Food and Drug Administration, HHS

§ 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

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 this part and each general condition established in §330.1 of this chapter.

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

(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.”

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