companies. FDA could determine which messages would be appropriate in consultation with other entities and offices within the Department of Health and Human Services, such as CDC's Office on Smoking and Health; with other federal agencies with expertise in consumer behavior and marketing, such as the Federal Trade Commission; and with consultants and contractors who are expert in communications theory and practice. FDA, in consultation with other federal agencies and other experts, could review the messages to ensure that their language and imagery are effective with 12- to 17-year olds. Each message would be evaluated to determine if it were designed to influence those beliefs and attitudes of 12- to 17- year olds that are most likely to affect the initial decision to smoke (or to start using smokeless tobacco products), the decision to continue smoking (or continue to use smokeless tobacco products), and/or the decision to quit. Examples of appropriate messages include those addressing addiction, weight control, effective ways to refuse a cigarette and other social influences that are related to youth smoking.

Moreover, an appropriate educational program could require each manufacturer to submit, on a quarterly basis, analyses of every television buy by time period on network television (referred to as "day part"), cable, and other media, prepared and executed by the party or parties responsible for the advertising. This requirement could fulfill the manufacturer's responsibility to report on the effectiveness of the program.

In addition, each manufacturer could conduct tracking studies of persons between the ages of 12 and 17. This would enable the manufacturers to determine how effective their educational programs and buys were. The studies could be performed twice per year and would need to meet recognized industry standards for tracking studies, such as measuring recall and recognition of the televised messages. These studies could be given to FDA, which could review the results of the industry's testing in consultation with other experts as needed, in order to help the agency refine its selection criteria for messages.

Finally, the remaining 20 percent of the messages could be placed in other media, with emphasis on radio and outdoor advertising. Consideration should be given to ensuring that these messages appear in media that are heavily used by young people.

Under proposed § 897.29, each manufacturer would devote an amount

of money to the corrective educational program proportionate to its share of the total advertising and promotional expenditures of the cigarette and smokeless tobacco industry. Thus, a company whose expenditures equal 40 percent of total industry expenditures would be required to allocate an amount equal to 40 percent of the total monies required. The agency calculated the amount of money that would be allocated to the initial corrective educational program by looking at the period of time when the Fairness Doctrine was in effect. It was estimated that, at that time, approximately \$75 million a year in air time was provided by broadcasters for anti-smoking messages, which translates to \$290 million in 1994 dollars. In order to ensure an effective program, the agency is proposing that approximately half that amount, or \$150 million a year, be allocated initially. Under this proposal, the agency could determine each manufacturer's proportionate share of the overall advertising and promotional expenditures of the cigarette or smokeless tobacco industry by referring to the most recent figures reported to the FTC under the Cigarette Act or the Smokeless Act. This provision is intended to ensure that the corrective educational programs are adequately funded in proportion to each manufacturer's overall reported advertising and promotion expenses.

D. Subpart D—Labeling and Advertising

1. Introduction

Proposed subpart D would establish certain requirements for cigarette and smokeless tobacco product labeling (excluding product labels) and advertising pursuant to sections 520(e), 502(q), and 502(r) of the act. The proposal would apply similar requirements to labeling and advertising in print media because both are used to convey information about the product; to promote consumer awareness interest, and desire; to change or shape consumer attitudes and images about the product; and/or to promote good will for the product. Therefore, FDA has decided to place the labeling provisions with the advertising requirements rather than place the labeling provisions with those pertaining to product labels.

Regulating cigarette and smokeless tobacco product labeling and advertising is essential to decrease young people's use of tobacco products. Proposed subpart D would preserve the informational component of labeling and advertising while decreasing their appeal to children and adolescents.

Briefly, the proposed regulations would require that advertising in any publication with a youth readership of more than 15 percent (youth being defined as under 18) or more than 2 million children and adolescents under 18 be limited to a text-only format in black and white. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Pursuant to section 502(r), the proposed regulations would require that cigarette advertising contain a statement of the product's established name, intended use, and a brief statement regarding relevant warnings, precautions, side effects, and contradictions. In addition, brand identifiable non-tobacco items, such as hats and tee shirts, and brand identifiable sponsorship of events, such as the Virginia Slims Tennis Tournament or a sponsored event using a tobacco product logo or symbol, would be prohibited.

Section 201(m) of the act (21 U.S.C. 321(m)) defines "labeling" as "all labels and other written, printed, or graphic matter" that are on an article or its containers or wrappers, or "accompanying such article." In interpreting the phrase "accompanying such article," the Supreme Court has held that it is not necessary for the labeling to physically accompany the product (see Kordel v. United States, 338 U.S. 345, 350 (1948)). Thus, labeling includes traditional promotional items, such as booklets, calendars, movies, etc., and also less obvious types of labeling, such as clocks, coffee mugs, desktop toys, and even tee shirts.94 FDA would, therefore, consider non-tobacco items distributed by cigarette and smokeless tobacco companies with the product's brand name or product identification printed on them (e.g., tee shirts, hats, pens, golf tees) to be "labeling," and these would be prohibited.

Subpart D is based, in part, on the recommendations of major U.S. and world health organizations and on current efforts by other countries to reduce tobacco use. These organizations and countries support advertising restrictions as an essential part of any comprehensive program to reduce or eliminate smoking by young people. The American Medical Association, American Heart Association, American Cancer Society, American Lung Association, American Academy of Family Physicians, the World Health Assembly, and the World Health Organization have recommended restrictions on advertising and promotion including a total ban of all promotional and advertising activities.95