proposed § 897.36 is meant to be illustrative rather than exhaustive. There may be other ways in which labeling or advertising would be "false or misleading." For example, advertising or labeling that stated that a study showed that smoking can cure emphysema would be false and misleading.

The agency's regulations concerning prescription drug advertising provide great specificity as to what constitutes violative advertising, 21 CFR part 202. The agency has decided that this same degree of specificity is not practical in the case of a widely used consumer product. Tobacco advertising contains an unlimited variety of claims that make categorization difficult. Therefore, the agency has tentatively concluded that it will provide general guidance for the types of advertising claims that will be considered violative, rather than to attempt to identify every possible type of false and misleading claim.

## E. Subpart E—Miscellaneous Requirements

Proposed subpart E would consist of three provisions. These provisions would provide record and report requirements, describe the rule's relationship to state and local laws, and require additional measures if the prevalence of tobacco use is not dramatically reduced within seven years of the date the final rule is published.

## 1. Section 897.40—Records and Reports

Proposed § 897.40 would address reports and records. In brief, proposed §897.40(a) would require each manufacturer to submit to FDA copies of all labels and labeling, and a representative sample of its advertising for enforcement purposes. The proposal would also permit a manufacturer to submit a representative sample of its labels if they would be similar for multiple packages or products. Proposed § 897.40(a) would direct manufacturers to send information and reports to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20857, with each section plainly marked, i.e., "Labels," or "Labeling and Advertising," whichever is appropriate.
This provision is the minimum

This provision is the minimum required by section 510(j) of the act (21 U.S.C. 360(j)), which requires submission to FDA of labels, labeling, and a representative sample of advertising for restricted devices. As explained elsewhere in this document, the agency intends to regulate cigarettes and smokeless tobacco products as restricted devices rather than as drug products, but will assign all of such products to the Center for Drug

Evaluation and Research (CDER). Thus, proposed §897.40(a) reflects the statutory requirement in section 510(j) and would direct copies of labels to the Documents and Records Section in CDER. Proposed § 897.40(b) would authorize FDA employees to inspect records, particularly for purposes of review, copying, or any other use related to the enforcement of the act. This requirement is similar to the inspection authority under the medical device tracking regulations at 21 CFR 821.50 and implements the agency's inspection authority contained in section 704 of the act.

## 2. Section 897.42—State and Local Requirements

Proposed § 897.42 would address preemption of State and local requirements. Section 521(a) of the act (21 U.S.C. 360k(a)) states that:

\* \* \* no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act. Proposed § 897.42(a) would require manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, or advertising of cigarettes and smokeless tobacco products provided that the State or local requirement does not conflict with FDA regulations. These more stringent state requirements would, therefore, be part of the regulatory scheme and would not be preempted. For example, the proposal would not preempt a State law raising the minimum age for purchasing cigarettes to 21 or prohibiting cigarette or smokeless tobacco product advertisements on billboards located near schools.

FDA is aware that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco products, and the agency encourages future activity in these areas. Moreover, because the proposed rule addresses only the sale, distribution, labeling, and advertising of cigarettes and smokeless tobacco products, State and local requirements in other areas are not affected. For example, the proposal clearly would not preempt State laws regarding licensing, taxes, or smoking in public areas.

If a State or local government is uncertain whether section 521(a) of the act preempts a particular law or regulation, proposed § 897.42(b) would permit the State or local government to easily and expeditiously request and receive an advisory opinion from FDA. Regulations governing applications for exemptions from Federal preemption of State and local requirements applicable to devices can be found at 21 CFR part 808.

FDA is aware of several recent court decisions construing section 521 of the act to preempt certain common law tort actions with respect to medical device products. FDA does not believe that section 521 should be read to give any preemptive effect to these proposed regulatory requirements over tort actions with respect to tobacco products. FDA specifically invites comment on this issue.

## 3. Additional Regulatory Measures

FDA is also proposing that additional provisions aimed at further reducing the appeal of tobacco advertising and thus discouraging young people from using cigarettes or smokeless tobacco products be required if, seven years from the date the final rule is published, FDA finds that the percentage of young people under the age of 18 who smoke, or the percentage of young men who use smokeless tobacco, has not decreased roughly by 50 percent. This goal could be measured using data of national tobacco use rates of children and adolescents. One method would be:

1. For cigarette manufacturers, the percentage of daily cigarette smokers among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program such as the Monitoring the Future Project (MTFP) for both the reference (1994) and target years (seven years from the date of the publication of the final rule); or

2. For smokeless tobacco product manufacturers, the percentage of male regular smokeless tobacco product users (any use in the past 30 days) among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program for both the reference (1994) and target years (seven years from the date of the publication of the final rule) and the percentage of female regular smokeless tobacco product users among 12th graders is no greater than it was in 1994 as measured in both the reference (1994) and target years.

The Institute for Social Research at the University of Michigan collects and maintains the data from the MTFP. The