

September 17, 2001

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**BY HAND**

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket 78N-036L  
Laxative Drug Products for OTC Human Use  
Submission of Information on Serious Adverse  
Events Associated with Sodium Phosphates Enemas  
And Oral Solution

Dear Sir/Madam:

We represent C.B. Fleet Company, Incorporated, of Lynchburg, Virginia (C.B. Fleet).

As indicated in my letter of July 25, 2001, in response to the letter of June 15, 2001, from Charles J. Ganley, M.D., Director, Division of OTC Drug Products, Office of Drug Evaluation V, Center for Drug Evaluation and Research, C.B. Fleet hereby submits redacted reports of all serious adverse reactions to Fleet® Ready-to-Use Enema and Fleet® Enema for Children (Sodium phosphates enemas) and Fleet® Phospho-Soda® (sodium phosphates oral solution) for the past ten (10) years, as agreed to with Mr. Al Rothschild of the Division of OTC Drug Products on July 25, 2001.

This information is being submitted voluntarily in response to the above-referenced FDA request. **Submission of this information does not constitute an admission by C.B. Fleet that the products caused or contributed to any of the adverse effects reported herein.** Furthermore, most of the adverse experiences and events reported herein appear to have resulted from over-dosage, use of the products in patients in whom their use is contraindicated, or other misuse of the products in contradiction to labeling.

The information included consists of the following information:

Fleet® Ready-to-Use Enema and Fleet® Enema for Children (Sodium Phosphate Enemas)

Tab A Total Units Sold (1991-2000) – U.S. only

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Tab B Summary of Published Reports of Serious Adverse Events Associated with Use of Fleet® Enema and Fleet® Enema for Children and Reprints of Articles (1991 - August 2001)

Tab C Summary of Reports of Serious Adverse Experiences Associated with Fleet Sodium Phosphate Enemas and relevant Product Log Reports from C.B. Fleet's Complaint Files (1991-August 2001)

Tab D Serious Adverse Events Associated with Sodium Phosphate Enemas Reported to FDA's Spontaneous Reporting System between 1991 and August 2001

Fleet® Phospho-Soda® (Sodium Phosphates Oral Solution)

Tab E Total Units Sold (1991-2000) – U.S. (Please note this includes information on Fleet® Prep Kits 1, 2 and 3, each of which contains one 1.5 fl. oz. unit of Fleet® Phospho-Soda®)

Tab F Summary of Published Reports of Serious Adverse Experiences Associated with Use of Fleet Phospho-soda and Reprints of Articles (1991 - August 2001)

Tab G Summary of Reports of Serious Adverse Events Associated with Fleet® Phospho-Soda® Oral Laxative and relevant Product Log Reports from C.B. Fleet's Complaint files. (1991-August 2001)

Tab H Serious Adverse Events Associated with Use of Fleet® Phospho-soda® Reported in the Australian Adverse Drug Reactions System

Tab I Serious Adverse Experiences Associated with Use of Fleet® Phospho-soda® Reported to FDA's Spontaneous Reporting System between 1991 and August, 2001

Please note, in the spirit of full and complete disclosure, all of the available information about serious adverse events from all sources – the literature, reports to C.B. Fleet (from all countries), and reports made to the FDA's Spontaneous Reporting System and the Australian Adverse Drug Reactions System have been included.

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C.B. Fleet believes that both Fleet® Encmas and Fleet® Phospho-soda® are safe and effective for use as laxatives and for bowel cleansing when used as directed, and should be found to be generally recognized as safe and effective for such uses.

Should there be any questions concerning this submission, please contact the undersigned.

Sincerely,



Peter S. Reichertz

Filed in triplicate

cc(w/enc.)(via Federal Express):

Mr. Albert Rothschild  
Division of OTC Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration  
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