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Rebecca MacPherson,

Assistant Chief Counsel for Regulations.

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 402

[Regulation No. 2; Docket No. SSA-2007-0020]

RIN 0960-AG46

Technical Amendments To Correct Cross-References

AGENCY: Social Security Administration.

ACTION: Correcting amendments.

SUMMARY: This document contains three technical corrections to our regulations. We are changing three cross-references because they are currently incorrect.

EFFECTIVE DATE: Effective on March 29, 2007.

FOR FURTHER INFORMATION CONTACT:

Rosemarie A. Greenwald, Social Insurance Specialist, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401. Call (410) 966-7813 or TTY 1-800-325-0778 for information about these correcting amendments. For information on eligibility or filing for benefits, call our national toll-free numbers 1-(800)-772-1213 or TTY 1-(800)-325-0778. You may also contact Social Security online at <http://www.socialsecurity.gov/>.

SUPPLEMENTARY INFORMATION: We are making corrections to our current regulations at 20 CFR 402.35(b)(2) which contain errors. The three cross-references in the last sentence of § 402.35(b)(2) incorrectly show §§ 404.984(b), 410.610c(b) and 416.1484(b). We are changing these to reflect the correct cross-references.

(Catalog of Federal Domestic Assistance Programs Nos. 96.001 Social Security—Disability Insurance; 96.002 Social Security—Retirement Insurance; 96.004 Social Security—Survivors Insurance and 96.006 Supplemental Security Income.

List of Subjects in 20 CFR Part 402

Administrative practice and procedure; Freedom of information.

Dated: March 21, 2007.

Paul Kryglik,

Acting SSA Regulations Officer.

■ For the reasons set out in the preamble, part 402 of chapter III of title 20 of the Code of Federal Regulations is

corrected by making the following correcting amendments:

PART 402—AVAILABILITY OF INFORMATION AND RECORDS TO THE PUBLIC

■ 1. The authority citation for part 402 continues to read as follows:

Authority: Secs. 205, 702(a)(5), and 1106 of the Social Security Act; (42 U.S.C. 405, 902(a)(5), and 1306); 5 U.S.C. 552 and 552a; 8 U.S.C. 1360; 18 U.S.C. 1905; 26 U.S.C. 6103; 30 U.S.C. 923(b); 31 U.S.C. 9701; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

■ 2. Section 402.35 is corrected by revising the last sentence of paragraph (b)(2) to read as follows:

§ 402.35 Publication.

* * * * *

(b) * * *

(2) * * * For a description of Social Security Acquiescence Rulings, see 20 CFR 404.985(c), 410.670c(b), and 416.1485(c) of this title.

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[FR Doc. E7-5494 Filed 3-28-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. 1978N-0036L] (formerly Docket No. 1978N-036L)

RIN 0910-AF38

Laxative Drug Products for Over-the-Counter Human Use; Psyllium Ingredients in Granular Dosage Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that over-the-counter (OTC) laxative drug products in granular dosage form containing the bulk-forming psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), psyllium seed husks, plantago ovata husks, and plantago seed) are not generally recognized as safe and effective (GRASE) and are misbranded. This final rule includes, but is not limited to, any granules that are swallowed dry prior to drinking liquid; dispersed, suspended, or partially dissolved in liquid prior to swallowing; chewed, partially chewed,

or unchewed, and then washed down (or swallowed) with liquid; or sprinkled over food. FDA is issuing this final rule after considering reports of esophageal obstruction associated with the use of psyllium laxatives in granular dosage form. These cases continue to occur despite efforts to promote safe use through label warnings and directions. This final rule does not apply to psyllium laxatives in nongranular dosage forms, such as powders, tablets, or wafers. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: *Effective Date:* This rule is effective October 1, 2007.

Compliance Date: The compliance date for all products subject to this final rule, including products with annual sales less than \$25,000, is October 1, 2007.

ADDRESSES: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993-0002, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the advance notice of proposed rulemaking (ANPRM) for OTC laxative, antidiarrheal, emetic, and antiemetic drug products (40 FR 12902 at 12906, March 21, 1975), the advisory review panel on OTC laxative, antidiarrheal, emetic, and antiemetic drug products (the Panel) recommended Category I (GRASE and not misbranded) status for the OTC bulk laxative psyllium ingredients, which included plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), and psyllium seed husks. FDA concurred with the Panel's Category I classification of these ingredients in the tentative final monograph (TFM) published in the **Federal Register** of January 15, 1985 (50 FR 2124 at 2152).

In the ANPRM, the Panel recommended a warning statement (21 CFR 334.52(a)(1)) for bulk-forming laxatives that advised drinking a full glass, 8 ounces (oz), of liquid with each