§ 19.5 Manufacturing products unfit for beverage use.

(a) General. Except as provided in paragraph (b) of this section, apothecaries, pharmacists, or manufacturers who manufacture or compound any of the following products using tax paid or tax determined distilled spirits are not required to register and qualify as a distilled spirits plant (processor):

(1) Medicines, medicinal preparations, food products, flavors, flavoring extracts, and perfume, conforming to the standards for approval of nonbeverage drawback products found in §§17.131 through 17.137 of this chapter, whether or not drawback is actually claimed on those products. Except as provided in paragraph (c) of this section, a formula does not need to be submitted if drawback is not desired;

(2) Patented and proprietary medicines that are unfit for use for beverage purposes;

(3) Toilet, medicinal, and antiseptic preparations and solutions that are unfit for use for beverage purposes;

(4) Laboratory reagents, stains, and dyes that are unfit for use for beverage purposes; and

(5) Flavoring extracts, syrups, and concentrates that are unfit for use for beverage purposes.

(b) Exception for beverage products. Products identified in part 17 of this chapter as being fit for beverage use are alcoholic beverages. Bitters, patent medicines, and similar alcoholic preparations that are fit for beverage purposes, although held out as having certain medicinal properties, are also alcoholic beverages. These products are subject to the provisions of this part and must be manufactured on the bonded premises of a distilled spirits plant.

(c) Submission of formulas and samples. When requested by the appropriate TTB officer or when the manufacturer wishes to ascertain whether a product is unfit for beverage use, the manufacturer will submit the formula and a sample of the product to the appropriate TTB officer for examination. TTB will determine whether the product is unfit for beverage use and whether manufacture of the product is exempt from qualification requirements.

(d) Change of formula. If TTB finds that a product manufactured under paragraph (a) of this section is being used for beverage purposes, or for mixing with beverage spirits other than by a processor, TTB will notify the manufacturer to stop manufacturing the product until the formula is changed to make the product unfit for beverage use and the change is approved by the appropriate TTB officer. However, the provisions of this paragraph will not prohibit products which are unfit for beverage use from use in small quantities for flavoring drinks at the time of serving for immediate consumption.

(26 U.S.C. 5002, 5171)