



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

Food and Drug Administration
Rockville MD 20857

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James H. Conover, Ph.D.
Executive Director
Drug Regulatory Affairs and Compliance
The Purdue Frederick Company
100 Connecticut Avenue
Norwalk, Connecticut 06850-3590

Re: Docket No. 78N-036L
Comments Nos. CP18, CP23,
LET79, LET111, LET136

Dear Dr. Conover:

We refer to your citizen petition, dated May 22, 1996, filed as Comment No. CP23 under Docket No. 78N-036L in the Food and Drug Administration's (FDA) Dockets Management Branch. The petition was submitted in response to a letter from William E. Gilbertson, Pharm. D., dated December 6, 1994 (LET79, copy enclosed), requesting additional information to support the over-the-counter (OTC) marketing of magnesium citrate powder for oral solution.

The petition requests that the agency amend the tentative final monograph (TFM) for OTC laxative drug products to:

- (1) clarify that magnesium citrate may be supplied in any dosage form meeting the requirements of the directions for use of magnesium citrate in proposed § 334.58(d)(2);
- (2) provide for use of a formulation of magnesium citrate (25 grams) in a solid mixture, to be reconstituted before oral administration, as a component in both of the bowel cleansing systems identified in proposed § 334.32 (a) and (b); and
- (3) amend § 334.80 (professional labeling, bowel cleansing) to include any dosage form of magnesium citrate identified in § 334.16(a).

For the reasons given below, the agency considers action on the petition completed.

The agency is aware that a draft monograph for magnesium citrate powder for oral solution was published in the May-June issue of Pharmacopeial Forum (vol. 23, No. 3) for public comment and may be presented to the United States Pharmacopoeia (USP) Committee of Revision for possible official adoption. In addition, data support the use of magnesium citrate

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powder for oral solution for use as a single ingredient laxative drug product for inclusion in the final monograph for OTC laxative drug products. However, at this time, no USP monograph exists for magnesium citrate powder for oral solution, therefore, this ingredient cannot be included in a final monograph. Should a USP monograph for magnesium citrate powder for oral solution be published by the USP, we will again consider item 1 of your petition request of May 22, 1996. Accordingly, item 1 of your petition is denied.

Your petition request in items 2 and 3 concerning use of magnesium citrate powder for oral solution for use as a part of the bowel cleansing systems identified in proposed § 334.32 (a) and (b) and § 334.80 is also denied. As you may be aware, in a letter dated May 10, 1996 (LET111) (copy enclosed), the agency expressed concern about the safety of certain stimulant laxative drug product ingredients, including phenolphthalein and bisacodyl, components of the proposed bowel cleansing systems in § 334.32 (a) and (b). As stated in that letter, the agency intends to propose Category III status (more data needed) for bisacodyl. Further, FDA published in the FEDERAL REGISTER of September 2, 1997 (62 FR 46223), a notice of proposed rulemaking to amend the tentative final monograph for OTC laxative drug products (copy enclosed). This amendment proposed to reclassify phenolphthalein from Category I (safe and effective) to Category II (not safe or ineffective). Thus, a condition of Category II or III status of any one component of a bowel cleansing system is imputed to the whole. For these reasons, the agency must deny your petition.

If you have any questions regarding the petition, please refer to the docket number above and submit all inquiries, in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857.

Sincerely yours,



Ronald G. Chesemore
Associate Commissioner
for Regulatory Affairs



Enclosures