§ 310.543 Drug products containing active ingredients offered over-the-counter (OTC) for human use in exocrine pancreatic insufficiency.

(a) Hemicellulase, pancreatin, and pancrelipase have been present as ingredients in exocrine pancreatic insufficiency drug products. Pancreatin and pancrelipase are composed of enzymes: amylase, trypsin (protease), and lipase. Significant differences have been shown in the bioavailability of marketed exocrine pancreatic insufficiency drug products produced by different manufacturers. These differences raise a potential for serious risk to patients using these drug products. The bioavailability of pancreatic enzymes is dependent on the process used to manufacture the drug products. Information on this process is not included in an OTC drug monograph. Therefore, the safe and effective use of these enzymes for treating exocrine pancreatic insufficiency cannot be regulated adequately by an OTC drug monograph. Information on the process is not included in an OTC drug monograph. Therefore, the safe and effective use of these enzymes for treating exocrine pancreatic insufficiency cannot be regulated adequately by an OTC drug monograph. Information on the product’s formulation, manufacture, quality control procedures, and final formulation effectiveness testing are necessary in an approved application to ensure that a company has the ability to manufacture a proper bioactive formulation. In addition, continuous physician monitoring of patients who take these drug products is a collateral measure necessary to the safe and effective use of these enzymes, causing such products to be available by prescription only.

(b) Any drug product that is labeled, represented, or promoted for OTC use in the treatment of exocrine pancreatic insufficiency is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act), for which an approved application under section 505 of the Act is required for marketing. In the absence of an approved application, such product is also misbranded under section 502 of the Act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use in the treatment of exocrine pancreatic insufficiency is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) After May 7, 1991, any such OTC drug product that contains hemicellulase initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(e) After October 24, 1995, any such OTC drug product that contains pancreatin or pancrelipase initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

§ 310.544 Drug products containing active ingredients offered over-the-counter (OTC) for use as a smoking deterrent.

(a) Any product that bears labeling claims that it “helps stop or reduce the cigarette urge,” “helps break the cigarette habit,” “helps stop or reduce smoking,” or similar claims is a smoking deterrent drug product. Cloves, coriander, eucalyptus oil, ginger (Jamaica), lemon oil (terpeneless), licorice root extract, lobeline (in the form of lobeline sulfate or natural lobelia alkaloids or Lobelia inflata herb), menthol, methyl salicylate, povidone-silver nitrate, quinine ascorbate, silver acetate, silver nitrate, and thymol have been present as ingredients in such drug products. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these or any other ingredients for OTC use as a smoking deterrent. Based on evidence currently available, any OTC drug product containing ingredients offered for use as a smoking deterrent cannot be generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, or promoted as a smoking deterrent is regarded as a new drug within the meaning of section...
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§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses:

(1) **Topical acne drug products.**

- Alcloxa
- Alkyl isoquinolinium bromide
- Aluminum chlorohydrex
- Aluminum hydroxide

Benzocaine
- Benzoic acid
- Boric acid
- Calcium polysulfide
- Calcium thiosulfate
- Camphor
- Chloroxylenol
- Cloxyquin
- Coal tar
- Dibenzothiophene
- Estrone
- Magnesium aluminum silicate
- Magnesium sulfate
- Phenol
- Phenolate sodium
- Phenyl salicylate
- Povidone-iodine
- Pyrrolidine maleate
- Resorcinol (as single ingredient)
- Resorcinol monoacetate (as single ingredient)
- Salicylic acid (over 2 up to 5 percent)
- Sodium borate
- Sodium thiosulfate
- Tetracaine hydrochloride
- Thymol
- Vitamin E
- Zinc oxide
- Zinc stearate
- Zinc sulfide

(2) **Anticaries drug products**—(i) Approved as of May 7, 1991.

- Hydrogen fluoride
- Sodium carbonate
- Sodium monofluorophosphate (6 percent rinse)
- Sodium phosphate

(ii) Approved as of October 7, 1996.

- Calcium sucrose phosphate
- Dicalcium phosphate dihydrate
- Disodium hydrogen phosphate
- Phosphoric acid
- Sodium dihydrogen phosphate
- Sodium dihydrogen phosphate monohydrate
- Sodium phosphate, dibasic anhydrous reagent

(3) **Antidiarrheal drug products**—(1) Approved as of May 7, 1991.

- Aluminum hydroxide
- Atropine sulfate
- Calcium carbonate
- Carboxymethylcellulose sodium
- Glycine
- Homatropine methylbromide
- Hyoscyamine sulfate
- Lactobacillus acidophilus
- Lactobacillus bulgaricus

2These ingredients are nonmonograph except when used to prepare acidulated phosphate fluoride treatment rinses identified in §355.10(a)(3) of this chapter.