

(k) *Manufacturer* means any person who manufactures, produces, or processes any smokeless tobacco product.

(l) *Packager* means any person who puts any smokeless tobacco product into packages to be offered for sale, sold, or distributed to consumers.

(m) *Importer* means any person who puts any smokeless tobacco product that was not manufactured inside the United States into commerce to be offered for sale, sold, or distributed to consumers.

(n) *Utilitarian objects* means items, other than smokeless tobacco products, that are sold or given or caused to be sold or given by any manufacturer, packager or importer to consumers for their personal use and that display the brand name, logo, or selling message of any smokeless tobacco product. Such items include, but are not limited to, pens, pencils, clothing or sporting goods.

[51 FR 40015, Nov. 4, 1986, as amended at 56 FR 11662, Mar. 20, 1991]

#### GENERAL REQUIREMENTS

##### § 307.4 Prohibited acts.

(a) No manufacturer, packager, or importer of any smokeless tobacco product shall distribute, or cause to be distributed, in commerce any smokeless tobacco product in a package that, in accordance with the labeling requirements of the Act and these regulations, does not bear one of the following warning statements.

WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER

WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS

WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES

Each smokeless tobacco product shall upon being prepared for distribution in commerce for retail sale, but before it is distributed to be offered for retail sale, be labeled in accordance with the Act and regulations in this part. In the case of an importer, the label statements may be affixed in the country of origin or after importation into the United States, but shall be affixed before the smokeless tobacco product is removed from bond for sale or distribution. This section does not apply to

any smokeless tobacco product that is manufactured, packaged, or imported in the United States for export from the United States, if the product is not in fact distributed in commerce for use in the United States.

(b) No manufacturer, packager, or importer of any smokeless tobacco product shall advertise or cause to be advertised (other than through the use of billboard advertising) within the United States any smokeless tobacco product unless the advertising bears one of the warning statements as required by the Act and the regulations and set forth in § 307.4(a). This requirement is not applicable to company and divisional names, when used as such, to signs on factories, plants, warehouses, and other facilities related to the manufacturer or factory storage of smokeless tobacco, to corporate or financial reports, to communications to security holders and others who customarily receive copies of these communications, to employment advertising, to advertising in tobacco trade publications, or to promotional materials that are distributed to smokeless tobacco wholesalers, dealers, or merchants, but not to consumers. In addition, this requirement does not apply to shelf-talkers and similar product locators with a display area of 12 square inches or less.

(c) No manufacturer, packager, or importer shall fail to submit a plan to the Commission which specifies the method that will be used to rotate, display, and distribute the statements required by the Act and regulations in this part. The Commission shall approve a plan if the plan provides for the rotation, display, and distribution of the statements in a manner that complies with the Act and these regulations. Authority to approve plans submitted by smokeless tobacco manufacturers, packagers, and importers has been delegated by the Commission to the Associate Director for Advertising Practices. Where significant issues not previously considered by the Commission are present, however, those plans will be referred by the Associate Director for Advertising Practices to the Commission in the first instance. This delegation is authorized by section 1(a) of the Reorganization Plan No. 4 of 1961 in order to enhance the efficiency and

### § 307.5

result in expedited treatment of these plans. Pursuant to section 1(b) of the Reorganization Plan, the Commission will retain the discretionary right to review the actions of the delegate. Any smokeless tobacco manufacturer, packager, or importer may within 30 days of the delegate's action file with the Secretary of the Commission a request for full Commission review of the action. If no review is sought by petition of the submitter of a plan or any intervenor or upon the Commission's own initiative within 30 days of the action, or if a review is sought and denied in this 30 day period, the delegate's action shall be deemed to be the action of the Commission.

(d) A manufacturer, packager, or importer of smokeless tobacco products shall be deemed to be in compliance with the Act and these regulations if it has taken reasonable steps to:

(1) Provide, by written contract or other clear instructions, for the rotation of the label statements required by the Act;

(2) Give clear instructions and, if possible, furnish materials (such as film negatives, acetates, or other facsimiles) for the production of smokeless tobacco packages and advertising that contain the required warning statements; and

(3) Prevent and correct mistakes, errors, or omissions that have come to its attention.

In the event of the distribution of labels or the publication of advertisements that do not conform with the Act and these regulations, the burden of establishing that reasonable steps have been taken (including fulfilling the conditions described in paragraphs (d)(1) through (3) of this section) to comply shall rest with the manufacturer, packager, or importer of smokeless tobacco.

[51 FR 40015, Nov. 4, 1986, as amended at 56 FR 11662, Mar. 20, 1991]

### § 307.5 Language requirements.

The warning statement on the label of a smokeless tobacco product required by the Act and these regulations shall be set out in the English language. If the label of a smokeless tobacco product contains a required warning in a language other than

### 16 CFR Ch. I (1-1-06 Edition)

English, the required warning must also appear in English. In the case of an advertisement for a smokeless tobacco product in a newspaper, magazine, periodical, or other publication that is not in English, the warning statement shall appear in the predominant language of the publication in which the advertisement appears. In the case of any other advertisement, the warning statement shall appear in the same language as that principally used in the advertisement.

#### LABEL DISCLOSURES

### § 307.6 Requirements for disclosure on the label.

(a) In the case of the label of a smokeless tobacco package, the warning statement required by the Act and these regulations must be in a conspicuous and prominent place on the package. A conspicuous and prominent place is a part of a label that is likely to be displayed, presented, shown, or examined. For example, in the case of the following types of packages, the following places shall be deemed to be conspicuous and prominent.

Cylindrical can—Side of the package

Pouch—Front of the package, provided that, in the case of a pouch with two identical face panels, the front of the pouch is the face panel upon which the warning is printed

Rectangular box of snuff, plug of chewing tobacco, or dispenser of individual packages of smokeless tobacco that may be purchased in its entirety—Any side of the package, provided that the side panel used does not bear any written or graphic matter other than the background color of the side panel and reasonable extensions of graphic matter from other panels

However, in the case of any package of smokeless tobacco, absent special circumstances, the required warning statement shall not be deemed to be in a conspicuous and prominent place if it appears on the bottom (that is, the underside) of the package or is printed on the tear line or on any other surface where it will be obliterated when the package is opened. However, in the case of a rectangular package that is wrapped in a continuous sheet of foil or plastic with randomly appearing label information, the required warning shall be deemed to be in a conspicuous