

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 15 2001 3:8 PM JUN 25 11:53

C.B. Fleet Company, Inc.
 Attention: Sarah S. Post
 Vice President of Administration
 P.O. Box 11349
 4615 Murray Place
 Lynchburg, Virginia 24506

Re.: Docket No. 78N-036L

Dear Ms. ^{Post} Payne:

This is in reference to Fleet's sodium phosphates products for laxative and bowel cleansing use.

As part of our continuing review of the data and information relating to the safety of all over-the-counter (OTC) drug products, we are reviewing information on the safety of sodium phosphates in OTC laxative drug products. In connection with the review, we will appreciate your providing us with reports, for the past 10 years, of all serious adverse drug experiences (for the definition of serious adverse drug experience see 21 CFR 310.305(b)) associated with Fleet's sodium phosphates oral solution and sodium phosphates enemas. Please send the reports, in triplicate, to:

Dockets Management Branch (HFA -305)
 Docket No. 78N-036L
 Food and Drug Administration
 5630 Fishers Lane
 Room 1061
 Rockville, MD 20852

Also, please note that the reports will be included in the public docket for the rulemaking for OTC laxative drug products. Therefore, to assure patient privacy, please purge all patient names or change patient names to initials before sending the reports.

Please notify us, within the next four weeks, as to when you will be providing us with the information.

78N-036L

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HFD-560	<i>[Signature]</i>	6-14-01						

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Please call Mr. Rothschild at 301-827-2222, if you have any questions regarding this request.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

CC: HFA 305 (Feedback Processing 78N-036L)
HFD-560 Ganley/Katz/Rachanow/Segal/Shetty/Cothran/Robinson/Kerovich
HFD-560 Div Files Laxatives

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