

product'' (or vice versa) may do so by resubmitting the applicable formula(s) on TTB Form 5154.1. Requirements pertaining to unfinished nonbeverage products are found in § 17.185(c).

APPROVAL OF FORMULAS

§ 17.131 Formulas on TTB Form 5154.1.

Upon receipt, formulas on TTB Form 5154.1 shall be examined and, if found to be medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume which are unfit for beverage purposes and which otherwise meet the requirements of law and this part, they shall be approved for drawback. If the formulas do not meet the requirements of the law and regulations for drawback products, they shall be disapproved.

§ 17.132 U.S.P., N.F., and H.P.U.S. preparations.

(a) *General.* Except as otherwise provided by paragraph (b) of this section or by TTB ruling, formulas for compounds in which alcohol is a prescribed quantitative ingredient, which are stated in the current revisions or editions of the United States Pharmacopoeia (U.S.P.), the National Formulary (N.F.), or the Homeopathic Pharmacopoeia of the United States (H.P.U.S.), shall be considered as approved formulas and may be used as formulas for drawback products without the filing of TTB Form 5154.1.

(b) *Exceptions.* Alcohol (including dehydrated alcohol and dehydrated alcohol injection), U.S.P.; alcohol and dextrose injection, U.S.P.; and tincture of ginger, H.P.U.S., have been found to be fit for beverage use and are disapproved for drawback. All attenuations of other H.P.U.S. products diluted beyond one part in 10,000 ("4x") are also disapproved for drawback, unless the manufacturer receives approval for a formula submitted on Form 5154.1 in accordance with this subpart. The formula for such attenuations shall be submitted with a sample of the product and a statement explaining why it should be classified as unfit for beverage use.

§ 17.133 Food product formulas.

Formulas for nonbeverage food products on TTB Form 5154.1 may be approved if they are unfit for beverage purposes. Approval does not authorize manufacture or sale contrary to State law. Examples of food products that have been found to be unfit for beverage purposes are stated below:

(a) *Sauces or syrups.* Sauces, or syrups consisting of sugar solutions and distilled spirits, in which the alcohol content is not more than 12 percent by volume and the sugar content is not less than 60 grams per 100 cubic centimeters.

(b) *Brandied fruits.* Brandied fruits consisting of solidly packaged fruits, either whole or segmented, and distilled spirits products not exceeding the quantity and alcohol content necessary for flavoring and preserving. Generally, brandied fruits will be considered to have met these standards if the container is well filled, the alcohol in the liquid portion does not exceed 23 percent by volume, and the liquid portion does not exceed 45 percent of the volume of the container.

(c) *Candies.* Candies with alcoholic fillings, if the fillings meet the standards prescribed for sauces and syrups by paragraph (a) of this section.

(d) *Other food products.* Food products such as mincemeat, plum pudding, and fruit cake, where only sufficient distilled spirits are used for flavoring and preserving; and ice cream and ices where only sufficient spirits are used for flavoring purposes. Also food adjuncts, such as preservatives, emulsifying agents, and food colorings, that are unfit for beverage purposes and are manufactured and used, or sold for use, in food.

§ 17.134 Determination of unfitness for beverage purposes.

The appropriate TTB officer has responsibility for determining whether products are fit or unfit for beverage purposes within the meaning of 26 U.S.C. 5111. This determination may be based either on the content and description of the ingredients as shown on TTB Form 5154.1, or on organoleptic examination. In such examination, samples of products may be diluted