DEPARTMENT OF HEALTH & HUMAN SERVICES

~~HFD~~ HFA-305
Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 16 2001

3809 '01 JAN 17 P2

Peter S. Reichertz
Arent Fox Kintner Plotkin & Kahn, PLLC
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5339

Re: Docket No. 78N-036L
Comments No. PRC2, CP7, CP8, LET40, LET41, PDN9, and C201/ANS

Dear Mr. Reichertz:

This is in response to your Petition for Reconsideration dated March 17, 2000, submitted on behalf of C.B. Fleet Company, Inc., and filed in FDA's Dockets Management Branch as Comment No. PRC2 under Docket No. 78N-036L. You referenced the agency's May 22, 1998 letter that denied two citizen petitions concerning bisacodyl as an over-the-counter (OTC) laxative (CP 7 and CP 8 under Docket No. 78N-036L), because of safety concerns. You stated that because the agency has now concluded that bisacodyl is safe , the agency should reconsider the May 22, 1998 denial and reinstate the findings of the two October 26, 1989 letters in which the agency proposed Category I (safe and effective) conditions for bisacodyl.

The Division of OTC Drug Products agrees with your Petition for Reconsideration to reinstate the findings of the October 26, 1989 letters. In a February 16, 2000 letter to Dr. Martin Kaplan, Boehringer Ingelheim, concerning results of carcinogenicity studies submitted to support the safety of bisacodyl, the Division stated that the totality of the data support the safety of bisacodyl for use as an OTC laxative. (See Comment No. C201/ANS, Docket No. 78N-036L.)

Therefore, the Division agrees that the Category I conditions discussed in the two October 26, 1989 letters in response to CP7 and CP8 (LET40 and LET41, respectively ) be included in the final monograph for OTC laxative drug products as follows:

1. Rectal enema dosage: Adults and children 12 years of age and over: 10 milligrams bisacodyl in 37.5 milliliters of aqueous suspension in a single daily dose. Children under 12: ask a doctor.

78N-036L

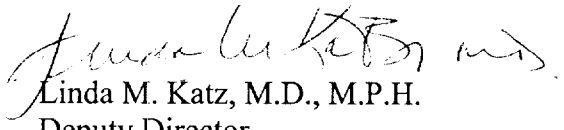
5
ANS/PRC2

2. A bowel cleansing kit containing the following 3 laxative drug products for sequential administration: dibasic sodium phosphate/monobasic sodium phosphate as an oral solution identified in § 334.16 and bisacodyl identified in § 334.18 in both an oral dosage form and a suppository dosage form.
3. A bowel cleansing kit containing the following 3 laxative drug products for sequential administration: dibasic sodium phosphate/monobasic sodium phosphate as an oral solution identified in § 334.16 and bisacodyl identified in § 334.18 in both an oral dosage form and an enema dosage form.

The Division of OTC Drug Products intends to recommend to the Commissioner that the agency respond to your petition for reconsideration in the above manner in the final monograph for OTC laxative drug products, which will be published in a future issue of the FEDERAL REGISTER.

Any comment you may wish to make on the above information should be submitted in three copies, identified with the docket and comment numbers shown at the beginning of this letter, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,



Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation
and Research