representative to visit a retail outlet and the type of promotional activities permitted. For instance, the ban on selfservice displays may cause manufacturers' representatives to spend less time conducting display inspections. Thus, FDA suspects that the above cost estimate may be high.

c. *Training.* Each manufacturer's representative would have to receive training on the requirements of the regulation and the new monitoring responsibilities of their position. FDA estimates that this training could be accomplished in about 8 hours. Thus, assuming that the 7,300 estimate for the number of manufacturers' representatives adequately accounts for normal employee turnover, the annual training costs would total about \$1 million.

d. *Label changes.* The proposed regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA has estimated the compliance costs for printing new labels in the event that new labels would be needed.

Approximately 933 varieties of cigarettes are currently produced in the United States.³⁴ FDA does not have information on the number of smokeless tobacco varieties, but has assumed that the total number of cigarette and smokeless tobacco varieties is 1,000. FDA also assumes that most varieties of cigarettes are packaged in both single packs and cartons, but that each variety of smokeless tobacco is packaged in only one type of package. Consequently, the total number of labels was calculated as: 933 cigarette varieties $\times 2$ package types per variety (individual packs and cartons) + 67 smokeless tobacco varieties = 1,933 package types.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach used information compiled by The Research Triangle Institute (RTI) in its report to FDA on the cost of changing food labels.35 RTI reported a cost of about \$700 for a 1-color change in a lithographic printing process. FDA multiplied this figure by 4 to account for a 2 color change on the actual warning labels and an additional 2 colors for modifications to the existing label to make room for the warning label. This calculation yielded incremental printing costs of about \$2,800 per label, or \$5,412,400 for all 1,933 varieties of affected tobacco products. Adjusting this figure downward by RTI's methodology to account for the current frequency of label redesign predicts that the total one-time cost of completing these label changes within a 1-year

compliance period would be approximately \$4 million.

The second approach was to use cost information provided in the regulatory impact analysis of a roughly comparable Canadian regulation.³⁶ The Canadian Government estimated a cost of \$30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are sold in two sizes and about 20 percent are also sold in flip top packages.³⁷ Canadian labels, however, are typically printed using a gravure method; which, according to RTI, is about 3.5 times as expensive as the lithography process used in the United States. Adjusting the Canadian estimate upward, to account for the larger number of cigarette and smokeless tobacco varieties; and downward, for the smaller number of packages per variety and the smaller cost of the lithography printing process, provides a \$17 million estimate for the total cost of these label changes.

e. Self-service ban. The proposed regulation would ban the use of selfservice displays by requiring vendors to physically provide the regulated tobacco product to all purchasers. An estimated one-time cost of \$22.5 million for effecting this change is derived below in section VIII.D.3. Although any new behind-the-counter shelving or locking cases must be located at the retail level, the prevailing business practice is for tobacco manufacturers' sales representatives to assist and even pay for this equipment.³⁸ Since FDA cannot know if manufacturers would continue this practice, this study assumes that manufacturers and retailers would share these costs equally by apportioning \$11 million to each.

f. *Educational program.* The proposed regulation requires manufacturers of both cigarettes and smokeless tobacco products to fund consumer educational programs. FDA estimates that the requirements of this provision equate to a total cost of about \$150 million annually for cigarette and smokeless tobacco product manufacturers.

g. Restricted advertising/promotion. The determination of the industry costs attributable to the proposed restrictions on tobacco product advertising is complex. While there is no doubt that individual companies realize enhanced goodwill asset values from advertising programs, the industry has long held that advertising prompts brandswitching, but does not increase aggregate sales. Of course, if this were true, advertising would be unprofitable from the standpoint of the industry as a whole and reduced levels would increase rather than decrease aggregate industry profits. FDA does not accept

industry's stated views on this issue, particularly with respect to the impact of advertising and promotional programs on youth. Nevertheless, FDA does not consider it appropriate to count as a societal cost the voluntary reduction in the consumption of tobacco products that would result from reduced advertising outlays. Although industry sales would fall, consumer dollars no longer used on tobacco products would be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales and profits would not be societal costs, but rather distributional effects, as discussed below under that heading. Moreover, as shown in that section, any short-term frictional or relocation impacts would be significantly moderated by the gradual phase-in of the economic effects. As there are different views regarding the appropriate methodology for assessing these advertising consequences, FDA asks for public comment on the correct approach.

h. Producer surplus. Although voluntary decreases in the sale of tobacco products would not impose substantial long-term societal costs, mandatory restraints on the access of consumers to desired products would imply economic costs. Economists typically measure inefficiencies attributable to product bans by calculating lost "producers' surplus," which is a technical term for describing the difference between the amount a producer is paid for each unit of a good and the minimum amount the producer would accept to supply each unit, or the area between the price and supply curve. Data from Cummings et al. indicate that youngsters under the age of 18 consume 318 million packs of cigarettes per year, leading to industry profits of \$117 million.³⁹ On the assumption that the proposed regulation would reduce teenage smoking by onehalf, these profits would fall by about \$58 million. However, since most of this profit is derived from illegal sales to youths, FDA has not counted this figure as a societal cost.

2. Outcome-Based Activities

FDA plans to propose additional requirements that would become effective only if the rule's outcomebased objectives are not met. To avoid these consequences, manufacturers may decide it is in their best interest to initiate or to increase their support of programs that discourage underage purchasing of tobacco products.

Alternative activities. Tobacco manufacturers may decide to actively support the achievement of the