Subpart A—General Provisions

§ 328.1 Scope.
Reference in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 328.3 Definitions.
As used in this part:
(a) Alcohol means the substance known as ethanol, ethyl alcohol, or Alcohol, USP.
(b) Inactive ingredient means any component of a product other than an active ingredient as defined in § 201.3(b)(7) of this chapter.

Subpart B—Ingredients

§ 328.10 Alcohol.

Subpart C—Labeling

§ 328.50 Principal display panel of all OTC drug products intended for oral ingestion that contain alcohol.

(a) The amount (percentage) of alcohol present in a product shall be stated in terms of percent volume of absolute alcohol at 60 °F (15.56 °C) in accordance with § 201.10(d)(2) of this chapter.

(b) A statement expressing the amount (percentage) of alcohol present in a product shall appear prominently and conspicuously on the “principal display panel,” as defined in § 201.60 of