imminent, after the agency has evaluated the comments to a proposed rule to include a new condition in a tentative final monograph as generally recognized as safe and effective and the agency has not changed its position as a result of the comments, and the condition complies with paragraph (i) of this section, the agency may publish a notice of enforcement policy that allows marketing to begin pending completion of the final monograph subject to the risk that the agency may, prior to or in the final monograph, adopt a different position that could require relabeling, recall, or other regulatory action.

(i) Compendial monograph. Any active ingredient or botanical drug substance included in a final OTC drug monograph or the subject of an enforcement notice described in paragraph (h) of this section must be recognized in an official USP-NF drug monograph that sets forth its standards of identity, strength, quality, and purity. Sponsors must include an official or proposed compendial monograph as part of the safety and effectiveness data submission listed in §330.10(a)(2) under item VII of the outline entitled “OTC DRUG REVIEW INFORMATION.”

[67 FR 3074, Jan. 23, 2002]
(4) Aluminum phosphate gel when used as part of an antacid combination product and contributing at least 25 percent of the total acid neutralizing capacity; maximum daily dosage limit is 8 grams.

(5) Dihydroxyaluminum sodium carbonate.

(b) Bicarbonate-containing active ingredients: Bicarbonate ion; maximum daily dosage limit 200 mEq. for persons up to 60 years old and 100 mEq. for persons 60 years or older.

(c) Bismuth-containing active ingredients:
   (1) Bismuth alumininate.
   (2) Bismuth carbonate.
   (3) Bismuth subcarbonate.
   (4) Bismuth subgallate.
   (5) Bismuth subnitrate.

(d) Calcium-containing active ingredients: Calcium, as carbonate or phosphate; maximum daily dosage limit 160 mEq. calcium (e.g., 8 grams calcium carbonate).

(e) Citrate-containing active ingredients: Citrate ion, as citric acid or salt; maximum daily dosage limit 8 grams.

(f) Glycine (aminoacetic acid).

(g) Magnesium-containing active ingredients:
   (1) Hydrate magnesium aluminia
tivated sulfate.
   (2) Magaldrate.
   (3) Magnesium aluminosilicates.
   (4) Magnesium carbonate.
   (5) Magnesium glycinate.
   (6) Magnesium hydroxide.
   (7) Magnesium oxide.
   (8) Magnesium trisilicate.
   (h) Milk solids, dried.

(i) Phosphate-containing active ingredients:
   (1) Aluminum phosphate; maximum daily dosage limit 8 grams.
   (2) Mono or dibasic calcium salt; maximum daily dosage limit 2 grams.
   (3) Tricalcium phosphate; maximum daily dosage limit 24 grams.

(j) Potassium-containing active ingredients:
   (1) Potassium bicarbonate (or carbon when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of bicarbonate ion for persons up to 60 years old and 100 mEq. of bicarbonate ion for persons 60 years or older.

(k) Sodium-containing active ingredients:
   (1) Sodium bicarbonate (or carbonate when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of sodium for persons up to 60 years old and 100 mEq. of sodium for persons 60 years or older.

Subpart C—Testing Procedures

§ 331.20 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient,