

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.

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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: