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May 19, 2004

VIA FEDERAL EXPRESS

Division of Dockets Management (HFN-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Citizen Petition
Laxative Drug Product for Over-the-Counter Human Use
Docket 1978N-036L

Dear Sir/Madam:

The undersigned on behalf of C. B. Fleet Company, Incorporated, submits this Citizen Petition under 21 U.S.C. 301 et seq. of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §10.30 to request that the Commissioner of Food and Drugs ("the Commissioner") reopen the administrative record on the proposed rulemaking on Laxative Drug Products for Over-the-Counter ("OTC") Human Use, proposed 21 C.F.R. §334, 50 Fed. Reg. 2124, et seq. (January 15, 1985). [Docket No. 1978N-036L]

A. Action Requested

C.B. Fleet Company, Incorporated ("C.B. Fleet") requests the reopening of the administrative record on OTC Laxative Drug Products to accept the attached comment which requests that proposed 21 C.F.R. §334.56(d)(2) be changed from:

> (2) *Rectal enema dosage.* Adults and children over 12 years of age and over: rectal enema dosage is 120 milliliters in a single daily dose. Children 2 to under 12 years of age:

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rectal enema dosage is 60 milliliters in a single dose. Children under 2 years of age: consult a doctor.

to

(2) *Rectal enema dosage.* Adults and children over 12 years of age and over: rectal enema dosage is 118 milliliters in a single daily dose. Children 2 to under 12 years of age: rectal enema dosage is 59 milliliters in a single dose. Children under 2 years of age: consult a doctor.

B. Statement of Grounds

C.B. Fleet submits this Citizen Petition to request the Commissioner to order the administrative record in Docket No. 1978N-036L be reopened to accept the attached minor comment on the proposed rule on OTC Laxative Drug Products. In support of this petition, Fleet states the following.

C.B. Fleet filed comments on the proposed rulemaking for OTC Laxative Drug Products on January 19, 2004, in response to the Agency's reopening of the administrative record on October 22, 2003, at 68 Fed. Reg. 60302.19 but overlooked the proposed dosing requirement for lubricant laxatives contained in proposed 21 C.F.R. § 334.56(d)(2). The Agency had previously accepted a comment filed by C.B. Fleet on August 10, 1987. See CP0005 attached as Exhibit A. In reviewing its labeling for Fleet® Ready-to-Use Mineral Oil Enema for compliance with the proposed rule, C.B. Fleet became aware of a minor discrepancy in the amount of mineral oil between what C.B. Fleet has historically used and what is in the proposed rule contained in proposed 21 C.F.R. §334.56(d)(2). Reopening of the administrative record is clearly warranted in this case as it is in the public interest to provide correct dosing information regarding use of rectal lubricant laxative drug products. Furthermore, C.B. Fleet is the only company which

markets such a product. Therefore, C.B. Fleet requests that the Agency reopen the administrative record in Docket No. 1978N-036L to permit the attached comment to be filed.

C. Environmental Impact

A statement is not required since the promulgation of an OTC drug monographs does not require Environmental Impact Statements pursuant to 21 C.F.R. §25.1(f)(4).

D. Economic Impact

Not yet required pursuant to 21 C.F.R. §10.30(b).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

SONNENSCHEIN NATH & ROSENTHAL LLP

By: _____

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Counsel for C.B. Fleet Company, Incorporated

Dated: May 19, 2004

cc: Ms. Sarah S. Post
Ms. Valerie Ramsey
Ms. Kim Whalen
Joseph Kanapka, Ph.D.