the mail-order card to verify, for example, that he/she is 21. The agency concludes that proposed § 897.16(c) would significantly reduce access to cigarettes and smokeless tobacco products by persons younger than 18. The ban of mail-order sales is recommended by the IOM ⁶⁷ and Philip Morris recently announced that it would discontinue mail-order sales in order to reduce access to young people. ⁶⁸

d. Free samples. Proposed § 897.16(d) would prohibit manufacturers, distributors, and retailers from distributing free samples of tobacco products. The agency is proposing this restriction because many young people, including elementary school children, receive free samples.69 Free samples are often distributed at "mass intercept locations" such as street corners and shopping malls, and events such as music festivals, rock concerts, and baseball games. They have been distributed at zoos, at bars and restaurants where entertainers perform and promote the product, and through the mail.70 Free samples give young people a "risk-free and cost-free way to satisfy their curiosity" about tobacco products and, when distributed at cultural or social events, may increase social pressure on young people to accept and use the free samples.71

For smokeless tobacco products, distribution of free samples to young people has been a foundation of the growth strategy of the UST (makers of Skoal, Copenhagen, Happy Days, and other smokeless tobacco products). ⁷² In 1992 and 1993, the smokeless tobacco industry spent nearly \$16 million annually on the distribution of free samples. The industry's largest expenditure in 1993 was on coupons and retail value-added articles to encourage trial use (\$32 million). ⁷³

Despite industry-imposed age restrictions on the distribution of samples, underage persons are able to obtain samples either by lying about their age or by enlisting older friends and relatives to obtain samples for them.⁷⁴ The lure of free samples can also be quite attractive; one advertising campaign offering a sample pack of Skoal Bandits reportedly generated 400,000 responses in a 3-month period.⁷⁵

Even elementary school children are able to obtain free cigarette samples easily. One survey examined five schools in Chicago and a sample of students at DePaul University. Four percent of the elementary school students reported receiving free samples of cigarettes themselves. Nearly half of the elementary and high school students and one-quarter of the college students

"* * reported having seen free cigarettes given to children and adolescents." ⁷⁶ In another survey, one-third of approximately 500 New Jersey high school students who were current or former smokers reported receiving free cigarette samples before the age of 16.⁷⁷

The distribution of free samples to minors occurs despite the industry's voluntary code against distributing cigarettes to persons under the age of 21. The recent IOM report noted several problems with the industry's voluntary code, stating that "distribution to minors appears to be nearly inevitable." 78 While the voluntary code instructs employees distributing samples to ask for identification and ask other questions if they suspect a potential recipient to be under age, distribution of samples to minors occurs anyway because the samplers are often placed in crowded places and constrained by time:

There is a significant time constraint in asking for proof of age from all young-looking individuals who solicit samples, not to mention the time required for the myriad of other questions which samplers are instructed to ask. Samplers are often surrounded on all sides by those soliciting samples and a dozen or more outstretched arms waiting (or grabbing) for samples * * * those passing out samples are usually quite young themselves. These youthful distributors may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group. 79

Consequently, the ineffectiveness of the industry's voluntary code and the fact that State laws that ban or restrict the distribution of free samples are rarely enforced led IOM to recommend prohibiting distribution of free samples in public places and through the mail.⁸⁰ The National Cancer Institute reached a similar conclusion in 1991, and stated, "The offer of free cigarettes and smokeless tobacco products is reminiscent of the drug pusher who gives the first sample free to get his customer hooked." ⁸¹ The proposed rule is consistent with IOM's and NCI's recommendations.

C. Subpart C—Labels and Educational Programs

Proposed subpart C would provide the established name for cigarettes and smokeless tobacco products that is required by sections 502 of the act. In addition, it would require that cigarette and smokeless tobacco manufacturers fund a national program including educational messages in order to undo the effects of young people's near constant exposure to pro-tobacco

messages and, thus, to discourage young people from using cigarettes and smokeless tobacco products, pursuant to sections 201, 502, and 520(e) of the act.

1. Section 897.24—Established Names for Cigarettes and Smokeless Tobacco Products

Proposed § 897.24 would provide the "established name" for cigarettes, cigarette tobacco, and smokeless tobacco products. This provision is intended to implement section 502(e)(2) of the act, which states that a device shall be deemed misbranded if its label fails to display the established name for the device "in type at least half as large as that used thereon for any proprietary name or designation for such device. Section 502(e)(4) of the act, in turn, explains that the "established name" for a device is the applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), the official title in a compendium if the device is recognized in an official compendium but has no official name, or "any common or usual name of such device.

In this case, no official names have been designated under section 508 of the act, and no compendium provides an established name for these products. Consequently, proposed § 897.24 would consider "cigarettes," "cigarette tobacco," and the common or usual names for smokeless tobacco products (such as "moist snuff" or "loose leaf chewing tobacco") as established names.

2. Section 897.29–Educational Programs Concerning Cigarettes and Smokeless Tobacco Products

The Surgeon General's 1994 Report suggested that "a nationwide, well-funded antismoking campaign could effectively counter the effects of cigarette advertising in its currently permitted media forms." 82 IOM also recommended that "counter-tobacco advertisements should be intensified to reverse the image appeal of pro-tobacco messages, especially those that appeal to children and youths." 83

FDA's proposal is consistent with the Surgeon General's and IOM's findings. Proposed 897.29 would require each manufacturer to establish and maintain a national public educational program, including major reliance on television messages, to combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products.

FDA based proposed 897.29, in part, on historical experience. From July 1, 1967 to December 31, 1970, the Federal Communications Commission, as part of