the proposed changes in classification made in § 341.40 of the cough-cold combination drug products tentative final monograph. All other combination classifications remain the same:

Table 3		
Cold-Cough Combinations	Tentative Final Monograph Proposed Classification	New Proposed Classification for Dephenhydramine-Containing Combinations
Oral antitussive and expectorant (if la-		
beled for nonproductive cough)	I	II
Oral antitussive and expectorant and oral		
nasal decongestant (if labeled for non-		
productive cough)	I	II
Oral antitussive and bronchdilator used		
as an antitussive (if labeled for produc-		
tive cough)	III	II
Oral antitussive and expectorant (if la-		
beled for productive cough)	III	II
Oral antitussive and expectorant and oral		
nasal decongestant (if labeled for pro-		
ductive cough)	III	II
Analgesic-antipyretic(s) and oral		
antitussive and expectorant and oral		
nasal decongestant	III	II
Antihistamine and oral antitussive (if la-		
beled "May cause marked drowsi-		
ness")	I	III
Analgesic-antipyretic(s) and oral		
antitussive and oral nasal deconges-		
tant and antihistamine	I	III
Antihistamine and oral antitussive and		
oral nasal decongestant	I	III

- 1. The agency is revising proposed § 341.40(d), (e), and (f) to replace the phrase "Any single antihistamine active ingredient identified in § 341.12 \* \* \*" with the phrase "any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) \* \* \*" to exclude the ingredients diphenhydramine citrate and diphenhydramine hydrochloride. (See section II.B.)
- 2. The agency is revising § 341.40(d) through (g) and (i) to replace the phrase "Any single oral antitussive active ingredient identified in § 341.14(a) \* \* \* " with the phrase "Any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) \* \* \* " to exclude the ingredients diphenhydramine citrate and diphenhydramine hydrochloride. (See sections II.A.(i) and II.B.)
- 3. The agency is proposing to include diphenhydramine citrate and diphenhydramine hydrochloride in combinations specified in § 341.40(h), (j), (k), (q), (u), (w), (x), and (z). (See section II.A.(ii).)
- 4. The agency is proposing in § 341.40(d), (e), and (f) the use of diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) as both the antihistamine and the antitussive active ingredient

provided that the product is labeled according to § 341.70.

- 5. The agency is revising § 341.40(f) and (k) to include the specific section numbers for allowed internal analysesic ingredients.
- 6. In the oral health care tentative final monograph published on September 24, 1991 (56 FR 48302), the agency redesignated the active anesthetic/analgesic ingredients previously proposed in § 356.10 as § 356.12. Accordingly, the agency is revising § 341.40(j), (q), (x), and (z) to replace the phrase "any single oral anesthetic/analgesic active ingredient identified in § 356.10 \* \* \*" with the phrase "any single oral anesthetic/analgesic active ingredient identified in § 356.12 \* \* \*".
- 7. The agency is proposing to add to § 341.70 labeling for diphenhydramine-containing drug products for concurrent antitussive and antihistamine use under the heading: Labeling of drug products containing diphenhydramine citrate or diphenhydramine hydrochloride for concurrent antitussive and antihistamine use either as a single ingredient product or as a single ingredient in combination with other active ingredients. (See section III.)

## V. Effective Date

The agency advises that any final rule resulting from this proposed rule will be effective 12 months after its date of

publication in the **Federal Register**. On or after that date, any OTC drug product that is not in compliance may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

## VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the