DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Servic

Food and Drug Administratio
Rockville MD 2085

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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
Comment No. CP18

Dear Dr. Conover:

This is in response to your citizen petition dated October 4, 1994, on behalf of The Purdue Frederick Company. The petition was filed on October 11, 1994 as Comment No. CP18 under Docket No. 78N-036L in FDA's Dockets Management Branch. The petition requested amendment of the tentative final monograph for over-the-counter (OTC) laxative drug products (50 FR 2124) to allow magnesium citrate to be supplied in any dosage form meeting the requirements of § 334.58(d)(2).

Specifically, the petition requested that a formulation of magnesium citrate (25 g) in a solid mixture, to be reconstituted before oral administration, be allowed in both of the bowel cleansing systems identified in § 334.32(a) and (b). The petition requested revision of a part of the professional labeling in proposed § 334.80(a)(2) from "For products containing magnesium citrate in oral solution identified in § 334.16(a)," to "For products containing magnesium citrate identified in § 334.16(a)".

The agency is denying your petition for the reasons stated in the letter dated December 6, 1994, from Dr. William E. Gilbertson of our Office of OTC Drug Evaluation (copy enclosed).

As Dr. Gilbertson advised in his letter, your petition did not provide adequate information to support the requested revision to allow magnesium citrate (25 g) to be supplied in a solid mixture to be reconstituted prior to oral administration. A United States Pharmacopeia (U.S.P.) monograph would need to be developed for magnesium citrate in a dosage form other than an oral solution in order for magnesium citrate in a solid mixture to be included in the monograph. Additional information regarding which form of magnesium citrate your company is proposing and how it will be reconstituted is also needed. (See specifically the discussion related to the Merck Index in Dr. Gilbertson's letter.) Also, as Dr. Gilbertson mentioned, safety issues need to be addressed and complete labeling text would be needed. Finally, as Dr.

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Gilbertson stated, you may submit a new petition when all of these issues have been addressed.

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

Sincerely yours,

Gary Dykstra

for Ronald Chesemore
Associate Commissioner for
Regulatory Affairs

Enclosure