U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration

Final Administrative Order (OTC000032)

Over-the-Counter Monograph M007: Laxative Drug Products for Over-the-Counter Human Use (Posted May 2, 2023)

I. Summary

Over-the-Counter Monograph M007: Laxative Drug Products for Over-the-Counter Human Use, as set forth in this document, is a final administrative order (final order) deemed by section 505G(b)(8) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(8)), and effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

II. Background

The CARES Act added section 505G of the FD&C Act, which revised the framework for the regulation of over-the-counter (OTC) monograph drug products. Among other things, section 505G of the FD&C Act provides as a baseline status that, as of the date of enactment of the CARES Act, drugs that satisfy certain requirements described in section 505G(a)(1) or (2) are deemed to be generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)), not a new drug under section 201(p), and not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). To obtain this status, among other things, a drug either must be one that is in conformity with the requirements for nonprescription use of a final monograph issued under part 330 (21 CFR part 330) (except as provided in section 505G(a)(2)),[1] as well as other requirements;[2] or must be one that is (i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330, and (ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph and any applicable subsequent determination by the Secretary, as well as other requirements.[3] Other applicable requirements in section 505G(a)(1) of the FD&C Act include conditions or requirements under section 505G(b) of the FD&C Act.

Complementary to the requirements for conformity to tentative final or final monographs described in section 505G(a)(1) and (2) of the FD&C Act, Congress provided that, under section 505G(b)(8) of the FD&C Act, a final monograph or tentative final monograph that establishes

[1] Section 505G(a)(2) of the FD&C Act is inapplicable here. It establishes the applicable requirements in terms of conformity with a final monograph, for purposes of section 505G(a)(1)(A)(i) of the FD&C Act, for sunscreen drugs subject to section 505G of the FD&C Act.
[2] Section 505G(a)(1)(A) of the FD&C Act.
[3] Section 505G(a)(1)(B) of the FD&C Act.

conditions of use for a drug described in section 505G(a)(1) or (2) and that represents the most recently promulgated version of the conditions of use, including as modified, in whole or in part, by any proposed or final rule, is deemed to be a final order. The final order may be amended, revoked, or otherwise modified in accordance with the procedures under section 505G of the FD&C Act. Under section 505G(b)(8)(C) of the FD&C Act, the deemed establishment of a final order is construed to include technical amendments necessary to ensure that the order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of the FD&C Act (and regulations) and any other final orders issued under section 505G of the FD&C Act.

In the *Federal Register* of January 15, 1985 (50 FR 2124), FDA published a tentative final OTC monograph (TFM) under the procedure in part 330, that would establish conditions under which OTC laxative drug products are generally recognized as safe and effective (GRASE). FDA amended the TFM by modifying the directions for the use of bulk laxatives (51 FR 35136, October 1, 1986). FDA amended the TFM to include conditions under which docusate salts are GRASE (58 FR 46589, September 2, 1993). In the *Federal Register* of March 31, 1994 (62 FR 15139), FDA amended the TFM to limit the OTC container size for sodium phosphate/sodium biphosphate oral solution, due to reports of overdosage. FDA also added a warning for all sodium phosphate/sodium biphosphate products not to exceed the recommended dosage unless directed by a doctor. FDA issued a proposed rule to amend the TFM to reclassify the stimulant laxative ingredients danthron and phenolphthalein from Category I (GRASE) to Category II (not GRASE) and add these ingredients to a list of nonmonograph active ingredients (62 FR 46223, September 2, 1997). In the *Federal Register* of May 21, 1998 (63 FR 27886), FDA issued a proposed rule to amend the TFM to include additional general and professional labeling for oral and rectal dibasic sodium phosphate/ monobasic sodium (sodium phosphates) drug products; this proposed rule included new warnings, directions, and time to effect for rectal products. FDA issued a proposed rule to amend the TFM to reclassify the stimulant laxative ingredients aloe, bisacodyl, Cascara sagrada, and senna (including sennosides A and B) from Category I (GRASE) to Category III (further testing required) (63 FR 33592, June 19, 1998). In the *Federal Register* of August 5, 2003 (68 Fed. Reg. 46113), FDA amended the TFM to reclassify the bulk-forming laxative psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blonde), psyllium seed husks, husks, and plantago seed) in a granular dosage form from Category I (GRASE) to Category II (not GRASE). Finally, FDA proposed that sodium phosphate salts (dibasic sodium phosphate, monobasic sodium phosphate, and the combination of dibasic sodium phosphate/monobasic sodium phosphate salts in solution form) are not GRASE for bowel cleansing (76 FR 7743, February 11, 2011). FDA also proposed to withdraw the professional labeling proposed for sodium phosphate salts.

FDA issued a final rule in the *Federal Register* on January 29, 1999 (64 FR 453) establishing that the stimulant laxative ingredients danthron and phenolphthalein are not GRASE and added these ingredients to 21 CFR 310.545. FDA issued a final rule stating that the stimulant laxative ingredients aloe (including aloe extract and aloe flower extract) and Cascara sagrada (including casanthranol, cascara fluidextract aromatic, Cascara sagrada bark, Cascara sagrada extract, and Cascara sagrada fluid extract) are not GRASE and added these ingredients to 21 CFR 310.545 (67 FR 31125, May 09, 2002). However, stimulant laxative ingredients bisacodyl and senna remained Category III. In the *Federal Register* of March 29, 2007 (72 FR 14669), FDA issued a

final rule establishing bulk-forming laxative psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blonde), psyllium seed husks, *Plantago ovata* husks, and plantago seed) in a granular dosage form are not GRASE and added these ingredients to 21 CFR 310.545.[4]

In the *Federal Register* of October 30, 1990 (55 FR 45782), FDA issued a proposed rule to require a warning in the labeling of OTC drug products containing as active ingredients water-soluble gums, e.g., guar gum, karaya gum, plantago seed (psyllium), tragacanth, and xanthan gum. FDA issued a final rule codified in 21 CFR 201.319 requiring specific warnings and directive statements of all OTC drug products containing as active ingredients water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (58 FR 45194, August 26, 1993).

FDA also issued a final rule codified in 21 CFR 201.307 for sodium phosphates that limited the container size for sodium phosphates oral solution and added warnings and directions for OTC sale (63 FR 27836, May 21, 1998).

Accordingly, this final order for OTC laxative drug products incorporates the requirements of the TFM for OTC laxative drug products as proposed in the *Federal Register* on January 1, 1985 (50 FR 2124) and the proposed rules published in the *Federal Register* on October 1, 1986 (51 FR 35736); September 2, 1993 (58 FR 46589); September 2, 1997 (62 FR 46223); March 31, 1994 (62 FR 15139); May 21, 1998 (63 FR 27886); June 19, 1998 (63 FR 33592); and February 11, 2011 (76 FR 7743), with technical amendments, including consolidating a professional use provision into its own part. This final order also incorporates the provisions of 21 CFR 201.307 and 21 CFR 201.319, as in effect on March 26, 2020, with technical amendments including the removal of the compliance dates, which are no longer relevant because any unexpired product will have been introduced or initially delivered for introduction into interstate commerce after such dates.

III. Final Administrative Order

Over-the-Counter Monograph M007:

Laxative Drugs Products for Over-the-Counter Human Use

Part A—General Provisions

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M007.3 Definitions

[4] Under section 505G(k)(2)(A) of the FD&C Act, the non-monograph conditions in 21 CFR 310.545 in effect on the day before the date of enactment of the CARES Act (i.e., March 26, 2020) were deemed to be a final administrative order. Final Administrative Order OTC000007 is entitled "Non-Monograph Conditions NM900: Drug Products Containing Certain Active Ingredients Offered Over-the-Counter for Certain Uses" (see Order ID OTC000007, available at OTC Monographs@FDA, https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm).

Part B—Active Ingredients

Part C—Labeling

Part D—Professional Use

SOURCE: 50 FR 2124, Jan. 1, 1985, unless otherwise noted.

Part A—General Provisions

§ M007.1 Scope

An over-the-counter (OTC) laxative drug product in a form suitable for oral or rectal administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1.

§ M007.3 Definitions

As used in this OTC monograph:

(a) Laxative. Any agent used for the relief of constipation.

(b) Laxation. To cause a bowel movement.

(c) Constipation. Infrequent or difficult bowel movement.

(d) Bulk-forming laxative. An agent that increases bulk volume and water content of the stool thereby promoting bowel movement.

(e) Carbon-dioxide-releasing laxative. A suppository dosage form containing several ingredients that release carbon dioxide, thereby inducing gentle pressure in the rectum which promotes bowel movement.

(f) Hyperosmotic laxative. An agent that attracts water into the stool thereby promoting bowel movement.

(g) Lubricant laxative. An agent that lubricates the contents of the intestinal tract thereby promoting bowel movement.

(h) Saline laxative. An agent that increases water in the intestine thereby promoting bowel movement.

(i) Stimulant laxative. An agent that promotes bowel movement by one or more direct actions on the intestine.

(j) Stool softener laxative. An agent that penetrates and softens the stool thereby promoting bowel movement.

Part B—Active Ingredients

§ M007.10 Bulk-forming laxative 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 § M007.52(d):

(a) Bran.

(b) Cellulose (semisynthetic) ingredients.

(1) Methylcellulose.

(2) Sodium carboxymethylcellulose.

(c) Karaya.

(d) Malt soup extract.

(e) Polycarbophil.

(f) Psyllium ingredients except those (in granular dosage form) listed in Non-Monograph Conditions NM900.[5]

(1) *Plantago ovata* husks.

(2) Plantago seed.

(3) Psyllium (hemicellulose).

(4) Psyllium hydrophilic mucilloid.

(5) Psyllium seed.

(6) Psyllium seed (blond).

(7) Psyllium seed husks.

[50 FR 2124, Jan. 15, 1985, as amended at 72 FR 14669, March 29, 2007]

§ M007.12 Hyperosmotic laxative 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 § M007.54(d):

(a) Glycerin.

(b) Sorbitol.

§ M007.14 Lubricant laxative active ingredients

The active ingredient of the product consists of mineral oil when used within the dosage limit established in § M007.56(d).

§ M007.16 Saline laxative 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 § M007.58(d) and when packaged according to § M007.58(f):

(a) Magnesium citrate.

(b) Magnesium hydroxide.

[5] Final Administrative Order (OTC000007), effective upon enactment of the Coronavirus Aid, Relief, and Economic Securities Act (CARES Act), Public Law 116-136, on March 27, 2020.

(c) Magnesium sulfate.

(d) Dibasic sodium phosphate/monobasic sodium phosphate marketed as a solution.

(e) Dibasic sodium phosphate.

(f) Monobasic sodium phosphate.

[50 FR 2124, Jan. 15, 1985, as amended at 59 FR 15139, Mar. 31, 1994; 63 FR 277886, May 21 1998)]

§ M007.18 Stimulant laxative 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 § M007.60(d):

(a) Castor oil.

(b) Dehydrocholic acid.

[50 FR 2124, Jan. 1, 1985, as amended at 63 FR 33592, Jun. 19, 1998; 64 FR 4535, Jan. 29, 1999; 67 FR 31125, May 9, 2002]

§ M007.20 Stool softener laxative 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 § M007.62(d):

(a) Docusate calcium.

(b) Docusate potassium.

(c) Docusate sodium.

[58 FR 46589, Sep. 2, 1993]

§ M007.22 Carbon-dioxide-releasing laxatives

The active ingredient of the product consists of the following when used within the dosage limits established in § M007.64(d):

(a) Carbon dioxide released from combined sodium biphosphate anhydrous, sodium acid pyrophosphate, and sodium bicarbonate.

(b) Carbon dioxide released from combined sodium bicarbonate and potassium bitartrate.

[63 FR 27843, May 21, 1998]

§ M007.30 Permitted combinations of active laxative ingredients

The active laxative ingredients of the product consist of a combination of ingredients listed below provided the combination meets the laxative criteria established in § M007.31.

(a) The following bulk laxative ingredients may be combined provided the combination is labeled according to § M007.52:

(1) Malt soup extract identified in § M007.10(d) and psyllium seed (blond) identified in § M007.10(f)(6).

(2) Malt soup extract identified in § M007.10(d) and psyllium seed husks identified in § M007.10(f)(7).

(3) Methylcellulose identified in § M007.10(b)(1) and *Plantago ovata* husks identified in § M007.10(f)(1).

(b) The following bulk laxative ingredient may be combined with the following lubricant laxative ingredient provided the combination is labeled according to § M007.52 and § M007.56: Psyllium seed identified in § M007.10(f)(5) and mineral oil identified in § M007.14.

(c) The following lubricant laxative ingredient may be combined with the following saline laxative ingredient provided the combination is labeled according to § M007.56 and § M007.58: Mineral oil identified in § M007.14 and magnesium hydroxide identified in § M007.16(b).

(d) The following stool softener laxative ingredient may be combined with the following bulk-forming laxative ingredient provided the combination is labeled according to § M007.52 and § M007.62: Docusate sodium identified in § M007.20(c) and sodium carboxymethylcellulose identified in § M007.10(b)(2).

(e) The following stool softener laxative ingredient may be combined with the following hyperosmotic laxative ingredients provided the combination is labeled according to § M007.54 and § M007.62:

(1) Docusate potassium identified in § M007.20(b) and glycerin identified in § M007.12(a).

(2) Docusate potassium identified in § M007.20(b) and sorbitol identified in § M007.12(b).

[50 FR 2124, Jan. 1, 1985, as amended at 58 FR 46589, Sep. 2, 1993; 63 FR 33592, Jun. 19, 1998]

§ M007.31 Laxative combination criteria

(a) The sum of the percentages of the effective dosage range (EDR) as determined in § M007.31(b) for each active ingredient in the combinations permitted in § M007.30 shall not exceed 100%.

(b) The method used for determining the EDR percentage value of each active ingredient is as follows:

$$\frac{\text{L maxd EDR (min)}}{\text{EDR (max)} - \text{EDR (min)}} \text{ x } 100 = \% \text{ of EDR of each ingredient where:}$$

(1) L max d is the labeled maximum daily dosage of the ingredient which must be within the effective daily dosage range for the ingredient established in §§ M007.52, M007.54, M007.56, M007.58, M007.60, or M007.62.

(2) EDR (min) is the effective daily dosage range (minimum) and EDR (max) is the effective daily dosage range (maximum) for the active ingredient established in §§ M007.52, M007.54, M007.56, M007.58, M007.60, or M007.62.

[63 FR 33592, Jun. 19, 1998]

Part C—Labeling

§ M007.50 Labeling of laxative drug products

In addition to the labeling described in §§ M007.52, M007.54, M007.56, M007.58, M007.60, M007.62, and M007.64, the labeling of laxative drug products contains the following statements unless otherwise specified.

(a) Indications. The labeling of the product contains a statement of the indications under the heading "Uses" that is limited to the phrase "For relief of occasional constipation" [which may be followed by "(irregularity)."]

(b) Warnings. The labeling of the product contains the following information under the heading "Warnings." If applicable, the warnings in § M007.50 may be combined with the warnings in §§ M007.58 and M007.60 to eliminate duplicative words or phrases so the resulting warning is clear and understandable.

(1) "Do not use laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor."

(2) "If you have noticed a sudden change in bowel habits that persists over a period of 2 weeks, consult a doctor before using a laxative."

(3) "Laxative products should not be used for a period longer than 1 week unless directed by a doctor."

(4) "Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult your doctor."

(5) For products containing more than 140 milligrams of sodium in the maximum recommended daily dose. "Ask a doctor before use if you have [in bold type] [bullet][6] a sodium restricted diet." The warnings in §§ M007.50(b)(5), (b)(6), (b)(7), and 21 CFR 201.70(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e g., a calcium or sodium restricted diet.

(6) For products containing more than 25 milliequivalents (975 milligrams) potassium in the maximum recommended daily dose. "Ask a doctor before use if you have [in bold type] [bullet] kidney disease [bullet] a potassium-restricted diet." The warnings in §§ M007.50(b)(5), (b)(6), (b)(7), and 21 CFR 201.70(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e g., a calcium or sodium restricted diet.

(7) For products containing more than 50 milliequivalents (600 milligrams) magnesium in the maximum recommended daily dose. "Ask a doctor before use if you have [in bold type] [bullet] kidney disease [bullet] a potassium-restricted diet." The warnings in §§ M007.50(b)(5), (b)(6), (b)(7), and 21 CFR 201.70(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e g., a calcium or sodium restricted diet.

(8) A product containing more than 1 milliequivalent (23 milligrams) sodium per maximum daily dose shall be labeled as to the sodium content per dosage unit.

(9) For products containing an active ingredient identified in § M007.10 that is a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid in an oral dosage form and marketed in a dry or incompletely hydrated form.[7] Under the subheading "Choking"

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[6] See 21 CFR 201.66(b)(4) for definition of bullet symbol.

[7] Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that esophageal obstruction and asphyxiation have been associated with the ingestion of water-soluble gums, hydrophilic gums, and hydrophilic mucilloids including, but not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum. Esophageal obstruction and asphyxiation due to orally-administered drug products containing water-soluble gums, hydrophilic gums, and hydrophilic mucilloids as active ingredients are significant health risks when these products are taken without adequate fluid or when they are used by individuals with esophageal narrowing or dysfunction, or with difficulty in swallowing. Additional labeling is needed for the safe and effective use of any OTC drug product for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient when marketed in a dry or incompletely hydrated form to include, but not limited to, the following dosage forms: Capsules, granules, powders, tablets, and wafers. Granular dosage forms containing psyllium are not generally recognized as safe and effective as OTC laxatives (see Final Administrative Order OTC000007, available at FDA's

> [highlighted in bold type]: "Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention."

(c) Directions. The labeling of the product contains the appropriate directions identified in §§ M007.52, M007.54, M007.56, M007.58, M007.60, M007.62, M007.64, and M007.66 under the heading "Directions" followed by "or as directed by a doctor."

(d) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this OTC monograph.

§ M007.52 Labeling of bulk-forming laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.10 includes the established name of the drug, if any, and identifies the product as a "bulk-forming laxative."

(b) Indications. Other required statement. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading "Uses" that is limited to the phrase: "This product generally produces bowel movement in 12 to 72 hours."

(c) Warnings. The labeling of the product contains the applicable warnings identified in § M007.50(b) under the heading "Warnings."

(d) Directions. The labeling of the product contains the following information under the heading "Directions."

> (1) For products containing an active ingredient identified in § M007.10 that is a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid in an oral dosage form and marketed in a dry or incompletely hydrated form.[8] "(Select one of the following, as appropriate: "Take" or "Mix") "this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning."
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> (2) For products containing bran identified in § M007.10(a). Adults and children 12 years of age and over: Oral dosage is up to 14 grams daily in divided doses of 1 to 7 grams per dose. Children 6 to under 12 years of age: Up to 7 grams daily in divided doses of 1 to 3.5 grams per dose. Children 2 to under 6 years of age: Up to 3.5 grams daily in divided doses of 1 to 1.75 grams per dose. Children under 2 years of age: Consult a doctor.

website OTC Monographs@FDA, https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm) and may not be marketed without an approved new drug application because the warnings and directions in this section have been found inadequate for these products.

[8] See footnote 7.

(3) For products containing methylcellulose and sodium carboxymethylcellulose identified in §§ M007.10(b)(1) and (2). Adults and children 12 years of age and over: Oral dosage is up to 6 grams daily in divided doses of 0.45 to 3 grams per dose. Children 6 to under 12 years of age: Up to 3 grams daily in divided doses of 0.45 to 1.5 grams per dose. Children under 6 years of age: Consult a doctor.

(4) For products containing karaya identified in § M007.10(c). Adults and children 12 years of age and over: Oral dosage is up to 14 grams daily in divided doses of 3.5 to 7 grams per dose. Children under 12 years of age: Consult a doctor.

(5) For products containing malt soup extract identified in § M007.10(d). Adults and children 12 years of age and over: oral dosage is up to 64 grams daily in divided doses of 3 to 32 grams per dose. Children 6 to under 12 years of age: Up to 32 grams daily in divided doses of 3 to 16 grams per dose. Children 2 to under 6 years of age: Up to 16 grams daily in divided doses of 3 to 8 grams per dose. Children under 2 years of age: Consult a doctor.

(6) For products containing polycarbophil identified in § M007.10(e). Adults and children 12 years of age and over: Oral dosage is up to 4 grams daily in divided doses of 1 gram per dose. Children 6 to under 12 years of age: Up to 2 grams daily in divided doses of 0.5 grams per dose. Children 2 to under 6 years of age: Up to 1 gram daily in divided doses of 0.5 grams per dose. Children under 2 years of age: Consult a doctor.

(7) For products containing any psyllium ingredient identified in § M007.10(f). Adults and children 12 years of age and over: Oral dosage is up to 30 grams daily in divided doses of 2.5 to 7.5 grams per dose. Children 6 to under 12 years of age: Up to 15 grams daily in divided doses of 2.5 to 3.75 grams per dose. Children under 6 years of age: Consult a doctor.

[50 FR 2124, Jan. 1, 1985, as amended at 51 FR 35136, Oct. 1, 1986]

§ M007.54 Labeling of hyperosmotic laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.12 includes the established name of the drug, if any, and identifies the product as a "laxative."

(b) Indications. Other required statement. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading "Uses" that is limited to the phrase: "This product generally produces bowel movement in ¼ to 1 hour."

(c) Warnings. In addition to the warnings identified in § M007.50(b), the labeling of the product contains the following statement under the heading "Warnings."

(1) For products containing glycerin identified in § M007.12(a). “May cause rectal discomfort or a burning sensation.”

(2) For products containing glycerin or sorbitol identified in §§ M007.12 (a) and (b). “For rectal use only.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions.”

(1) For products containing glycerin identified in § M007.12(a).

(i) Rectal suppository dosage. Adults and children 6 years of age and over: rectal suppository dosage is 2 to 3 grams glycerin in a single daily dose. Children 2 to under 6 years of age: rectal suppository dosage is 1 to 1.7 grams glycerin in a single daily dose. Children under 2 years of age: consult a doctor.

(ii) Rectal enema dosage. Adults and children 6 years of age and over: rectal enema dosage is 5 to 15 milliliters of an 80% volume/volume solution in a single daily dose. Children 2 to under 6 years of age: rectal enema dosage is 2 to 5 milliliters as an 80% volume/volume solution in a single daily dose. Children under 2 years of age: consult a doctor.

(2) For products containing sorbitol identified in § M007.12(b). Adults and children 12 years of age and over: rectal enema dosage is 120 milliliters as a 25 to 30% weight/volume solution in a single daily dose. Children 2 to under 12 years of age: rectal enema dosage is 30 to 60 milliliters as a 25 to 30% weight/volume solution in a single daily dose. Children under 2 years of age: consult a doctor.

§ M007.56 Labeling of lubricant laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.14 includes the established name of the drug, if any, and identifies the product as a “lubricant laxative.”

(b) Indications. Other required statements. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading “Uses” that is limited to the following:

(1) Oral dosage forms. “This product generally produces bowel movement in 6 to 8 hours.”

(2) Rectal dosage forms. “This product generally produces bowel movement in 2 to 15 minutes.”

(c) Warnings. In addition to the warnings identified in § M007.50(b), the labeling of products containing mineral oil identified in § M007.14 for oral use contains the following statement under the heading "Warnings."

(1) "Do not administer to children under 6 years of age, to pregnant women, to bedridden patients, or to persons with difficulty swallowing."

(2) "As with any drug, if you are nursing a baby, seek the advice of a health professional before using this product."

(3) "Drug interaction precaution: Do not take this product if you are presently taking a stool softener laxative."

(4) "Do not take with meals."

(5) The warnings in §§ M007.56(c)(1) and (2) supersede the general warning required in 21 CFR 201.63.

(d) Directions. The labeling of products containing mineral oil identified in § M007.14 contains the following information under the heading "Directions."

(1) Oral dosage. Adults and children 12 years of age and over: oral dosage is a minimum single dose of 15 milliliters to a maximum daily dose of 45 milliliters. Children 6 to under 12 years of age: oral dosage is a minimum single dose of 5 milliliters to a maximum daily dose of 15 milliliters. The dose may be taken as a single daily dose or in divided doses. Children under 6 years of age: consult a doctor.

(2) Rectal enema dosage. Adults and children 12 years of age and over: rectal enema dosage is 120 milliliters in a single daily dose. Children 2 to under 12 years of age: rectal enema dosage is 60 milliliters in a single daily dose. Children under 2 years of age: consult a doctor.

§ M007.58 Labeling of saline laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.16 includes the established name of the drug, if any, and identifies the product as a "saline laxative."

(b) Indications. Other required statements. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading "Uses" that is limited to the following:

(1) Oral dosage forms. "This product generally produces bowel movement in ½ to 6 hours."

(2) Rectal dosage forms. “This product generally produces bowel movement in 1 to 5 minutes.”

(c) Warnings. In addition to the warnings identified in § M007.50(b), the labeling of the product contains the following statements under the heading “Warnings”

(1) For products containing magnesium citrate identified in § M007.16(a) when formulated in oral solution. “Store at temperatures between 46 and 86 °F (8 and 30 °C).”

(2) For products containing dibasic sodium phosphate or monobasic sodium phosphate identified in §§ M007.16 (d), (e), or (f).

(i) The following sentences shall appear in boldface type as the first statement under the heading “Warnings.”[9]

(A) Oral dosage forms. “Taking more than the recommended dose in 24 hours can be harmful.”

(B) Rectal enema dosage forms. “Using more than one enema in 24 hours can be harmful.”

(ii) “Do not use if” (these four words in bold print) “you have kidney disease, heart problems, or are dehydrated, or for more than 3 days, without asking a doctor.”

(iii) Oral dosage forms. “Do not give to children under 6 years of age, without asking a doctor.”

(iv) Rectal dosage forms. “Do not use in children under 2 years of age.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”

(1) Oral dosage forms. “Drink a full glass (8 ounces) of liquid with each dose.”

(2) For products containing magnesium citrate identified in § M007.16(a). Adults and children 12 years of age and over: oral dosage is 11 to 25 grams. Children 6 to under 12 years of age: oral dosage is 5.5 to 12.5 grams. Children 2 to under 6 years of age: oral dosage is 2.7 to 6.25 grams. The dose may be taken as a single daily dose or in divided doses. Children under 2 years of age: consult a doctor.

(3) For products containing magnesium hydroxide identified in § M007.16(b). Adults and children 12 years of age and over: oral dosage is 2.4 to 4.8 grams. Children 6 to under 12 years of age: oral dosage is 1.2 to 2.4 grams. Children 2 to under 6 years of age: oral

[9] See footnote 7.

dosage is 0.4 to 1.2 grams. The dose may be taken as a single daily dose or in divided doses. Children under 2 years of age: consult a doctor.

(4) For products containing magnesium sulfate identified in § M007.16(c). Adults and children 12 years of age and over: oral dosage is 10 to 30 grams. Children 6 to under 12 years of age: oral dosage is 5 to 10 grams. Children 2 to under 6 years of age: oral dosage is 2.5 to 5 grams. The dose may be taken as a single daily dose or in divided doses. Children under 2 years of age: consult a doctor.

(5) For products containing sodium phosphates identified in §§ M007.16(d), (e), and (f). The labeling of all orally or rectally administered OTC drug products containing sodium phosphates shall contain the following directions in boldface type immediately preceding the dosage information: "Do Not" ("take" or "use") "more unless directed by a doctor. See Warnings."[10]

(6) For products containing dibasic sodium phosphate/monobasic sodium phosphate identified in § M007.16(d) and marketed as a solution

(i) Oral dosage. Adults and children 12 years of age and over: Oral dosage is dibasic sodium phosphate 3.42 to 7.56 grams and monobasic sodium phosphate 9.1 to 20.2 grams (20 to 45 milliliters (mL) dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 45 mL (9 teaspoonfuls or 3 tablespoonfuls) in a 24-hour period." Children 10 and 11 years of age: Oral dosage is dibasic sodium phosphate 1.71 to 3.78 grams and monobasic sodium phosphate 4.5 to 10.1 grams (10 to 20 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 20 mL (4 teaspoonfuls) in a 24-hour period." Children 6 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 gram and monobasic sodium phosphate 2.2 to 5.05 grams (5 to 10 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 10 mL (2 teaspoonfuls) in a 24-hour period." Children under 6 years of age: ask a doctor.

[10] Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that multiple container sizes of sodium phosphates oral solution available in the marketplace have caused consumer confusion and appear to have been involved in several consumer deaths. Sodium phosphates oral solution has been marketed in 45-milliliter (mL), 90 mL, and 240 mL container sizes. The 45 mL and 90 mL container sizes of sodium phosphates oral solution are often recommended and prescribed by physicians for bowel cleansing prior to surgery and diagnostic procedures of the colon. Sodium phosphates oral solution (adult dose 20 mL to 45 mL) is also used as an over-the-counter (OTC) laxative for the relief of occasional constipation. Accidental overdosing and deaths have occurred because the 240 mL container was mistakenly used instead of the 45 mL or 90 mL container. The Food and Drug Administration is limiting the amount of sodium phosphates oral solution to not more than 90 mL (3 ounces (oz)) per OTC container because of the serious health risks associated with the ingestion of larger than intended doses of this product. Further, because an overdose of either oral or rectal enema sodium phosphates can cause an electrolyte imbalance, additional warning and direction statements are required for the safe use of any OTC laxative drug product containing sodium phosphates.

(ii) Rectal enema dosage.

(A) Adults and children 12 years of age and over: Enema dosage is dibasic sodium phosphate 6.84 to 7.56 grams and monobasic sodium phosphate 18.24 to 20.16 grams in a single daily dose. Children 2 to 11 years of age: Enema dosage is dibasic sodium phosphate 3.42 to 3.78 grams and monobasic sodium phosphate 9.12 to 10.08 grams in a single daily dose. "Do not use in children under 2 years of age." (Manufacturers should convert these dosages to the amount of solution to be used.)

(B) "If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur."

(C) "Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care."

(7) For products containing dibasic sodium phosphate identified in § M007.16(e). Adults and children 12 years of age and over: Oral dosage is 3.42 to 7.56 grams in a single daily dose. Children 10 to 11 years of age: Oral dosage is 1.71 to 3.78 grams in a single daily dose. Children 6 to 9 years of age: Oral dosage is 0.86 to 1.89 grams in a single daily dose. Children under 6 years of age: ask a doctor.

(8) For products containing monobasic sodium phosphate identified in § M007.16(f). Adults and children 12 years of age and over: Oral dosage is 4.5 to 20.2 grams in a single daily dose. Children 10 to 11 years of ages: Oral dosage is 2.25 to 10.1 grams in a single daily dose. Children 6 to 9 years of age: Oral dosage is 1.12 to 5.05 grams in a single daily dose. Children under 6 years of age: ask a doctor.

(f) Package size limitation.

Package size limitation for sodium phosphates oral solution: Container shall not contain more than 90 mL (3 oz)[11]

[50 FR 2124, Jan. 1, 1985, as amended at 63 FR 27886, May 21, 1998]

§ M007.60 Labeling of stimulant laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.18 includes the established name of the drug, if any, and identifies the product as a "stimulant laxative."

[11] See footnote 10.

(b) Indications. Other required statement. In addition to the indication identified in § M007 (a), the product also contains a statement under the heading “Uses” that is limited to the following:

(1) Oral dosage forms. “This product generally produces bowel movement in 6 to 12 hours.”

(c) Warnings. The labeling of the product contains the applicable warnings identified in § M007.50(b) under the heading “Warnings.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions.”

(1) For products containing castor oil identified in § M007.18(a). Adults and children 12 years of age and over: oral dosage is 15 to 60 milliliters in a single daily dose. Children 2 to under 12 years of age: oral dosage is 5 to 15 milliliters in a single daily dose. Children under 2 years of age: consult a doctor.

(2) For products containing dehydrocholic acid identified in § M007.18(b). Adults and children 12 years of age and over: oral dosage is 250 to 500 milligrams three times a day, not to exceed 1500 milligrams in 24 hours. Children under 12 years of age: consult a doctor.

[50 FR 2124, Jan. 1, 1985, as amended at 62 FR 46227, Sep. 2, 1997; 63 FR 33592, Jun. 19, 1998]

§ M007.62 Labeling of stool softener laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.20 includes the established name of the drug, if any, and identifies the product as a “stool softener laxative.”

(b) Indications. Other required statements. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading “Uses” that is limited to the following:

(1) Oral dosage forms. “This product generally produces bowel movement in 12 to 72 hours.”

(2) Rectal dosage forms. “This product generally produces bowel movement in 2 to 15 minutes.”

(c) Warnings. In addition to the warnings identified in § M007.50(b), the labeling of the product contains the following statement under the heading “Drug Interaction Precaution”: “Do not take this product if you are presently taking mineral oil, unless directed by a doctor.”

(d) Directions. The labeling of the product contains the following information under the heading "Directions."

(1) For products containing docusate calcium identified in § M007.20(a). Adults and children 12 years of age and over: oral dosage is 50 to 360 milligrams. Children 2 to under 12 years of age: oral dosage is 50 to 150 milligrams. The dose may be taken as a single daily dose or in divided doses. Children under 2 years of age: consult a doctor.

(2) For products containing docusate potassium identified in § M007.20(b). Adults and children 12 years of age and over: rectal enema dosage is 50 to 250 milligrams in a single daily dose. Children 2 to under 12 years of age: rectal enema dosage is 100 milligrams in a single daily dose. Children under 2 years of age: consult a doctor.

(3) For products containing docusate sodium identified in § M007.20(c). Adults and children 12 years of age and older: oral dosage is 50 to 360 milligrams. Children 2 to under 12 years of age: oral dosage is 50 to 150 milligrams. This dose may be taken as a single daily dose or in divided doses. Children under 2 years of age: consult a doctor.

[50 FR 2124, Jan. 1, 1985, as amended at 58 FR 46589, Sep. 2, 1993]

§ M007.64 Labeling of carbon-dioxide-releasing laxative drug products

(a) Statement of identity. The labeling of the product containing any ingredient identified in § M007.22 includes the established name of the drug, if any, and identifies the product as a "laxative."

(b) Indications. Other required statement. In addition to the indication identified in § M007.50(a), the product also contains a statement under the heading "Uses" that is limited to the phrase: "This product generally produces bowel movement in 5 to 30 minutes."

(c) Warnings. In addition to the warnings identified in § M007.50(b), the product also contains the following information under the heading "Warnings."

(1) "For rectal use only."

(2) "Do not lubricate with mineral oil or petrolatum prior to rectal insertion."

(d) Directions. The labeling of the product contains the following information under the heading "Directions."

(1) For products containing the carbon-dioxide-releasing ingredients identified in § M007.22(a). Adults and children 12 years of age and over: rectal dosage is one suppository containing 1.2 to 1.5 grams of sodium biphosphate anhydrous, 0.04 to 0.05 gram of sodium acid pyrophosphate and 1 to 1.5 grams of sodium bicarbonate in a single daily dose. Children under 12 years of age: consult a doctor.

(2) For products containing the carbon-dioxide-releasing ingredients identified in § M007.22(b). Adults and children 12 years of age and over: rectal dosage is one suppository containing 0.6 gram of sodium bicarbonate and 0.9 gram of potassium bitartrate in a single daily dose. Children under 12 years of age: consult a doctor.

(3) For products containing the carbon-dioxide-releasing ingredients identified in §§ M007.22(a) and (b). "Moisten suppository by placing it under a water tap for 30 seconds or in a cup of water for at least 10 seconds before insertion."

[50 FR 2124, Jan. 1, 1985, as amended at 63 FR 33592, Jun. 19, 1998]

Part D—Professional Use

§ M007.80 Professional labeling

The labeling of the product provided to health professionals (but not to the general public) contains the following information in addition to the labeling identified in §§ M007.50, M007.52, M007.54, M007.56. M007.58 and M007.60, and M007.62.

(a) Indications.

(1) For products containing mineral oil identified in § M007.14. "For preparing the colon for x-ray or endoscopic examination."

(2) For products containing magnesium citrate in oral solution identified in § M007.16(a). "For use as part of a bowel cleansing regimen in preparing the patient for surgery or for preparing the colon for x-ray or endoscopic examination."

(3) For products containing castor oil identified in § M007.18(a). "For preparing the colon for x-ray or endoscopic examination."

(b) Warnings. The labeling of the product contains the following information under the heading "Warnings."

(1) For products containing karaya identified in § M007.10(c).

(i) "Rare cases of allergic reactions and urticaria caused by karaya have been reported."

(ii) "Inadequate fluid intake may cause obstruction of the large bowel."

(2) For products containing mineral oil identified in § M007.14. "Side effects with the proper use of mineral oil are few. However, laxation, anal leakage, and dermatologic reactions may occur with chronic use and particularly with excess dosage. Owing to its property as a lipid solvent, mineral oil may interfere with the absorption of provitamin A, vitamin A, and vitamin D, leading to impairment of calcium and phosphorus metabolism.

This occurs only under conditions of chronic usage. Administration of mineral oil may lower prothrombin levels, probably secondary to impaired vitamin K absorption, and regular use in pregnancy may predispose to hemorrhagic disease of the newborn. Because of possible interference with nutrition, mineral oil should not be ingested in close proximity to meals. These side effects occur very rarely and then only with chronic and abusive use."

(c) Directions. The labeling of the product may contain the following additional information under the heading "Directions."

(1) For products containing malt soup extract identified in § M007.10(d). Children under 2 years of age: oral dosage is 6 to 32 grams in a single daily dose.

(2) For products containing polycarbophil identified in § M007.10(e). Children under 2 years of age: oral dosage is 0.5 to 1 gram in a single daily dose.

(3) For products containing glycerin identified in § M007.12(a). Children under 2 years of age:

(i) Rectal suppository dosage is 1 to 1.7 grams of glycerin, in a single daily dose.

(ii) Rectal enema dosage is 2 to 5 milliliters of glycerin, as an 80% solution, in a single daily dose.

(4) For products containing magnesium hydroxide identified in § M007.16(b). Children under 2 years of age: oral dosage is 0.035 to 0.043 gram per kilogram per dose.

(5) For products containing castor oil identified in § M007.18(a). Children under 2 years of age: oral dosage is 1 to 5 milliliters in a single daily dose.

(6) For products containing docusate calcium identified in § M007.20(a). Children under 2 years of age: oral dosage is 25 milligrams in a single daily dose or in divided doses.

(7) For products containing docusate sodium identified in § M007.20(c). Children under 2 years of age: oral dosage is 20 to 50 milligrams in a single daily dose or in divided doses.

[50 FR 2124, Jan. 1, 1985, as amended at 58 FR 46589, Sep. 2, 1993; 63 FR 33592, Jun, 19, 1998; 76 FR 7743 Feb. 11, 2011]