

### § 310.536

### 21 CFR Ch. I (4–1–03 Edition)

marketing. In the absence of an approved new drug 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 as an oral wound healing agent 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 the effective date of the final regulation, any OTC drug product that is labeled, represented, or promoted for use as an oral wound healing agent may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application.

[51 FR 26114, July 18, 1986, as amended at 55 FR 11579, Mar. 29, 1990]

### § 310.536 Drug products containing active ingredients offered over-the-counter (OTC) for use as a nailbiting or thumbsucking deterrent.

(a) Denatonium benzoate and sucrose octaacetate have been present in OTC nailbiting and thumbsucking deterrent drug products. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these and any other ingredients (e.g., cayenne pepper) for OTC use as a nailbiting or thumbsucking deterrent. Based on evidence currently available, any OTC drug product containing ingredients offered for use as a nailbiting or thumbsucking deterrent cannot be generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, and promoted as a nailbiting or thumbsucking deterrent 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 or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug 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 as a nailbiting or thumbsucking deterrent 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 March 2, 1994, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

[58 FR 46754, Sept. 2, 1993]

### § 310.537 Drug products containing active ingredients offered over-the-counter (OTC) for oral administration for the treatment of fever blisters and cold sores.

(a) L-lysine (lysine, lysine hydrochloride), *Lactobacillus acidophilus*, and *Lactobacillus bulgaricus* have been present in orally administered OTC drug products to treat fever blisters and cold sores. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these or any other orally administered ingredients for OTC use to treat or relieve the symptoms or discomfort of fever blisters and cold sores. Based on evidence currently available, any OTC drug product for oral administration containing ingredients offered for use in treating or relieving the symptoms or discomfort of fever blisters and cold sores cannot be generally recognized as safe and effective.

(b) Any OTC drug product for oral administration that is labeled, represented, or promoted to treat or relieve the symptoms or discomfort of fever blisters and cold sores 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 and part 314 of this chapter 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 for oral administration labeled,