PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec. 336.1 Scope.
336.3 Definition.

Subpart B—Active Ingredients

336.10 Antiemetic active ingredients.

Subpart C—Labeling

336.50 Labeling of antiemetic drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiemetic.”

(b) Indications. The labeling of the product states the following under the heading “Indications.” “For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings:”

(1) For products containing any ingredient identified in §336.10—(i) When labeled for use in adults and for those products that can be and are labeled for use in children under 12 years of age. “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(ii) For those products that can be and are labeled only for children under 12 years of age. “Do not give this product to children who have a breathing problem such as chronic bronchitis or who have glaucoma, without first consulting the child’s doctor.”

(2) For products containing cyclizine hydrochloride identified in §336.10(a). “Do not give to children under 6 years of age unless directed by a doctor.”

(3) For products containing dimenhydrinate identified in §336.10(b). “Do not give to children under 2 years of age unless directed by a doctor.”

(4) For products containing diphenhydramine hydrochloride identified in §336.10(c). “Do not give to children...