§ 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.

§ 338.3 Definition.
As used in this part:
Nighttime sleep-aid. A drug that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

Subpart B—Active Ingredients
§ 338.10 Nighttime sleep-aid active ingredients.
The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in §338.50(d):
(a) Diphenhydramine hydrochloride.
(b) Diphenhydramine citrate.

Subpart C—Labeling
§ 338.50 Labeling of nighttime sleep-aid 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 a “nighttime sleep-aid.”
(b) Indications. The labeling of the product states, under the heading “In-