PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec. 346.1 Scope.
346.3 Definitions.

Subpart B—Active Ingredients

§ 346.10 Local anesthetic active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration or within the dose specified in this part and each general condition established in §330.1 of this chapter.

Subpart C—Labeling

§ 346.50 Labeling of anorectal drug products.

§ 346.52 Labeling of permitted combinations of anorectal active ingredients.


SOURCE: 55 FR 31779, Aug. 3, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 346.1 Scope.

(a) An over-the-counter anorectal drug product in a form suitable for external (topical) or intrarectal (rectal) administration is generally recognized as safe and effective and is not misbranded if it meets each condition in

(1) “Flammable [in bold type]: Keep away from fire or flame.”

(2) “Do not use [in bold type] in the eyes.”

(3) “Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.”

(4) “Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.”

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”:

optional, bullet] “apply 4 to 5 drops in each affected ear.”

[65 FR 48905, Aug. 10, 2000]