

motor vehicle or operating machinery.”

(7) *For products containing dimenhydrinate identified in § 336.10(b) or diphenhydramine hydrochloride identified in § 336.10(c).* “May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.”

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

(1) *For products containing cyclizine hydrochloride identified in § 336.10(a).* Adults and children 12 years of age and over: Oral dosage is 50 milligrams every 4 to 6 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(2) *For products containing dimenhydrinate identified in § 336.10(b).* Adults and children 12 years of age and over: Oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 400 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(3) *For products containing diphenhydramine hydrochloride identified in § 336.10(c).* Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor.

(4) *For products containing meclizine hydrochloride identified in § 336.10(d).* Adults and children 12 years of age and

over: Oral dosage is 25 to 50 milligrams once daily, or as directed by a doctor.

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

[52 FR 15892, Apr. 30, 1987, as amended at 53 FR 35809, Sept. 15, 1988; 59 FR 16982, Apr. 11, 1994]

§ 336.80 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indications.

(a) *For products containing cyclizine hydrochloride, dimenhydrinate, and diphenhydramine hydrochloride identified in § 336.10 (a), (b), and (c).* “For the treatment of vertigo of motion sickness.”

(b) *For products containing meclizine hydrochloride identified in § 336.10(d).* “For the treatment of vertigo.”

PART 338—NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

- Sec.
- 338.1 Scope.
- 338.3 Definition.

Subpart B—Active Ingredients

- 338.10 Nighttime sleep-aid active ingredients.

Subpart C—Labeling

- 338.50 Labeling of nighttime sleep-aid drug products.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 54 FR 6826, Feb. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 338.1 Scope.

(a) An over-the-counter nighttime sleep-aid drug product in a form suitable for oral 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.