



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AFA 325

Food and Drug Administration  
Rockville MD 20857

AUG 22 1997

Peter S. Reichertz, Esquire  
Arent, Fox, Kintner, Plotkin & Kahn  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339

8728 '97 AUG 29 A10:10

Re: Docket No. 78N-036L  
Comment No. CP10.  
Docket No. 78N-036L  
Comment No. CP14.  
Docket No. 78N-036L  
Comment No. CP16.

Dear Mr. Reichertz:

This letter concerns your above referenced citizen petitions submitted on behalf of C. B. Fleet Company, Inc., requesting amendment of the tentative final monograph (TFM) on over-the-counter (OTC) laxative drug products. The TFM was published in the Federal Register on January 15, 1985 (50 FR 2124).

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

**78N-036L\CP10**

The petition, dated April 22, 1991, requests that the TFM be amended to list the response times for the different forms of rectally administered stimulant laxatives so as to include a different response time (5-20 minutes) for enemas.

On July 23, 1991, Dr. Gilbertson issued a letter to you indicating that your request is reasonable and that based on your earlier petition 78N-036L\CP7, we plan to address the issue of response time for a stimulant laxative enema in the final monograph for OTC laxative drug products (copy enclosed).

Therefore, this petition (CP10) is moot. We are adding the petition to the public record for this rulemaking.

78N-036L

PDNS

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**78N-036LACP14**

The petition, dated March 23, 1993, requests that the TFM be amended to include two 45 mL doses of dibasic sodium phosphate/monobasic sodium phosphate solution (sodium phosphates oral solution, U.S.P.) in sequential administration 10 to 12 hours apart as a bowel cleansing system.

On March 1, 1996, Debra Bowen, M.D., Director, Division of OTC Drug Products, issued a letter to you concluding that the data submitted with the petition support the effectiveness, but not the safety, of two 45-mL doses of sodium phosphates oral solution given 10 to 12 hours apart, for OTC use as a bowel cleansing system (copy enclosed).

Accordingly, this petition is denied.

**78N-036LACP16**

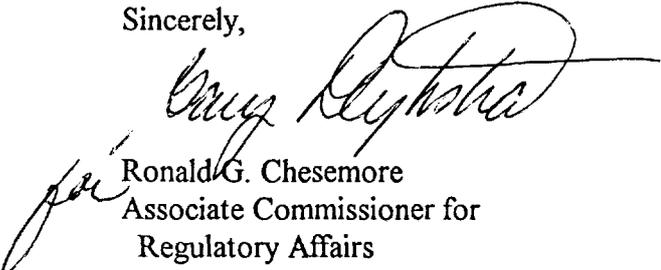
The petition, dated November 8, 1993, requests that the TFM be amended to include the following statement for an enema dosage form of glycerin: "This product generally produces a bowel movement in 2 to 15 minutes."

On July 24, 1995, Debra Bowen, M.D., Director, Division of OTC Drug Products, issued a letter to you concluding that the data submitted with the petition were inadequate to support your requested amendment of the TFM (copy enclosed).

Accordingly, this petition is denied.

If you have any questions regarding any of the petitions, please refer to the docket and comment numbers 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,



Ronald G. Chesemore  
Associate Commissioner for  
Regulatory Affairs

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Attachments:

July 23, 1991, letter from  
William E. Gilbertson, Pharm. D.  
To Peter S. Reichertz, Esq.

July 24, 1995, letter from  
William E. Gilbertson, Pharm. D.  
To Peter S. Reichertz, Esq.

March 1, 1996, letter from  
Debra Bowen, M.D.  
to Peter S. Reichertz, Esq.