

self-manufactured ingredient made with taxpaid spirits and intended for the manufacturer's own use in nonbeverage products, unless the formula for any such ingredient is fully expressed as part of the approved formula for each nonbeverage product in which that ingredient is used, or unless the formula for the ingredient is contained in one of the pharmaceutical publications listed in § 17.132.

(b) Upon receipt of Form 5154.1 covering a self-manufactured ingredient made with taxpaid spirits, the formula shall be examined under § 17.131. If the formula is approved for drawback, the ingredient shall be treated as a finished nonbeverage product for purposes of this part, rather than as an intermediate product, notwithstanding its use by the manufacturer. (For example, 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 ("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