SHEPPARD MULLIN
SHEPPARD MULLIN RICHTER & HAMPTON LLP
ATTORNEYS AT LAW

333 South Hope Street | 48th Floor | Los Angeles, CA 90071-1448
213-620-1780 *office* | 213-620-1398 *fax* | ***www.sheppardmullin.com***
Peter S. Reichertz
Writer's Direct Line: 202-772-5333
preichertz@sheppardmullin.com

2745 FEB 28 A9:27

February 27, 2006

Our File Number: 11GN-122370

VIA FEDEX

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

Re: Citizen Petition Requesting That FDA Modify the Tentative Final Monograph on Laxative Drug Products for Over-the-Counter Human use to Include Professional Labeling for 2 x 30 mL to 2 x 45 mL Dosing of Sodium Phosphates Oral Solution, Administered 10-12 Hours Apart
Docket No. 78N-036L/CP-28

Dear Sir or Madam:

On behalf of C.B. Fleet Company, Incorporated ("Fleet") of Lynchburg, Virginia, which markets an Over-the-Counter ("OTC") Sodium Phosphates Oral Solution under the brand name Fleet® Phospho-soda®, the undersigned submitted the above-referenced Citizen Petition requesting that the Food and Drug Administration ("FDA" or "the Agency") modify the Tentative Final Monograph on Laxative Drug Products for OTC Human Use ("TFM") to include professional labeling for 2 x 30 mL to 2 x 45 mL dosing of Sodium Phosphates Oral Solution, administered 10-12 hours apart. The purpose of the proposed professional labeling was to enable physicians to safely and effectively use Sodium Phosphates Oral Solution at a dosing regimen of 2 x 30 mL to 2 x 45 mL administered 10-12 hours apart for bowel cleansing purposes, prior to diagnostic procedures such as colonoscopy or x-ray, or prior to surgery.

Fleet has recently become aware of a letter dated October 27, 2005, from Braintree Laboratories, Inc. addressing a publication by Markowitz, et. al., reporting 21 cases of nephrocalcinosis, or, as identified by the authors, acute phosphate nephropathy, following

78N-036L LET 204

administration of sodium phosphates bowel cleansers, including Fleet® Phospho-soda® (Sodium Phosphates Oral Solution) and Visicol Tablets. Fleet had brought that article to the attention of the FDA and has made numerous submissions to the Agency with regard to this issue, and met with the Agency in January 2004 to discuss the issue. Fleet issued a "Dear Doctor" letter in February 2005 about this issue and has undertaken non-clinical and clinical studies, and made labeling changes to address the safety concerns raised by Markowitz, et. al., in this and other publications.

Fleet intends to submit in the near future a comprehensive amendment to the Petition with revised professional labeling and to submit all of the information it is aware of with regard to the relationship of sodium phosphates and nephrocalcinosis.

Please note the change of address of counsel of record with regard to the Petition:

Peter S. Reichertz
Sheppard Mullin Richter & Hampton LLP
1300 I Street, N.W.
11th Floor East
Washington, DC 20005-3314
Phone: 202-772-5333
Fax: 202-312-9426
preichertz@sheppardmullin.com

Respectfully Submitted,

Peter S. Reichertz
Counsel to C.B. Fleet Company, Incorporated

for SHEPPARD MULLIN RICHTER & HAMPTON LLP

Filed in Triplicate