

In this subpart, the term “article” means any substance or preparation in the manufacture of which denatured spirits are used, including the product obtained by further manufacture or by combination with other materials, if the article subjected to further manufacture or combination contained denatured spirits.

§ 20.132 General requirements.

(a) *Internal medicinal preparations and flavoring extracts*—(1) *Manufacture.* No person shall use denatured spirits in the manufacture of medicinal preparations or flavoring extracts for internal human use where any of the spirits remain in the finished product.

(2) *Sale.* No person shall sell or offer for sale for internal human use any medicinal preparations or flavoring extracts manufactured from denatured distilled spirits where any of the spirits remain in the finished product.

(3) *Labeling and advertising.* Labeling and advertising of articles shall not imply that the article is intended for or suitable for internal human use.

(b) *Beverage use.* No person shall sell or offer for sale any article containing denatured spirits for beverage purposes. Labeling and advertising of articles shall not imply that the article is intended for or suitable for use as a beverage.

(c) *Trafficking in articles.* The appropriate TTB officer may impose the requirements of § 20.133 on any person who reprocesses, rebottles, or repackages articles, deals in articles, or receives articles in containers exceeding one gallon.

§ 20.133 Registration of persons trafficking in articles.

(a) Upon written notice from the appropriate TTB officer, any person who reprocesses, rebottles, or repackages articles, deals in articles, or receives articles in containers exceeding one gallon may be required to submit any of the following:

- (1) Nature of activities to be conducted;
- (2) Name and address of supplier;
- (3) Size and type of containers in which articles will be received and, if applicable, rebottled or repackaged;

(4) Maximum quantity of each article to be obtained during any calendar month;

(5) Description of the reprocessing operation;

(6) Samples of the reprocessed article;

(7) Labels and advertising materials; and,

(8) Names and addresses of recipients of articles and quantities received;

(b) The appropriate TTB officer shall prohibit any of the activities described in paragraph (a) of this section if the activities pose a jeopardy to the revenue, or a burden in administering this part.

(Approved by the Office of Management and Budget under control number 1512-0336)

§ 20.134 Labeling.

(a) *General.* Except as provided in paragraph (b) or (c) of this section, each article shall, before removal from the manufacturer’s premises, have a label affixed to its immediate container identifying (1) the name, trade name or brand name of the article, and (2) the name and address (city and State) of the manufacturer or distributor of the article.

(b) *Articles for external human use.* Except as provided in paragraph (c) of this section, an article intended for external human use shall, before removal from the manufacturer’s premises, have a label affixed to its immediate container identifying the name, trade name or brand name of the article. If the volume of the article in the container exceeds 8-fluid ounces, the label shall also show the information required by paragraph (b) (1) or (2) of this section.

(1) If the article was packaged or bottled by the person who manufactured it, the label shall identify—

(i) The manufacturer’s name and the address (city and State) of the actual place or places where article was manufactured, or

(ii) The name and principal office address (city and State) of the manufacturer, and the permit number or numbers of the place or places of manufacture. However, in lieu of such permit number or numbers, the place or places where the manufacturing operation occurred may be indicated by a coding