

## § 17.122

### § 17.122 Amended or revised formulas.

Except as provided in this section, amended or revised formulas are considered to be new formulas and shall be numbered accordingly. Minor changes may be made to a current formula on TTB Form 5154.1 with retention of the original formula number, if approval is obtained from the appropriate TTB officer. In order to obtain approval to make a minor formula change, the person holding the Form 5154.1 shall submit a letter of application to the appropriate TTB officer, indicating the formula change and requesting that the proposed change be considered a minor change. Each such application shall clearly identify the original formula by number, date of approval, and name of product. The application shall indicate whether the product is, has been, or will be used in alcoholic beverages, and shall specify whether the proposed change is intended as a substitution or merely as an alternative for the original formula. No changes may be made to current formulas without specific TTB approval in each case.

[T.D. ATF-179, 61 FR 31412, June 20, 1996, as amended by T.D. ATF-436, 66 FR 5471, Jan. 19, 2001]

### § 17.123 Statement of process.

Any person claiming drawback under the regulations in this part may be required, at any time, to file a statement of process, in addition to that required by TTB Form 5154.1, as well as any other data necessary for consideration of the claim for drawback. When pertinent to consideration of the claim, submission of copies of the commercial labels used on the finished products may also be required.

### § 17.124 Samples.

Any person claiming drawback or submitting a formula for approval under the regulations in this part may be required, at any time, to submit a sample of each nonbeverage or intermediate product for analysis. If the product is manufactured with a mixture of oil or other ingredients, the composition of which is unknown to the claimant, a 1-ounce sample of the mixture shall be submitted with the

## 27 CFR Ch. I (4-1-08 Edition)

sample of finished product when so required.

### § 17.125 Adoption of formulas and processes.

(a) *Adoption of predecessor's formulas.* If there is a change in the proprietorship of a nonbeverage plant and the successor desires to use the predecessor's formulas at the same location, the successor may, in lieu of submitting new formulas in its own name, adopt any or all of the formulas of the predecessor by filing a notice of adoption with the appropriate TTB officer. The notice shall be filed with the first claim relating to any of the adopted formulas. The notice shall list, by name and serial number, all formulas to be adopted, and shall state that the products will be manufactured in accordance with the adopted formulas and processes. The notice shall be accompanied by a certified copy of the articles of incorporation or other document(s) necessary to prove the transfer of ownership. The manufacturer shall retain a copy of the notice with the related formulas.

(b) *Adoption of manufacturer's own formulas from a different location.* A manufacturer's own formulas may be adopted for use at another of the manufacturer's plants. Further, a wholly owned subsidiary may adopt the formulas of the parent company, and vice versa. A letterhead notice must be filed with the appropriate TTB officer and be accompanied by two photocopies of each formula to be adopted. The notice shall list the numbers of all formulas to be adopted and shall indicate the plant where each was originally approved and the plant(s) where each is to be adopted. Some evidence of the relationship between the plants involved in the adoption shall be attached to the notice. The notice shall be referenced in Part IV of the supporting data (TTB Form 5154.2) filed with the first claim relating to the adopted formula(s).

[T.D. ATF-179, 61 FR 31412, June 20, 1996, as amended by T.D. ATF-436, 66 FR 5471, Jan. 19, 2001]

### § 17.126 Formulas for intermediate products.

(a) The manufacturer shall submit a formula on TTB Form 5154.1 for each

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