administrative proceedings for imposition of a civil penalty for violation(s) of Public Law 107–228. The authority to enforce penalty provisions of Public Law 107–228 will be delegated to the Office of Export Enforcement of the Bureau of Industry and Security, U.S. Department of Commerce, and/or the U.S. Department of Homeland Security.

In addition, the Census Bureau will address other issues in the forthcoming rulemaking process discussed above. Because the changes discussed above will result in a major revision of the Foreign Trade Statistics Regulations, we plan to use this as an opportunity to improve the regulations' clarity and readability. It is possible that we could make some additional changes to the rules as part of this process.

An additional purpose of this notice is to announce and request comment on the Census Bureau's intention, subject to agreement with the CBP and other federal agencies participating in the AES, to modify the AES Option 4 post-departure filing program. Currently, Option 4 is a method of post-departure filing that considers the trade community's business practices and also provides for an approval process that ensures that only the most compliant companies are approved for this method of filing. With Option 4 privileges, shipment information can be transmitted to the AES no later than ten working days from the date of exportation. (Refer to Foreign Trade Statistics Regulations, title 15, Code of Federal Regulations, part 30, sections 30.61 and 30.62, for information on AES filing Option 4.)

The Census Bureau also has had numerous discussions over the past several months with the trade community and several federal government agencies regarding a proposal to develop and implement the AES Filer Licensing and Permit Program. After consultation both internally and externally, the Census Bureau has decided not to move forward with the development and implementation of an AES filer licensing program concurrently with requiring full mandatory electronic filing of export information through the AES. However, the Census Bureau will continue to explore the need for an AES filer licensing program.

Executive Orders

This program notice has been determined to be not significant for purposes of Executive Order (E.O.) 12866. This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

Notwithstanding any other provisions of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. The forthcoming rules will contain a collection of information subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). In accordance with the PRA, this collection of information will be submitted to OMB for approval.

Program Change

The actual effective date of full AES mandatory filing requirements and implementation of the penalty provision regarding mandatory filing are dependent upon the publication and implementation of final regulatory amendments by the Census Bureau. Proposed and final rules defining the regulatory revisions that will be made to implement the legislation will be published in the **Federal Register**, as discussed above.

Dated: October 16, 2003.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. 03–26576 Filed 10–21–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 334

[Docket No. 1978N–036L]

RIN 0910–AA01

Laxative Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until January 20, 2004, the administrative record for the rulemaking for over-the-counter (OTC) laxative drug products to accept comments and data concerning these drug products that have been filed with FDA's Division of Dockets Management, because the administrative record officially closed at various times during the course of this rulemaking. The administrative record will remain open until January 20, 2004, to allow for public comment on the comments and data being accepted into the rulemaking at this time. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments and data by January 20, 2004.

ADDRESSES: Submit written comments and data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary S. Robinson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has, on numerous occasions, received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a tentative final monograph (TFM). Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

FDA published a TFM on laxative drug products for OTC human use on January 15, 1985 (50 FR 2124). On a number of occasions since the TFM was published, FDA reopened the administrative record for this rulemaking for various reasons. (See table 1 of this document for reopening dates and reasons.)

TABLE 1.—CHRONOLOGY OF THE OTC LAXATIVE DRUG PRODUCTS RULEMAKING PUBLICATIONS

Federal Register date and cite	Document
January 15, 1985 (50 FR 2124)	Proposed Rule (TFM) to Establish a Monograph for OTC Laxative Drug Products
October 1, 1986 (51 FR 35136)	TFM Amendment to Modify the Directions for Use and Dosages of OTC Bulk-Forming Laxatives
June 2, 1992 (57 FR 23174)	Notice to Reopen the Administrative Record to Accept Data and Information on Stimulant Laxative Active Ingredients Derived from Senna and Data on the Combination of Psyllium and Bran Active Ingredient
September 2, 1993 (58 FR 46589)	TFM Amendment to Include Docusate Salts, i.e., Docusate Calcium, Docusate Potassium, and Docusate Sodium, as Generally Recognized as Safe and Effective (GRASE) and Not Misbranded
March 31, 1994 (59 FR 15139)	TFM Amendment to Limit the OTC Drug Container Size for Sodium Phosphates Oral Solution to Not Greater Than 90 Milliliters (ml) (3 ounces (oz)) and to Add Warning
September 2, 1997 (62 FR 46223)	TFM Amendment to Reclassify the Stimulant Laxatives Danthron and Phenolphthalein from Category I (GRASE and Not Misbranded) to Category II (Not GRASE or Misbranded)
May 21, 1998 (63 FR 27886)	TFM Amendment to Include Additional General and Professional Labeling for Oral and Rectal Sodium Phosphates Drug Products
June 19, 1998 (63 FR 33592)	TFM Amendment to Reclassify the Stimulant Laxative Ingredients Aloe, Bisacodyl, Cascara Sagrada, and Senna Preparations from Proposed Category I to Category III (More Data Needed)
December 9, 1998 (63 FR 67817)	Notice of Withdrawal of Proposed TFM Amendment for Additional Professional Labeling for Oral and Rectal Sodium Phosphates Drug Products with Intent to Repropose
August 5, 2003 (68 FR 46133)	TFM Amendment to Reclassify the Bulk-Forming Laxative Psyllium Ingredients (Psyllium (Hemi-Cellulose), Psyllium Hydrophilic Mucilloid, Psyllium Seed, Psyllium Seed (Blond), Psyllium Seed Husks, Plantago Ovata Husks, and Plantago Seed)) in a Granular Dosage Form From Proposed Category I to Category II

Under § 330.10(a)(7)(v), new data and information submitted after the administrative record closed, before the establishment of a final monograph (FM), are considered a petition to amend the monograph and are to be considered only after a FM has been published unless FDA finds that good cause has been shown that warrants earlier consideration. Further, under § 330.10(a)(10)(ii), FDA shall make all decisions and issue all orders under § 330.10 in the FM solely on the basis of the administrative record and shall not consider data or information not included as part of the administrative record.

FDA has received new data and information submitted to the rulemaking for OTC laxative drug products after the administrative record closed on the various dates after the TFM amendments listed in table 1 of this document (excluding August 5, 2003, for which the administrative record remains open until November 3, 2003). In some cases, interested persons submitted a petition to reopen the record. In other cases, they submitted new data and information to the Division of Dockets Management as comments on the amended TFM. A number of the petitions and comments submitted to the amended TFM contain new data and information.

FDA has previously answered a number of these petitions (Refs. 1 through 7), and its response has been a final action on the petition. Thus, the current reopening of the administrative record does not include further comment on or consideration of the issues in these petitions. A summary of these petitions is included in table 2 of this document.

TABLE 2.—SUMMARY OF CITIZEN PETITIONS ON WHICH FDA HAS TAKEN FINAL ACTION

Docket code	Date of letter	Action	Subject
PDN14	June 4, 1996	Denial of CP18	Magnesium Citrate in Other Ddosage Forms
PDN4	August 22, 1997	Denial of CP14	Two 45 Milliliter Doses of Sodium Phosphates Oral Solution 10 to 12 Hours Apart as a Bowel Cleansing System

TABLE 2.—SUMMARY OF CITIZEN PETITIONS ON WHICH FDA HAS TAKEN FINAL ACTION—Continued

Docket code	Date of letter	Action	Subject
PDN5	August 22, 1997	Denial of CP16	Time to Action Statement for Enema Dosage of Glycerin
PDN6	September 5, 1997	Denial of CP13	Sorbitol in an Oral Dosage Form
ANS4	October 15, 1997	Denial of CP17	1,200 Milligram Single Dose of Magnesium Hydroxide
PDN7	January 7, 1998	Denial of CP23	Magnesium Citrate Powder for Oral Solution
PDN11	July 2, 2001	Denial of CP20 and response to C205	Bowel Cleansing System Using a Large Volume Tap Water Enema as the Final Cleansing Step

Because the data in other petitions and comments are relevant to the final classification of conditions for marketing OTC laxative drug products under the FM, FDA has determined that good cause exists to consider these new data and information in developing the FM for these products. By this document, FDA announces that it is treating all of these submissions (excluding the petitions listed in table 2 of this document), received after the administrative record closed at various times, as petitions to reopen the administrative record, and is granting the petitions by allowing the new data and information contained therein to be included in the administrative record for the rulemaking for OTC laxative drug products.

II. Reopening of the Administrative Record

Accordingly, FDA is reopening the administrative record for this rulemaking to provide the following actions: (1) Accept data and information previously submitted to the Division of Dockets Management after the administrative record closed following publication of the TFM and the various reopenings of the record listed in table 1 of this document and (2) provide interested persons an opportunity to submit comments on these data and information before the closing of the record.

FDA is providing a period of 90 days for these comments and new data and information to be submitted. Interested persons have already had an opportunity to submit objections or requests for an oral hearing on the amended TFM. Thus, this reopening of the administrative record to submit comments and information does not include submission of objections and requests for an oral hearing. Any comments at this time should specifically identify the data and information on which the comments are being provided. In addition, only new information related to the submissions being included in the administrative record at this time should be submitted.

Any data and information previously submitted to this rulemaking need not be resubmitted. In establishing an FM, FDA will consider only comments, data, and information submitted prior to the closing of the administrative record following this current reopening.

On August 5, 2003, FDA reopened the administrative record to reclassify the bulk-forming laxative psyllium ingredients (psyllium (hemicellulose), psyllium hydrophilic mucilloid, psyllium seed, psyllium seed (blond), psyllium seed husks, plantago ovata husks, and plantago seed)) in a granular dosage form from proposed Category I to Category II. Comments and information in response to that reopening of the administrative record should be submitted by November 3, 2003.

III. 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 three 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.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 1978N–036L and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. PDN14.
2. Comment No. PDN4.
3. Comment No. PDN5.
4. Comment No. PDN6.
5. Comment No. ANS4.
6. Comment No. PDN7.
7. Comment No. PDN11.

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26570 Filed 10–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–133791–02 and REG–105606–99]

RIN 1545–BABB and 1545–AX05

Credit for Increasing Research Activities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to proposed regulations that were published in the **Federal Register** on July 29, 2003 (68 FR 44499). This regulation relates to the computation and allocation of the credit for increasing research activities for members of a controlled group of corporations or a group of trades or businesses under common control.

FOR FURTHER INFORMATION CONTACT: Jolene J. Shiraishi at (202) 622–3120 (not a toll free number).

SUPPLEMENTARY INFORMATION: