

## V. Paperwork Reduction Act of 1995

FDA tentatively concludes that any relabeling resulting from this proposed rule is not subject to review by the Office of Management and Budget because it does not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the relabeling statements are in the TFM for OTC laxative drug products (50 FR 2124 and 51 FR 35136) and are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

## VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order, and, consequently, a federalism summary impact statement has not been prepared.

## VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IX. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal

become effective 180 days after its date of publication in the **Federal Register**.

## X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 78N-036L, unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Adverse Drug Reaction Reports, Ref. 7 in OTC vol. AF, Docket No. 90N-0200, Division of Dockets Management.

2. Comment No. C00100.

3. Comment No. LET45.

4. Comment No. LET46.

5. Adverse Event Reports from 1966 to 2000 for Psyllium Laxative Products (Perdiem, Metamucil, and Serutan) collected by FDA's Office of Compliance, in OTC vol. 090TFM6.

6. FDA, Office of Postmarketing Drug Risk Assessment (OPDRA) (Project ID (PID) 000607) regarding Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, November 17, 2000, in OTC vol. 090TFM6.

7. Adverse Event Reports from January 1999 to January 2001 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in January 2001, in OTC vol. 090TFM6.

8. Adverse Event Reports from October 2000 to January 2002 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in April 2002, in OTC vol. 090TFM6.

9. FDA, Cases of Esophageal Obstruction Associated with PERDIEM (January 1999 to January 2001), in OTC vol. 090TFM6.

10. FDA, OPDRA Postmarketing Safety Review (PID D020201) regarding Senokot and Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, May 15, 2002, in OTC vol. 090TFM6.

## List of Subjects

### 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

### 21 CFR Part 334

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310 and 334 (as proposed in the **Federal Register** of January 15, 1985 (50 FR 2124), October 1, 1986 (51 FR 35136), September 2, 1993 (58 FR 46589), March 31, 1994 (59 FR 15139), September 2, 1997 (62 FR 46223), May 21, 1998 (63 FR 27886), and June 19, 1998 (63 FR 33592)), be amended as follows:

## PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e, 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by redesignating paragraph (a)(12)(i) as paragraph (a)(12)(i)(A), by adding new paragraph (a)(12)(i)(B), by revising paragraph (d) introductory text and paragraph (d)(1), and by adding new paragraph (d)(38) to read as follows:

### § 310.545 Drug products containing active ingredients offered over-the-counter (OTC) for certain uses.

(a) \* \* \*

(12) \* \* \*

(i)(B) *Bulk laxatives*—Approved as of [date of publication of final rule in the **Federal Register**].

Psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), psyllium seed husks, plantago husks, plantago seed, in a granular dosage form including, but not limited to any granules that are:

(1) Swallowed dry prior to drinking liquid,

(2) Dispersed, suspended, or partially dissolved in liquid prior to swallowing,

(3) Chewed, partially chewed, or unchewed, and then washed down (or swallowed) with liquid, or

(4) Sprinkled over food.

\* \* \* \* \*

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(38) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4)(i), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), paragraphs (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i)(A), (a)(12)(ii) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), (a)(16) through (a)(18)(i)(A), (a)(18)(ii) (except as covered by paragraph (d)(22) of this section), paragraphs (a)(18)(iii), (a)(18)(iv), (a)(18)(v)(A), and (a)(18)(vi)(A) of this section.

\* \* \* \* \*

(38) [Date 180 days after date of publication of final rule in the **Federal Register**], for products subject to paragraph (a)(12)(i)(B) of this section.