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release carbon dioxide when dissolved in water.


Subpart B—Active Ingredients

§ 341.12 Antihistamine active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient:

(a) Brompheniramine maleate.
(b) Chlorcyclizine hydrochloride.
(c) Chlorpheniramine maleate.
(d) Dextromethorphan hydrobromide.
(e) Dextromethorphan hydrobromide.
(f) Diphenhydramine citrate.
(g) Diphenhydramine hydrochloride.
(h) Doxylamine succinate.
(i) Phenindamine tartrate.
(j) Pheniramine maleate.
(k) Pyrilamine maleate.
(l) Triprolidine hydrochloride.

§ 341.14 Antitussive active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in §341.74(d):

(a) Oral antitussives. (1) Chlorpheniramine hydrochloride.

(2) Codeine ingredients. The following ingredients may be used only in combination in accordance with §290.2 and 21 CFR 1308.15(c).

(i) Codeine.
(ii) Codeine phosphate.
(iii) Codeine sulfate.

(b) Topical antitussives. (1) Camphor.

(ii) Menthol.

§ 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

(a) Ephedrine.
(b) Ephedrine hydrochloride.
(c) Ephedrine sulfate.
(d) Epinephrine.
(e) Epinephrine bitartrate.
(f) Racemephrine hydrochloride.
(g) Racemephrine hydrochloride.

§ 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in §341.76(d).

[54 FR 8509, Feb. 28, 1989]

§ 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:

(a) Oral nasal decongestants. (1) Phenylephrine hydrochloride.

(2) Pseudoephedrine hydrochloride.

(3) Pseudoephedrine sulfate.

(4) Phenylephrine bitartrate in an effervescent dosage form.

(b) Topical nasal decongestants. (1) Levmetamfetamine.

(2) Ephedrine.

(3) Ephedrine hydrochloride.

(4) Ephedrine sulfate.

(5) [Reserved]

(6) Naphazoline hydrochloride.

(7) Oxymetazoline hydrochloride.

(8) Phenylephrine hydrochloride.

(9) Propylhexedrine.

(10) Xylometazoline hydrochloride.


§ 341.40 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the dosage limits established in parts 341, 343, and 356 of this chapter and the product is labeled in accordance with §§341.70 or 341.85: