game of chance to any person purchasing cigarettes or smokeless tobacco products in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event, in the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar or identical to those used for cigarettes or smokeless tobacco products. A manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation which manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence prior to January 1, 1995.

§ 897.36 False or misleading labeling and advertising.

Labeling or advertising of any cigarette or smokeless tobacco product is false or misleading if the labeling or advertising contains any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made for the product.

Subpart E—Miscellaneous Requirements

§897.40 Records and reports.

- (a) Each manufacturer shall, on an annual basis, submit:
- (1) Copies of all labels, except that a manufacturer may submit a representative sample of such labels if the labels will be similar for multiple packages or products; and
- (2) Copies of all labeling and a representative sampling of advertising.
- (b) The manufacturer shall send this information to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. The information

should be plainly marked as "Labels", or "Labeling and Advertising", whichever is appropriate.

(c) Manufacturers, distributors, and retailers shall, upon the presentation by an FDA representative of official credentials, make all records and other information collected under this part and all records and other information related to the events and persons identified in such records available to the FDA representative for purposes of inspection, review, copying, or any other use related to the enforcement of the Federal Food, Drug, and Cosmetic Act and this part.

§ 897.42 Preemption of State and local requirements and requests for advisory opinions.

- (a) General. In addition to the requirements imposed under this part, manufacturers, distributors, and retailers shall comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco products, provided that those State or local requirements do not conflict with the requirements under this part. These more stringent State or local requirements are not preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).
- (b) Requests for advisory opinions. (1) Any State or political subdivision of a State may request an advisory opinion from the Food and Drug Administration with respect to the preemptive effect of this part on any particular State or local requirement. The request for an advisory opinion should comply with the requirements at § 10.85 of this chapter. The agency may, in its discretion and after consulting the State or political subdivision, treat a request for an advisory opinion as an application for exemption from preemption under § 808.20 of this chapter.
- (2) The Commissioner, on his or her own initiative, may issue an advisory opinion relating to a State or local requirement if he or she finds that:

- (i) Section 521(a) of the Federal Food, Drug, and Cosmetic Act does not preempt a State or local requirement for which an application for exemption from preemption has been submitted under § 808.20 of this chapter because the State or local requirement is equal to or substantially equivalent to a requirement under the Federal Food, Drug, and Cosmetic Act, is not a requirement within the meaning of section 521(a) of the Federal Food, Drug, and Cosmetic Act, or is more stringent than and does not conflict with the requirements under this part, or
- (ii) Issuance of an advisory opinion is in the public interest.

§897.44 Additional regulatory measures.

Seven years after the publication date of any final rule based on the proposed rule published in the Federal Register on (date of publication of the final rule), if the percentage of people under the age of 18 years who smoke cigarettes has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and/or if the percentage of males under the age of 18 years who use smokeless tobacco products has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and the percentage of females under the age of 18 years who use smokeless tobacco products has increased since 1994 (as determined by an objective, scientifically valid, and generally accepted program), then the agency shall take additional measures to help achieve the reduction in the use of tobacco products by children and adolescents described above.

Dated: August 9, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services. [FR Doc. 95–20051 Filed 8–10–95; 8:45 am] BILLING CODE 4160–01–P