see §17.152(d).) If the formula is disapproved for drawback, the ingredient may be treated as an intermediate product in accordance with this part. Requirements pertaining to intermediate products are found in §17.185(b).

(c) If there is a change in the composition of an intermediate product, the manufacturer shall submit an amended or revised formula, as provided in §17.122.

§ 17.127 Self-manufactured ingredients treated optionally as unfinished nonbeverage products.

A self-manufactured ingredient made with taxpaid spirits, which otherwise would be treated as an intermediate product, may instead be treated as an unfinished nonbeverage product, if the ingredient's formula is fully expressed as a part of the approved formula for the nonbeverage product in which the ingredient will be used. A manufacturer desiring to change the treatment of an ingredient from ''intermediate product'' to ''unfinished nonbeverage 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 (''4×'') 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 with water to an alcoholic concentration of 15% and tasted. Sale or use for beverage purposes is indicative of fitness for beverage use.

[T.D. ATF–379, 61 FR 31412, June 20, 1996, as amended by T.D. TTB–79, 74 FR 37402, July 28, 2009]

§ 17.135 Use of specially denatured alcohol (S.D.A.).

(a) *Use of S.D.A. in nonbeverage or intermediate products*—(1) *General.* Except as provided in paragraph (b) of this section, the use of specially denatured alcohol (S.D.A.) and taxpaid spirits in the same product by a nonbeverage manufacturer is prohibited where drawback of tax is claimed.

(2) *Alternative formulations.* No formula for a product on TTB Form 5154.1 shall be approved for drawback under this subpart if the manufacturer also has on file an approved TTB Form 1479–A or Form 5150.19, Formula for Article Made With Specially Denatured Alcohol or Rum, pertaining to the same product.

(b) *Use of S.D.A. in ingredients*—(1) *Purchased ingredients.* Generally, purchased ingredients containing S.D.A. may be used in nonbeverage or intermediate products. However, such ingredients shall not be used in medicinal preparations or flavoring extracts intended for internal human use, where any of the S.D.A. remains in the finished product.

(2) *Self-manufactured ingredients.* Self-manufactured ingredients may be made with S.D.A. and used in nonbeverage or intermediate products, provided—

(i) No taxpaid spirits are used in manufacturing such ingredients; and

(ii) All S.D.A. is recovered or dissipated from such ingredients prior to their use in nonbeverage or intermediate products. (Recovery of S.D.A. shall be in accordance with subpart K of part 20 of this chapter; recovered S.D.A., with or without its original denaturants, shall not be reused in nonbeverage or intermediate products.)

(Sec. 201, Pub. L. 85–859, 72 Stat. 1372, as amended (26 U.S.C. 5273))

§ 17.136 Compliance with Food and Drug Administration requirements.

A product is not a medicine, medicinal preparation, food product, flavor, flavoring extract, or perfume for nonbeverage drawback if its formula would violate a ban or restriction of the U.S. Food and Drug Administration (FDA) pertaining to such products. If FDA bans or restricts the use of any ingredient in such a way that further manufacture of a product in accordance with its formula would violate the ban or restriction, then the manufacturer shall change the formula and resubmit it on TTB Form 5154.1 . This section does not preclude approval for products manufactured solely for export or for uses other than internal human consumption (e.g. tobacco flavors or animal feed flavors) in accordance with laws and regulations administered by FDA. Under §17.123, manufacturers may be required to demonstrate compliance with FDA requirements applicable to this section.

§ 17.137 Formulas disapproved for drawback.

A formula may be disapproved for drawback either because it does not prescribe appropriate ingredients in sufficient quantities to make the product unfit for beverage use, or because the product is neither a medicine, a medicinal preparation, a food product, a flavor, a flavoring extract, nor a perfume. The formula for a disapproved