§ 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) Doxylamine succinate.
(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 maleate.

(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.
(iv) Dextromethorphan.
(v) Dextromethorphan hydrobromide.
(vi) Diphenhydramine citrate.
(vii) Diphenhydramine hydrochloride.

(b) _Topical antitussives._ (1) Camphor.
(2) 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) Racephedrine hydrochloride.
(g) Racedpinephrine hydrochloride.

§ 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in §341.78(d).

§ 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 hydrochloride.
(5) Xylometazoline hydrochloride.
(6) Phenylephrine hydrochloride.
(7) Propylhexedrine.
(8) Xylometazoline hydrochloride.

(b) _Topical nasal decongestants._ (1) Levmetamfetamine.
(2) Ephedrine.
(3) Ephedrine hydrochloride.
(4) Ephedrine sulfate.
(5) Naphazoline hydrochloride.
(6) Oxymetazoline hydrochloride.
(7) Naphazoline hydrochloride.
(8) Oxymetazoline 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 346 of this chapter and the product is labeled in accordance with §§341.70 or 341.85.