§ 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.


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.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.
your doctor. Insomnia may be a symptom of serious underlying medical illness.''

(3) ‘‘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.’’

(4) ‘‘Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.’’

(5) ‘‘Do not use [bullet] \(^1\) with any other product containing diphenhydramine, even one used on skin’’.

(d) Directions. The labeling of the product contains the following information under the heading ‘‘Directions’’:

(1) For products containing diphenhydramine hydrochloride identified in § 338.10(a). Adults and children 12 years of age and over: Oral dosage is 50 milligrams at bedtime if needed, or as directed by a doctor.

(2) For products containing diphenhydramine citrate identified in § 338.10(b). Adults and children 12 years of age and over: Oral dosage is 76 milligrams at bedtime if needed, 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.


PART 340—STIMULANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
340.1 Scope.
340.3 Definition.

Subpart B—Active Ingredient

340.10 Stimulant active ingredient.

\(^1\) See § 201.66(b)(4) of this chapter for definition of bullet symbol.