising outlays would fall sharply and subscription prices rise. According to the Barents Group, imagery is a prerequisite for effective promotion and, in its absence, magazine and newspaper advertising revenues would fall by 25 to 75 percent. It also predicted that the reduced revenues would, in turn, force publication subscription prices to rise.

FDA agrees that there will be adverse impacts on certain publications, but notes that the tobacco industry is currently shifting its advertising budget away from print media and that only 6 of the 32 affected magazines identified by the Barents Group received over 10 percent of their revenues from tobacco products. Moreover, as noted earlier, while FDA cannot project the tobacco industry's marketing strategies, the agency suggests that restricted promotion alternatives could reestablish print advertising as a relatively attractive option for conveying product information to adult readers; thereby slowing or even reversing the recent slide in this type of tobacco advertising.

The Barents Group also asserted that the commercial printing industry, as well as other industry sectors, would be harmed by restrictions on coupons and ''retail value added'' promotions. These expenditures, which account for $2.6 billion, or 42 percent of the total tobacco advertising and promotional outlays reported to FTC in 1993, include outlays associated with cents-off coupons and multiple pack promotions, such as ''buy one, get one free'' or ''buy two, get one free;'' as well as other give-away promotions, such as ''buy cigarettes and get a free promotional item.'' The former activity will be permitted but the latter prohibited under the final regulation. Although a comment submitted by the Tobacco Institute noted that, ''[a]nalytically, such spending is more akin to a price cut than to advertising,''[355] the Barents Group, nonetheless, concluded that, ''[a] considerable part of this spending would likely be eliminated by the proposed regulations.'' FDA, however, does not agree that the printing industry will be significantly affected by changes in ''coupons and value added'' outlays. Cents-off coupons and multiple pack promotions are the principal components of these promotions and will continue to be available under the final rule.

b. *Advertising agencies and other suppliers.* Advertising agency revenues are directly tied to the level of advertising expenditures by product manufacturers. If tobacco manufacturers reduce advertising outlays, these agencies will lose income. The Barents Group found that, in 1993, tobacco companies routed almost $1 billion through ad agencies (less than 1 percent of the reported $131.3 billion spent on U.S. media advertising in 1992).[356] Assuming agency fees of 10 percent (while overlooking the proposed $150 million educational campaign), it suggested that advertising declines of 25 to 75 percent would decrease agency annual revenues by $25 million to $77 million. Assuming a 50 percent drop ($140 million) in magazine and newspaper advertising, the Barents Group next applied a simulation model to predict that supplier firms among advertising agencies, government, business and professional services, and commercial printers businesses would lose revenues of from $12 to $23 million. While acknowledging that, ''* * * there will be eventual offsetting revenue gains in other industries not shown * * *,'' these other sectors were not identified and the offsetting revenues not explicitly quantified. The Barents Group correctly noted that the adjustments will involve short-term costs to the affected sectors, but did not estimate the expected magnitude of these adjustment costs.

c. *Outdoor advertising industry and public transit authorities.* The final rule restricts tobacco billboards and public transit advertising to black text on a white background and bans all stationary outdoor tobacco ads within a 1,000-foot radius of any school or public playground. The Barents Group predicted that almost all urban areas would be covered by the ban and expected almost no new outdoor tobacco advertising ''even in permitted areas due to the relative ineffectiveness of black-and-white text as an advertising medium.'' Further, explaining that the $232 million spent on outdoor advertising in 1993 accounts for about 14 percent of all outdoor advertising in the United States, the Barents Group found it unlikely that the industry could find new means of maintaining its current revenues.

In fact, the billboard industry and public transit districts will have to find replacements irrespective of this regulation. According to the Barents Group projections, spending on outdoor advertising by tobacco companies will fall by almost 40 percent between 1988 and 1996 (Appendix Table). One billboard trade source notes that, ''almost 60 percent of the industry's 1979 revenues were derived from

[354] *Statistical Abstract of the United States,* p. 750, 1995.

[355] Beales, J. H., ''Advertising and the Determinants of Teenage Smoking Behavior,'' vol. 44, p. 13, 1993.

[356] Endicott, R. C., ''Top Advertisers Rebound, Spending to $36 Billion,'' *Advertising Age,* vol. 64, No. 41, p. 1, September 29, 1993.

tobacco and alcohol advertisers. Today that number is down to 13 percent, replaced by retail, business and consumer services, entertainment, and travel advertisers.'' [357] Similarly, FDA's preliminary economic analysis had recognized that Canada's billboard industry had rapidly adjusted to a recently imposed advertising ban and ''quickly replaced $20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer.'' [358]

In 1993, tobacco industry spending on public transit ads ($39.1 million) contributed less than 1 percent to total public transit revenues, having declined by 35 percent from 1990 to 1993. Acknowledging that these expenditures would continue to fall, irrespective of this rule, the Barents Group argued that since relatively few transit authorities accept tobacco ads, the impact of the regulation would be significant for those few.

d. *Specialty item suppliers.* The prohibition of nontobacco specialty items bearing the name or logo of tobacco products will affect a substantial number of specialty manufacturers. In earlier comments to FTC, [359] the Specialty Advertising Association International noted that it ''represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses.'' It is likely that some of these firms would, at least initially, lose part of this $760 million market and would experience short-term costs while exploring other business options.

The Barents Group projected that manufacturer outlays for these promotional items, in the absence of the FDA rule, would triple between 1993 and 1996, rising from $760 million to $2.2 billion, assumed that the rule would cause revenue decreases of 25 to 75 percent, and modeled the impacts among other affected industry sectors (e.g., miscellaneous manufacturers producing matches and matchbooks, cigarette lighters, pens and pencils, sporting goods, etc.). The revenue and employment losses, therefore, were measured from a baseline that assumed a tripling of future industry revenues. While these growth projections may be optimistic, they demonstrate the rapid swings that typify the market for many of these industries. Indeed, the Barents Group's forecasts imply that even if the FDA rule were to reduce the 1996 level of tobacco industry advertising on specialty items by 50 percent, these outlays would still exceed the 1995 level.

In any case, FDA believes that the Barents Group's forecasted impacts may be overestimated, as they primarily reflect static outcomes, whereas firms supplying such products are constantly adjusting production in response to rapidly shifting patterns of demand. While these regulatory changes will impose short-term dislocation costs, these costs will be significantly mitigated in view of the extensive lead time provided. Again, the Barents Group noted that FDA had not quantified these transitory costs, but it also provided no estimate.

e. *Sponsorship recipients.* According to reports submitted to FTC, U.S. tobacco companies spent $107 million on public entertainment, primarily sporting events, in 1993. [360] In comparison, total spending on corporate sponsorships for sports, arts, and other entertainment by all North American companies is estimated to reach $5.4 billion in 1996. [361] FDA received numerous public comments asserting that the loss of sponsorship revenues for sporting events would increase ticket prices and, in turn, reduce spectator attendance. In particular, comments pointed to the potential loss of jobs, employee benefits, and business revenues associated with race track events.

The Barents Group contended that a substantial part of the payments made by tobacco manufacturers would be eliminated by a ban on tobacco brand sponsorships, because few sponsors would agree to continue sponsorships under corporate names. Acknowledging the lack of reliable information on economic impacts; it, nonetheless, referenced several studies showing that lost sponsorship dollars decrease revenues and temporary jobs for local economies. The Barents Group predicted that, as tobacco companies eliminate payments, other advertisers would replace the major sponsorships, but leave reduced or no funding for the less popular events. On this basis, it projected a 25 to 75 percent reduction in sponsorship dollars, calculated to result in revenue losses of $27 to $80 million.

Among the affected U.S. sporting events, the auto racing industry receives the greatest amount of tobacco sponsorship revenues. The Barents Group relied on various editions of the *IEG Intelligence Reports* (IEG) to list these sponsorships. In reviewing the IEG data and other sources, FDA found that about $29 million worth of 1995 tobacco sponsorship revenues were designated for the National Association for Stock Car Auto Racing (NASCAR); [362] which amounted to about 8.3 percent of estimated NASCAR sponsorship revenues [363] and about 1.4 percent of estimated NASCAR total revenues. [364] The IEG data listed Indy Car tobacco sponsorships totaling only about $13 million, although these data did not cover all events.

As the majority of the NASCAR tobacco sponsorship revenues were directed to the Winston Cup or other lead series, FDA agrees that a major effect of the ban will be to decrease the price of sponsorships, permitting smaller sponsors to ''trade up'' to the more prestigious sponsorships left vacant by tobacco companies. Although new company sponsors will be attracted by the lower overall sponsorship costs, this ''ripple effect'' will impose shortfalls for some smaller or lower profile events. This economic impact will be somewhat mitigated, however, by the rapid growth in nontobacco sponsorships. According to IEG estimates, over the past year, motorsport sponsorship spending rose by about 17 percent [365] and total North American corporate sponsorship spending by about 15 percent. [366]

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[357] Burns, K., ''Driving Into the Future with New Technology,'' *Outdoor Advertising Magazine,* p. 5, January/February 1995.

[358] Wolfson, A., ''Canada's Ad Ban Puts Cigarettes Out of Sight,'' *The Courier-Journal,* pp. A1, A4, August 1, 1994.

[359] 56 FR 11661 (March 20, 1991).

[360] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, p. 18, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986, p. 24, 1995.

[361] EPM Communications, Inc. ''Entertainment Marketing Letter,'' February 1, 1996. Based on IEG Sponsorship Report.

[362] 1995 IEG Intelligence Report lists $26.7 million in tobacco sponsorships of NASCAR. Two tobacco-sponsored events did not list the sponsorship fees, which FDA estimates at about $1 million apiece.

[363] Koenig, B., ''NASCAR takes Lead in Race for Sponsors: Stock-car Racing Gains Corporate Funds as CART and IRL Lag in Money and Ratings'', *The Indianapolis Star,* March 8, 1996, *Business* p. F01.; MacCrae, M., ''Ricky Craven Collectibles Boost Intensive Fan Interest in Driver'', *Bangor Daily News,* May 2, 1996.

[364] Oliver, S., ''A Fan-Friendly Sport,'' *Forbes,* p. 70, July 3, 1995; Horovitz, B., ''Fine-Tuning an Image-New Sponsors Race to NASCAR,'' *USA Today,* Final Edition, p. 1B, April 5, 1996.

[365] MacCrae, M., ''Ricky Craven Collectibles Boost Intensive Fan Interest in Driver,'' *Bangor Daily News,* May 2, 1996.

[366] *IEG's Complete Guide to Sponsorship,* p. 3, 1995.

5. Retail Sector

In addition to incurring the economic costs described earlier, certain segments of the retail industry will experience adverse distributional impacts to the extent that they receive smaller promotional allowances (slotting fees) from manufacturers. In 1993, industry promotional allowances totaled $1.6 billion dollars. According to FTC:

Promotional allowances are designed to encourage wholesalers and retailers to stock and promote a company's products, including such things as trade allowances and slotting allowances. Trade allowances provide deals to cigarette wholesalers, dealers and merchants in the form of free goods or price reductions in return for the purchase of specific quantities of goods. Slotting allowances include fees that the cigarette manufacturers pay retailers to encourage them to carry a new product or to allocate premium shelf space to a product. Trade contests and incentives, training programs, and trade shows may also be counted as promotional allowances.

One major convenience store association, estimating that its members currently receive about $5,000 per store, remarked that convenience stores would ''bear a disproportionate burden should such allowances be eliminated as a result of the ban on self-service displays.'' Other retailers expressed similar concerns over the prohibition of self-service displays and promotional advertising, fearing it would lead to the elimination of these revenues.

The Barents Group argued that there were strong reasons to believe that promotional allowances would fall sharply as ''tobacco products are withdrawn to inaccessible areas of the store, [and] the products taking their place will offer lower allowances.'' While acknowledging that, ''[t]he possibility of promotional payments continuing may depend on whether the proposed regulations would allow the tobacco packages and cartons to be displayed from behind the check-out counter or from some other secured location in the stores,'' they nonetheless presented ''illustrative'' revenue reductions of from 25 to 50 percent and projected total revenue losses to the retail sector of $556 to $1,112 million. Using the higher percentage, their analysis implies that pretax profit margins would fall 12.4 percent for the average sized convenience store and even more for smaller stores. Moreover, they predicted that about 2 percent of currently profitable convenience stores would thereafter incur losses.

FDA suspects that many of these concerns are unwarranted as tobacco manufacturers will continue to place significant value on having their products situated in highly visible locations. Although desirable locations behind counters or in locked display cases will be more limited, there is little reason to believe that manufacturers would stop competing for the best display space available. One comment indicated that following a self-service ban in a local area of Northern California, some retailers:

* * * reported losses of tobacco industry-paid slotting fees * * * because of the removal of self-service promotional tobacco displays, racks and kiosks; * * * other retailers reported they did not loose [sic] tobacco industry-paid slotting fees if tobacco displays, racks or kiosks are relocated behind the counter or if they are replaced by locking cases * * * [There were] no reported losses of other tobacco industry-paid advertising fees, promotional allowances or other financial incentives paid to retailers for advertising, promoting and marketing tobacco products in their stores. [367]

Because of the regional aspects of this ban, it was a ''worst case'' situation for retail stores. If self-service displays were a prerequisite for promotional allowances, tobacco manufacturers would have quickly transferred them to other near-by localities, where self-service was permitted. The fact that this did not generally occur demonstrates that factors other than self-service displays can support manufacturer promotional payments to retailers.

Another comment noted that, ''[i]n at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves.'' In discussing the effects of the Canadian advertising ban, a Canadian study [368] suggested that, ''[i]n 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.'' Moreover, because FDA has not banned all point-of-purchase tobacco advertising, ''text only'' advertising at retail stores will be extremely important to tobacco product marketers.

In addition, alternative opportunities for point of purchase (POP) advertising have climbed briskly, as POP experts ''cite in-store advertising as the fastest growing segment of the media industry.'' [369] That same Northern California study expressly noted the ''[r]eplacement of self-service tobacco displays, racks and kiosks with * * * non-tobacco products such as candy, gum and soft drinks for which the retailer receives slotting fees from the manufacturers of these products.'' [370]

In sum, FDA cannot predict with certainty the direction of future payments by product manufacturers to retailers. The agency points out, however, that this rule would affect neither the trade allowances that are commonly paid to both wholesalers and retailers, nor the slotting allowances paid to retailers to encourage them to carry a new product or to assure the availability of a particular brand in a retail outlet. Further, while many current promotional activities will be prohibited, a substantial number will remain available. As the competitive pressures that drive promotional allowances are unlikely to abate, manufacturers will continue to compete vigorously through programs involving both ''text only'' promotions and select product placements.

6. Other Private Sectors

FDA is aware of several recent studies that address the contribution of tobacco to the U.S. economy; or alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related expenditures. The Tobacco Institute's Price Waterhouse report [371] purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. That

[367] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[368] ''When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products,'' Expert Panel Report, Prepared at the request of Health Canada, p. 140, March 1995.

[369] ''P-O-P Scores with Marketers,'' *Advertising Age*, p. 2, September 26, 1994.

[370] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[371] ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, October 1992.

report concluded that the induced or multiplier effects support 2.4 jobs for every 1 job in the core and supplier sectors combined, and over $3 in compensation for every $1 in the other two sectors. However, a review of that report, by Arthur Andersen Economic Consulting, explained that such multipliers lead to ''massive and unrealistic estimates.'' [372] That review further emphasized that ''money now being spent on tobacco would not disappear if demand for tobacco were to fall,'' though the Price Waterhouse report implicitly made that assumption. The Arthur Andersen review concluded that these multipliers ''provide no basis by themselves for predicting how many jobs would be lost by a reduction in tobacco spending.'' FDA strongly supports this latter view.

The American Economics Group (AEG), in a new study submitted by the Tobacco Institute, employed a national input-output model to project broad sectoral and regional estimates of ''the induced impact of the FDA proposed regulations nationwide.'' Applying the low and high illustrative costs estimated by the Barents Group, AEG predicted job losses of between 32,000 and 92,500. In addition to the printing and publishing industries, significant employment cutbacks were found for food, apparel and textiles, paper, metals, motor vehicles, and other miscellaneous manufacturers.

FDA is skeptical of the results of this AEG study. First, the input-output methodology employs an inherently static approach for estimating economic impacts. Indeed, the Barents Group, in its second report for the Tobacco Institute, explained that input-output models will not capture changing economic conditions, because they fail to account for changing market prices. Thus, ''the input-output approach fails to measure the effects of reallocating displaced workers and resources to other parts of the economy.'' Furthermore, the AEG study suffers from the same fundamental problem as the earlier Price Waterhouse analysis: It assumes that all reduced industry revenues are lost to the economy. This methodology is simply inappropriate. Finally, the AEG study is based upon the illustrative cost estimates of the Barents Group. As described in detail above, these cost estimates are unreasonably high. Although some tobacco advertising may decrease, a significant portion will be redirected towards the remaining permissible promotional activities.

In a second report, the Barents Group presented the results of using its own cost estimates in a general equilibrium model to simulate the impacts of the estimated reductions in advertising and promotional spending on revenue and employment for 56 sectors of the U.S. economy. This model predicted 21,000 to 44,000 U.S. job losses, largely among wholesale and retail businesses, but also within advertising, printing, apparel and miscellaneous manufacturing industries. FDA finds, however, that this study also is subject to several serious deficiencies. In particular, the Barents Group relies on its own illustrative cost estimates as model inputs. As noted above, FDA believes these estimates are far too high. Next, the study focuses solely on those industry sectors predicted to lose jobs, while ignoring those sectors expected to gain jobs. In fact, the study explicitly acknowledges that the underlying model assumes that:

> the aggregate level of employment is not changed in the long run as a result of implementing the new regulations. In other words, though particular jobs in particular industries are expected to disappear permanently, the number of man-hours worked per year in the economy as a whole is assumed not to change in the long run
> * * *

The Barents Group selectively shows changes in revenue and employment for the losers only.

Other analysts concluded that such models should not be used to assess longer term national economic impacts, because resources diverted from one use would be reallocated to the production of other goods and services. As one economist explained ''[i]f the focus is longer term, involving a period of, say, more than 2 years, then the induced effect should not be included in the measure because money not spent in one industry would find another outlet with equal (undistinguishable) induced effects.'' [373]

Some comments addressed regional issues, pointing to the importance of tobacco products to the economies of several states. Comments noted, for example, that about 177,000 North Carolinians were employed by tobacco and that Price Waterhouse estimated that the economic activity of these workers supported total State employment of 260,000. FDA is aware that tobacco growing states will experience some adverse economic effects. Nevertheless, as discussed above, the agency finds that the income and employment impacts associated with reduced tobacco consumption will be extremely gradual. Moreover, reduced tobacco consumption will minimally affect or even boost the economies of nontobacco states. For example, a recent economic simulation of the regional impacts of spending on tobacco products by Warner, et al., found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment); whereas the nontobacco regions of the United States would gain 56,300 jobs. [374] That study concluded that ''[t]he primary concern about tobacco should be the enormity of its toll on health and not its impact on employment.''

7. Excise Tax Revenues

The rule will decrease State and Federal tobacco tax revenues as fewer youths will become addicted to tobacco products. These excise tax losses will increase as more youths become nonsmoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled $6.2 billion for the year ending June 30, 1993. [375] As State excise taxes on other tobacco products (including smokeless tobacco) are reported at $226 million, FDA assumes that the value of all State excise taxes affected by this regulation is about $6.4 billion annually. Federal excise taxes on cigarettes totaled $5.5 billion for the year ending June 30, 1993. Federal excise taxes on smokeless tobacco are expected to be about $27 million, according to the Smokeless Tobacco Council. As described above, FDA estimates that compliance will reduce tobacco product sales by a gradually increasing rate over time; tobacco sales will fall by 0.5 percent in the 1st year, 1.9 percent in the 5th year, and 3.7 percent in the 10th year. Thus, the rule will decrease State excise taxes on affected tobacco products by from $30 million in the 1st year to $231 million in the 10th year and Federal tobacco

[372] ''A Review of the Price Waterhouse Economic Impact Report and Tobacco Institute Estimates of 'Economic Losses from Increasing the Federal Excise Tax','' Arthur Andersen Economic Consulting, p. 93, October 6, 1993.

[373] Gray, H. P., and I. Walter, ''The Economic Contribution of the Tobacco Industry,'' in *Smoking and Society: Toward a More Balanced Assessment*, edited by R. D. Tollison, Lexington Books, p. 248, 1986.

[374] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, ''Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States,'' *JAMA*, April 24, 1996.

[375] The Tobacco Institute, ''The Tax Burden on Tobacco,'' vol. 28, p. 4, 1993.

taxes by from $25 million in the 1st year to $196 million in the 10th year.

Since tobacco taxes represented less than 1 percent of total revenues on both the State and Federal level in 1992,[376] even the estimated tenth year impact measures only 0.03 percent of all State tax revenues and less than 0.02 percent of all Federal revenues. Nonetheless, if necessary, governments could raise tobacco product excise rates to offset these revenue losses. A full evaluation of the fiscal consequences, however, would involve a variety of public health ramifications. For example, State Medicaid programs will benefit from reduced tobacco-related medical care expenditures, but will need to finance additional nursing home expenditures associated with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a rule will have a significant economic impact on a substantial number of small entities. Analyses in this section, as well as in other sections of this preamble, constitute the agency's compliance with this requirement. According to the Regulatory Flexibility Act, the final regulatory flexibility analysis must contain ''a succinct statement of the need for, and objectives of, the rule.'' Section XV.B. of this document explains that the need for action stems from the enormous toll on the public health that is directly attributable to the consumption of tobacco by children and adolescents under the age of 18. As described, the primary objective of the regulation is to achieve the ''Healthy People 2000'' goal of reducing by one-half the number of youngsters who use tobacco.

The final regulatory flexibility analysis must also provide ''a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.'' The analyses presented previously in this section addressed the first two of these elements.

With respect to the changes made in the proposed rule as a result of public comments, the agency has reconsidered several of its earlier decisions, at least partly due to their projected effect on small businesses. The preamble above describes these changes and presents the agency's rationale for each modification. For example, the proposed regulation banned all vending machine sales of tobacco products. In response to public comment, the final regulation exempts from the ban those vending machines in ''adult only'' locations. FDA does not know how many small businesses will be able to take advantage of this exemption, but it will maintain at least one line of sales for small vending machine operators without jeopardizing the protection of young people.

In addition, the proposed regulation prohibited direct mail-order sales of tobacco products. The public comments, however, indicated that many adults, especially those who are elderly or who have limited mobility, would be substantially inconvenienced and several small businesses would be adversely affected by this ban. Even more importantly, studies suggest that teenagers purchase cigarettes from vending machines or retail merchants rather than from nonretail channels. FDA took these considerations into account and the final regulation does not prohibit mail-order sales of cigarettes.

The final regulatory flexibility analysis must also include ''a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.'' U.S. Census data for 1993 indicate that most cigarette manufacturers are large businesses, with only 4 employing fewer than 500 employees.[377] The small business size standard established by the U.S. Small Business Administration (SBA) for this industry is 1,000 employees.[378] The Federal Trade Commission (FTC) provided a list of 52 cigarette importers and small cigarette manufacturers filing plans with that agency, but could not distinguish manufacturers from importers.[379] The 1993 Census data show that 14 of the 20 firms manufacturing chewing and smoking tobacco employ fewer than 500 employees, the SBA size standard for this sector.[380] Also, most of the nation's 124,000 tobacco farms are small; almost 99 percent of the farms growing tobacco in 1992 had total farm sales under the SBA small business size standard of $500,000, and almost 91 percent had total farm sales under $50,000.[381] Further, 1993 Census data show that 1,332 of 1,365 tobacco wholesale trade firms (98 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA.[382] As noted above, the effect of the regulation on tobacco manufacturing, growing, and wholesale trade operations will be very gradual, taking over 10 years to reach a 4 percent reduction.

The regulation will affect numerous retail establishments, including food stores, small general merchandise stores, small tobacco stores and small gasoline stations. Table 15 displays the relative share of the tobacco market for the major types of tobacco-dispensing outlets with payroll in 1992. As shown, food stores and service stations received about 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 7 percent of the total sales of many of these establishments. Table 16 indicates that the great majority of all retail outlets in these sectors are small businesses.

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[376] U.S. Department of Commerce, *Statistical Abstract of the United States 1994*, 114th edition, No. 464, p. 298, 1994.

[377] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 68.

[378] U.S. Small Business Administration, ''Table of Size Standards,'' March 1, 1996.

[379] Federal Trade Commission, ''Cigarette Importers and Small Manufacturers Plans Filed, May 26, 1993–October 14, 1994.''

[380] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 69.

[381] 1992 Census of Agriculture, U.S., vol. 1, excerpts from pp. 109–110, 125–126.

[382] Special Census Tabulation prepared by U. S. Bureau of Census for U.S. Small Business Administration, Table 3—United States.

TABLE 15.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1992
(Establishments with Payroll Only)

Establishment Type	Tobacco Sales		% of Total Sales	
	($ Mils)	(%)	Establish-ments Handling Tobacco	All Estab-lishments
All	**30,559**	**100**	4.5	2.9
Food Stores	16,132	52	4.5	4.4
Service Stations	7,136	23	7.1	5.3
Drug and Proprietary	2,235	7	3.7	2.9
General Merchandise	3,182	10	2.4	1.3
Liquor Stores	1,045	3	8.0	5.1
Eating and Drinking	219	1	3.0	0.1
Tobacco Stores & Stands	610	2	78.1	78.1

Source: 1992 Census of Retail Trade, Merchandise Line Sales

TABLE 16.—NUMBER OF SMALL RETAIL BUSINESSES

Establishment Type	Firms With Payroll		Establishments Without Payroll
	Total	Small[1]	
All	588,505	473,668	275,432
Food Stores	127,575	104,541[2]	97,061
Service Stations	62,585	53,288[3]	14,248
Drug and Proprietary	28,606	25,396	3,031
General Merchandise	10,264	8,176	28,010
Liquor Stores	26,565	22,859	8,811
Eating and Drinking	331,703	258,381	124,271
Tobacco Stores & Stands	1,207	1,027	n.a.

[1] Assumes Small Business Administration size standard of $20 million in annual sales for food stores, $6.5 million for service stations and $5 million for all others.
[2] Due to data limitations, includes firms with annual sales up to $25 million.
[3] Due to data limitations, includes firms with annual sales up to $10 million.
Source: 1992 Census of Retail Trade, Establishment and Firm Size, 1992 Census of Retail Trade, Summary.

To illustrate the effects of this proposal on a typical small retail store, FDA separately utilized Census data to estimate that the average-sized convenience store sells 177 packages of tobacco products daily, of which about 25 might be purchased by young adults aged 18 to 26.[383] Based on the cost assumptions described previously, the outlet's first year costs would total about $400, with the largest single cost, $199, the labor cost for checking identification. For those stores that already verify the age of young customers of tobacco products, the additional costs fall to $137.

This estimate does not account for the possible reduction in promotional allowances, as FDA believes that competitive pressures will continue to lead manufacturers to rely on promotional allowances to compete for the best shelf space available for their products. Because FDA rejected the idea of prohibiting any visible display of tobacco products, retailers can retain slotting fees by choosing to display tobacco products either behind counters or in transparent locked display cases. Nevertheless, some small establishments might experience reduced promotional payments following a ban on self-service marketing.

Census data for 1992 indicate that almost 4,000 of 4,800 merchandising machine operator businesses (83 percent) reported annual receipts below the SBA size standard of $5 million.[384] One trade association noted that almost three quarters of all vending machine operators had annual sales of less than $1 million.[385] As explained earlier, prohibiting all cigarette vending machines would initially reduce the revenues of vending machine operators by an average of 2.8 percent. Because only about one-half of the merchandising machine establishments sell cigarettes, some businesses specializing in cigarette sales would experience greater revenue declines; although this effect will be moderated to the extent that cigarette vending machines are placed in areas restricted to adults, which would not be prohibited by the final rule.

The rule would also affect the distribution of specialty items showing a tobacco product logo or name. Industry comments do not provide precise data on the size distribution of these firms, but as noted above, the Specialty Advertising Association International indicates that 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below $2 million. While the marketplace in which these firms traditionally compete demands a quick response to shifting consumer trends, this rule would have at least short-term impact on some small firms.

FDA has received no data that would allow it to estimate the number of small firms that are currently involved with some aspect of tobacco advertising or the fraction of these firms that will be affected. In 1992, 861 of 904 year-round outdoor advertising firms (95 percent) reported sales revenues of less than the SBA size standard of $5 million.[386] The impact of this rule, however, is difficult to assess without knowing how the tobacco industry will alter its advertising strategies. Indeed, one of the largest outdoor advertising firms recently decided to reject all tobacco business, potentially increasing sales to the smaller firms.[387]

The regulation restricts tobacco advertising to ''text only'' in magazines with youth readership above the regulatory threshold. Of the identified 101 magazines with tobacco ads in 1994, 79 were published by large firms (over 500 employees). Less than 3 percent of the total revenue of the remaining 22 publications (which include, Inc., Rolling Stone and Penthouse) was derived from tobacco ads.[388] It is likely, moreover, that many of these magazines could avoid the ''text only'' restriction for tobacco advertising by demonstrating a low youth readership.

The regulation will also affect a substantial number of small race tracks, although FDA does not know how many small tracks currently receive significant revenues from tobacco sponsors. As discussed previously, some small operations will likely lose promotional revenues from tobacco companies, but the sport is growing rapidly and other product manufacturers should make up a substantial part of the shortfall.

The final regulatory flexibility analysis must include ''a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.'' A full description of the requirements and classes of affected small entities has been provided earlier in this section and a quantitative review of the paperwork burdens imposed by the rule is provided in section XVI. of this document. No special professional skills will be required to prepare the reports or records required by the regulation.

The final regulatory flexibility analysis must also include ''a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.''

The earlier sections of this document provide a full explanation of the agency's basis for selecting each provision of the final rule. In each instance, FDA evaluated the implications of each reasonable regulatory alternative and selected only those requirements that were absolutely necessary to satisfy the agency's statutory goals. As described, FDA found that its objectives for reducing the use of tobacco by young people could not be achieved with a partial or one-dimensional approach, but required a comprehensive set of regulatory restrictions. Thus, the final set of selected provisions reflect a careful examination of the relevant facts presented to the rulemaking record, the agency's objective of curtailing the use of tobacco by youngsters without creating unnecessary economic burdens, and a full assessment of the agency's legal authorities. Because the rejected alternatives would either provide less protection of public health, or achieve

[383] Based on data form the 1994 SGR, p. 85, and the ''Tobacco Situation and Outlook Report'' April, 1995, p. 4, FDA estimates that smokers aged 18 to 26 account for about 10 percent of all cigarettes smoked. Alternatively, data from the Statistical Abstract, tables 16 and 218, show that smokers aged 18 to 26 comprise 18 percent of all smokers. FDA used the midpoint of the 10 to 18 percent range to avoid underestimating the cost to small retailers. In addition, data from the 1996 Census of Retail Trade, Subject Series-Merchandise Line Sales, pp. 3–9 on the number of convenience stores with payroll and their total tobacco sales, and the average price per pack, were used to estimate the average number of packs sold daily at convenience stores to smokers aged 18 to 26.

[384] 1992 Census of Retail Trade, ''Establishment and Firm Size,'' Table 4 p. 1–99.

[385] ''1993: Industry Posts Best Growth in Four Years,'' *Automatic Merchandiser*, p. A2, August 1994.

[386] 1992 Census of Service Industries, pp. 1-145 and 1-195.

[387] Collins, G., ''Major Advertising Company to Bar Billboard Ads for Tobacco,'' *New York Times*, A15, May 3, 1996.

[388] *1996 Directory of Corporate Affiliations U.S. Private Companies*, New Providence, NJ; Reed Elsevier, Inc.; ''Company Profiles'' database, Information Access Co., Foster City, CA.

only minimal improvements at unwarranted cost, the agency found that the approach selected for the final rule best fit its statutory mandate.

As noted, earlier sections of the preamble fully describe the agency's rationale for selecting each provision of the final rule and for rejecting each alternative approach. Although many alternatives were considered, specific exemptions based solely on business size were not adopted, because FDA believes that children would too frequently exploit such opportunities. Unlike certain other regulations where restrictions on large firms alone might be acceptable, tobacco products are purchased easily from small, as well as large firms. An exemption for small retailers, for instance, would shift underage sales to those locations, lessening or eliminating the benefits of the remaining access restrictions. The following discussion summarizes the agency's consideration of several other regulatory alternatives.

G. Other Alternatives

One regulatory alternative would have banned all tobacco advertising; or alternatively, all tobacco advertising in selected media, such as all written publications, or all outdoor billboards. FDA rejected this approach in order to focus on those media and aspects of advertising that children are routinely exposed to and that have the greatest effect on youngsters. For example, the final rule permits black and white ''text only'' tobacco advertising in all written publications and color and imagery in magazines with fewer than 2 million youthful readers if youth constitute less than 15 percent of the publication's readership. Billboards are permitted to show black and white ''text only'' ads if located at least 1,000 feet from schools or public playgrounds. Thus, the rule leaves the informational aspects of advertising largely untouched.

Another suggested alternative was to combat underage tobacco use by relying on either voluntary compliance or on better enforcement of laws prohibiting sales to minors. As discussed earlier in this document, the tobacco industry's voluntary advertising code has failed to stop illegal sales to underage buyers. FDA agrees that these approaches can be partially effective, but finds that they inadequately counter the appeal of tobacco products for young people that is created by advertising and promotions. Thus, the agency concludes that there is no less burdensome alternative for achieving its goals that would exclude appropriately tailored restrictions on tobacco advertising.

One alternative considered by the agency was a far more prescriptive monitoring requirement for tobacco manufacturers. Under this rule, each manufacturer of tobacco products would have been required to adopt a system for monitoring the sales and distributions of retail establishments. These monitoring systems were to: (1) Include signed written agreements with each retailer, (2) contain adequate organizational structure and personnel to monitor the labeling, advertising, and sale of tobacco products at each retail distribution point, and (3) establish, implement, and maintain procedures for receiving and investigating reports regarding any improper labeling, advertising, or distribution. The additional costs for this monitoring were estimated at about $85 million per year. FDA rejected this alternative, because it decided that the industry might employ its resources more efficiently if permitted to choose among alternative compliance modes.

Another suggested alternative would have required package inserts containing educational information in cigarette and smokeless tobacco. FDA had incomplete data to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, tentatively projected one-time costs of about $490 million and annual operating costs of about $54 million. This alternative was not selected because the agency was not certain that the benefits of this provision would justify the compliance costs.

FDA also considered setting the permissible age for purchase at 19 rather than 18, because many 18-year-old adolescents are still in high school and can easily purchase tobacco products for younger classmates. This alternative would have added costs of about $34 million annually, mostly due to lost producer profits. The final regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

H. Unfunded Mandates Reform Act of 1995

On the basis of the preceding discussion, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives as discussed in section XV.G. of this document and determined that the current rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule.

XVI. Paperwork Reduction Act of 1995

The 1995 proposed rule would have collected information from manufacturers, distributors, and retailers of cigarettes and smokeless tobacco. Proposed § 897.24 would have required such persons to use established names for cigarettes and smokeless tobacco. Proposed § 897.29 would have required manufacturers to establish and maintain educational programs. Proposed § 897.32 would have required manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising. Proposed § 897.40 would have required manufacturers to submit labels, labeling, and advertising to FDA.

The preamble to the 1995 proposed rule, in discussing the Paperwork Reduction Act, also invited comments on four questions: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden (60 FR 41314 at 41356).

A. Comments on the Paperwork Reduction Act Statement

A small number of comments, primarily from a trade association representing cigarette manufacturers and from distributors, addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA's figures were incorrect or that the rule would duplicate existing reporting requirements. Few comments provided any figures or evidence to justify using different estimates.

(1) One comment, submitted by a trade association representing major cigarette manufacturers, said FDA's Paperwork Reduction Act statement underestimated the paperwork burden due to the exclusion of burden on retailers. The comment asserted that FDA did not explain how it calculated the number of respondents and burden hours for these sections and that the absence of an explanation made it difficult to assess the agency's estimate.

The comment explained that the agency's Paperwork Reduction Act estimate said there would be 200,000 respondents for proposed § 897.40, but that the agency's analysis of impacts estimated that 700,000 retail stores sell tobacco products. The comment also asserted that the average burden per response, under proposed §§ 897.32 and 897.40, should be 1 hour instead of 20 minutes. Thus, the comment concluded that if all 700,000 outlets spend only 60 minutes annually to comply with all recordkeeping requirements, at a cost of $10 per hour, retailers, alone, would spend 700,000 hours and $7 million to comply with the recordkeeping requirements in §§ 897.32 and 897.40.

The agency believes that the comment misinterprets the figures in the proposed rule's Paperwork Reduction Act statement. To begin with, the comment mistakenly equates the Paperwork Reduction Act statement's reference to ''annual number of responses'' with the annual numbers of people or firms that might be affected. The annual number of responses simply refers to the annual number of things, whether those things are pieces of labeling, labels, advertisements, or other items, that the agency might receive under that particular regulatory requirement. So, for example, if the agency expected to receive only 500 labels, the ''annual number of responses'' would be 500, regardless of whether the number of firms who might be affected by the rule was greater or less than 500.

Focusing on §§ 897.32 and 897.40 (the provisions cited by the comment), proposed § 897.32 would have established specific format and content requirements for labeling and advertising. For example, proposed § 897.32(a) would have required labeling and advertising to use only black text on a white background; the only exception would be advertising appearing in ''adult'' periodicals. Proposed § 897.32(b) would have required advertising to carry the product's established name and a statement of intended use, and specified those names and the statement of intended use. Proposed § 897.32(c) would have required advertising to carry a specific brief statement. The agency believed that these proposed requirements and specific statements were so precise that manufacturers, distributors, or retailers could determine their regulatory obligations quickly. For example, it should be quite simple to determine whether an advertisement uses black text on a white background.

Proposed § 897.40(a) would have required manufacturers to provide copies of labels, labeling, and a representative sampling of advertising to FDA. This, too, would not appear to be an extremely time-consuming task, particularly when the rule permits manufacturers to provide a representative sampling of advertising.

To estimate the time required to comply with proposed §§ 897.32 and 897.40, the agency tried to examine other large-scale labeling and reporting programs. FDA found that one Federal department conducts a large-scale labeling program that receives approximately 200,000 labels annually and that each label requires a maximum of 20 minutes to review. Consequently, the 1995 proposed rule adopted the 200,000 figure as the estimated number of responses. In the absence of better data, the proposed rule assigned the maximum review time (20 minutes) to its estimates for average burden per response.

FDA, however, has revised the 200,000 figure and now estimates that approximately 25,000 pieces of labeling or advertising will be affected by § 897.32. (The agency has deleted § 897.40 from the rule in favor of other, preexisting regulations.) As described in greater detail elsewhere in this document, the agency derived these figures by using advertising expenditures by the cigarette and smokeless tobacco industries and by the pharmaceutical industry, applying the ratio of such expenditures against the 25,000 pieces of advertising that the agency receives from the pharmaceutical industry, and projecting that printed advertisements may increase due to the rule's effect on promotional activities. Consequently, FDA now estimates that 25,000 pieces of labeling and advertising will be affected.

Thus, the agency does not agree that the estimated number of responses should be 700,000 or more because the response rate is not determined by the number of retailers. However, because the comment estimated that firms would require 1 hour to comply, the agency will use the 1 hour figure and has adjusted its paperwork estimates accordingly.

(2) The same comment also asserted that FDA's recordkeeping estimate was incorrect for manufacturers. The comment stated that FDA did not explain how it calculated the burden hour response for manufacturers under proposed § 897.40 and asserted that manufacturers would need 40 hours to document compliance with the educational program requirements in proposed § 897.29 alone. The comment estimated that the recordkeeping costs for the manufacturers' educational programs would be $25 per hour, for a total cost between $55 and 57 million annually. The comment explained that the costs may be even higher because highly skilled persons would be needed to comply with the rule.

The comment misinterprets the agency's Paperwork Reduction Act burden estimate. For § 897.29, FDA estimated that 1,000 hours would be needed to comply with the educational program requirements; this estimate included all functions related to the development of an educational program, including recordkeeping. Section 897.40(b), would have required manufacturers, distributors, and retailers to make records (including records on a manufacturer's educational program efforts) available to FDA on inspection. Because the estimate for proposed § 897.29 included time spent on recordkeeping associated with the educational program, the agency's estimates for proposed § 897.40 properly excluded time spent on maintaining educational program records. Otherwise, this time would have been counted twice. In any event, the comment is moot because FDA has deleted § 897.29 and § 897.40 from the final rule.

(3) FDA received several comments from distributors, claiming that the 1995 proposed rule would result in substantial paperwork and provide duplicative information. The comments stated that the device listing provisions of part 807 require each medical device wholesaler to prepare and file reports of all regulated products. If each brand and package style of cigarettes and smokeless tobacco are considered a separate device, this would substantially increase paperwork and duplicative reporting.

The comment correctly notes that part 807, as currently written, requires distributors to register and list devices (21 CFR 807.20). However, FDA has amended part 807 to exempt distributors of cigarettes and smokeless tobacco. Thus, distributors do not have to comply with part 807, nor do they have to comply with § 897.40 because FDA has deleted § 897.40 from the final rule.

(4) Several comments, primarily from small businesses and convenience stores, said that the 1995 proposed rule would have no impact and that adding paperwork would not curb underage smoking.

The agency disagrees with the comments. The final rule restricts young people's access to cigarettes and smokeless tobacco and reduces their appeal to young people. FDA believes that the final rule, in conjunction with State and local government efforts, will prevent large numbers of young people from using or experimenting with these products. Yet, insofar as any information collection burden is concerned, FDA points out that the rule's paperwork requirements are a function of the act and are being imposed to further the purposes of the act and of this final rule, not in any attempt to curb underage smoking by simply adding paperwork for paperwork's sake.

(5) One comment said that FDA could reduce the information collection burden in proposed § 897.29 (the educational program) by requiring manufacturers to contribute to an educational fund that an independent agency, such as FDA, CDC, or NIH, could use. The comment said that this would create a positive incentive for companies to change their marketing practices and would reduce the need for extensive recordkeeping and regulatory oversight of manufacturers.

The agency has deleted the educational program provision from the final rule. Consequently, the information collection burden associated with proposed § 897.29 no longer exists.

(6) In response to comments, FDA has amended the final rule to include a medical device reporting requirement for manufacturers and distributors at §§ 803.19 and 804.25. For manufacturers, these reports are limited to adverse events (resulting from product contamination, a change in ingredient or in any manufacturing process, or serious adverse events that are not well-known or well-documented by the scientific community. For distributors, these reports are limited to adverse events related to contamination. FDA estimates that it will receive 50 reports and each report will require 8 hours to prepare. The agency has amended the information collection burden to reflect these changes to the rule.

(7) FDA has also revised the information collection figures for § 897.24 which requires an established name on labels. The revision changes the number of respondents from 1,000 to 2,000 to reflect the agency's position that there are 1,000 varieties of cigarettes and smokeless tobacco products and that each variety has 2 labels, thus resulting in 2,000 affected labels.

(8) FDA has also revised the information collection figures for § 897.32 to account for the survey evidence that is needed to establish that a magazine, newspaper, or other periodical is an ''adult'' publication that is exempt from the requirement of black text on a white background. The agency estimates that such surveys will result in a capital cost of $2 million, with annual costs of $1 million. FDA estimates that 31 recordkeepers would be affected at a total burden hour figure of 100,000 hours.

B. Information Collection Provisions in the Final Rule

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with the estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents.

Description: The final rule requires the collection of information regarding cigarettes and smokeless tobacco. The final rule requires manufacturers, importers, and distributors to report certain adverse events to FDA and requires manufacturers to use established names for cigarettes and smokeless tobacco. The final rule also requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations.

Description of Respondents: Businesses.

Table 17.—Estimated Annual Reporting and Disclosure Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
803.19	49	1	49	8	392	21,000	13,680
804.25	1	1	1	8	8	231,000	35,220
897.24	2,000	1	2,000	40	80,000	17,000,000	0
897.30	1	1	1	1	1	0	0
897.32	25,000	1	25,000	1	25,000	0	0
Total Burden					105,401	17,250,000	48,900

TABLE 18.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
897.32	31	1	31	3,226	100,000	2,000,000	1,000,000
Total Burden					100,000	2,000,000	1,000,000

The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the Federal Register of October 16, 1995, 60 FR 53560). As discussed previously, the revised burden hour estimates in the final rule are based partially on comments received.

The information collection provisions in the proposed rule were approved under OMB no. 0910–0312. Because of changes made since the proposed rule, FDA has submitted the information collection provisions of the final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

XVII. Congressional Review

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121). FDA is submitting the information and reports as required by that statute.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 804, 807, and 820 are amended and a new part 897 is added as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.126 is added to subpart D to read as follows:

§ 801.126 Exemptions for cigarettes and smokeless tobacco.

Cigarettes and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

4. Section 803.19 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 803.19 Exemptions, variances, and alternative reporting requirements.

* * * * *

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

5. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

6. Section 804.25 is amended by adding a new paragraph (c) to read as follows:

§ 804.25 Reports by distributors.

* * * * *

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

7. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

8. Section 807.65 is amended by adding a new paragraph (j) to read as follows:

§ 807.65 Exemptions for device establishments.

* * * * *

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

9. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

10. Section 820.1 is amended by adding and reserving new paragraph (e) and adding new paragraph (f) to read as follows:

§ 820.1 Scope.

* * * * *

(e) [Reserved]

(f) This part does not apply to distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

11. New part 897 is added to read as follows:

PART 897—CIGARETTES AND SMOKELESS TOBACCO

Subpart A—General Provisions

Sec.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

Authority: Secs. 502, 510, 518, 519, 520, 701, 704, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393).

Subpart A—General Provisions

§ 897.1 Scope.

(a) This part 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.

(b) The 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.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part 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.

§ 897.3 Definitions.

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means 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. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) *Package* means 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.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open 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; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product 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.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other ''impersonal'' modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C—Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: ''Cigarettes'', ''Cigarette Tobacco'', ''Loose Leaf Chewing Tobacco'', ''Plug Chewing Tobacco'', ''Twist Chewing Tobacco'', ''Moist Snuff'', or ''Dry Snuff'', whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: ''Nicotine-Delivery Device for Persons 18 or Older''.

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD–40), rm. 17B–20, Rockville, MD 20857.

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

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self- service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: ''Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older'', ''Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older'', or ''Loose Leaf Chewing Tobacco'', ''Plug Chewing Tobacco'', ''Twist Chewing Tobacco'', ''Moist Snuff'' or ''Dry Snuff'', whichever is appropriate for the product, followed by the words ''A Nicotine-Delivery Device for Persons 18 or Older''.

§ 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other then cigarettes or smokeless tobacco) to any person

purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Dated: August 22, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

NOTE: The following Annex will not appear in the Code of Federal Regulations.

BILLING CODE 4160–01–F