project is funded through the National Institute on Drug Abuse. The survey utilizes both a cross-sectional and a longitudinal design, with selfadministered surveys in a sample of selected schools. Data for daily smoking by 12th graders have been collected annually since 1976. Smokeless data for any use within past 30 days are available for the years 1986 to 1989 and 1992 to 1994 for 12th graders. (Twelfth graders are a suitable surrogate for the upper age of the prohibited smoking age because twelth graders are 17-18 years old.) The MTFP is one of the more consistent and complete data sets available on young people and provides a stable and reliable basis for measuring the proposed reductions. FDA is requesting comment on the appropriateness of using this data set, including whether the methodology used by MTFP is appropriate for this purpose or on whether other measures would be more reliable and enforceable.

FDA derived its outcome-based objectives from the "Healthy People 2000" objectives. "Healthy People 2000" discusses national health promotion and disease prevention objectives in this country. This report was facilitated by IOM of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments. The report was the product of eight regional hearings and testimony from more than 750 individuals and organizations. Contributors included the CDC, the National Institutes of Health, the American Academy of Pediatrics, the American Heart Association, the American Medical Association, the American Cancer Society, the American Lung Association, the Blue Cross and Blue Shield Association, the American College of Physicians, and the Federation of American Societies for Experimental Biology

Recognizing that reducing cigarette smoking by youth is an important national priority, the "Healthy People 2000" report established a basic goal for the year 2000 to reduce by half the initiation of cigarette smoking by children and youth and to reduce by 39.4 and 55.1 percent the use of smokeless tobacco by young men.

The "Healthy People 2000" objectives for cigarettes required the smoking prevalence among young people (ages 20 to 24) to be cut in half in 13 years—from 30 percent in 1987 to 15 percent by the year 2000. The proposed regulation takes as its premise the type of outcome established in "Healthy People 2000." However, because the

time frame is different, the proposed regulation would use data as it measures actual usage by high school seniors, a group closer in age to the relevant age group. The prevalence of daily cigarette smoking among high school seniors was 19.4 percent in 1994. Calculating from 1994, daily smoking prevalence among high school seniors must be reduced by half to 9.7 percent seven years after date of the final publication of the rule. Any major changes in the methodology of this survey would require a reassessment of the objective in light of the influences of the changes on the survey's prevalence estimates.

survey's prevalence estimates. The "Healthy People 2000" smokeless tobacco goals are to reduce use in 12- to 17-year-old males by 39.4 percent in 12 years—from 6.6 percent in 1988 to 4.0 percent in the year 2000 and for 18- to 24-year-old males by 55.1 percent—from 8.9 percent in 1987 to 4.0 percent by the year 2000. The proposed rule also modifies the "Health People 2000" reflecting the different time frame. The objectives also will use data for the nation's high school seniors to monitor progress in reducing the prevalence of smokeless tobacco use. Since high school seniors are 17- to 18-years-old, the percent reduction for high school seniors should be about midway between that required for males 12- to 17-years-old (i.e., 39.4 percent) and 18to 24-years-old (i.e., 55.1 percent). Thus, a 50 percent reduction would be required to be in compliance with this proposed regulation. Smokeless tobacco use rates (once in 30 days) for senior high school boys was 20.3 percent in 1994. Therefore, the goal would be 10.2 percent. (Failure to reach these objectives would justify the imposition of additional regulatory requirements on the sale, distribution, and use of cigarettes and smokeless tobacco products. Recognizing that smokeless tobacco use by young girls is not extensive (2.6 percent in 1994), the agency believes that an additional goal might be considered—that smokeless tobacco use by young females not increase. This goal would help prevent the development of a new market for smokeless tobacco products.

While the agency finds that the proposed rule is a comprehensive approach that should prove effective in regulating these products, it recognizes that additional measures might be necessary because many different factors may affect a young person's decision to start smoking or use smokeless tobacco products.

Additionally, the tobacco industry has shown its ability to find new outlets for promoting its products when restrictions are imposed; for example,

within a relatively short period of time after the federally imposed electronic media ban became effective, the cigarette industry redirected the funds spent on television and radio advertising to traditional print and outdoor media. Over time, more nontraditional forms of advertising emerged, including using non-tobacco items (e.g., tee shirts and hats) that served as "walking billboards," placing products in movies, creating massive lists of smokers to target by direct mail, publishing magazines with articles as well as advertising, creating "friendly familiarity" and good will for tobacco products by sponsoring sporting and artistic events and by having its sponsored events appear on television (in spite of the television advertising ban).243 In addition, in Canada, the cigarette companies evaded a ban on sponsorship in the name of a brand variety (but not in the company's corporate name), by creating corporate identities for relevant brands. These new corporations could then legally sponsor events.244

Therefore, to guard against this possibility, and to provide for an additional incentive for the companies to take appropriate actions, the agency is proposing that one or more additional measures would be imposed in the event that the outcome-base objectives provided in proposed § 897.44 are not achieved.

At the time a final rule is published, FDA intends to propose specific additional measures. The agency invites public comment on what regulatory measures(s) should be considered. The agency reiterates that additional measures would become operational only if the outcome-based objectives are not achieved.

Finally, the agency requests comment on what would be the appropriate schedule for implementing the provisions of the final rule. It is likely that the final rule would contain some provisions that could not be complied with immediately following the date that the final rule becomes effective. FDA is seeking comment on, and information about, such matters as size of inventories, manufacturing practices, retooling, useful life of equipment, and other similar business considerations. The agency will take the information provided on these issues into account when it established the implementation schedule for the final rule.

F. Other Amendments

The proposed rule would also make two minor amendments to existing regulations. The proposal would exempt cigarettes and smokeless tobacco