



OCT - 6 2004

Peter S. Reichertz, Esq.  
Sonnenschein, Nath & Rosenthal LLP  
1301 K Street, N.W.  
Suite 600, East Tower  
Washington, D.C. 20005

Re: Docket No. 1978N-036L  
Comment No. CP30

Dear Mr. Reichertz:

This letter is in response to your citizen petition (CP30), dated May 19, 2004, and filed under Docket No. 1978N-036L in the Division of Dockets Management on May 20, 2004, on behalf of C. B. Fleet Company, Inc. The petition requested that the Food and Drug Administration (FDA) reopen the administrative record for the tentative final monograph (TFM) on OTC laxative drug products (50 FR 2124) to accept a comment on the dosage of mineral oil enemas.

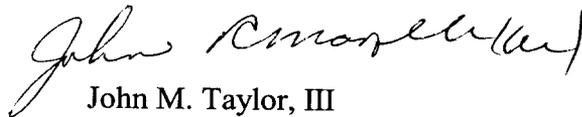
Your petition states that there is a minor discrepancy in the amount of mineral oil that C.B. Fleet has historically provided in its labeling for mineral oil enemas and what is proposed in the TFM. Specifically, you requested that the proposed rectal enema dosage for adults and children over 12 years of age in § 334.56(d)(2) be changed from 120 milliliters (mL) in a single dose to 118 mL. You also requested that the dosage for children 2 to under 12 years be changed from 60 mL to 59 mL. You stated that reopening of the administrative record is clearly warranted because it is in the public interest to provide correct dosing information for rectal lubricant drug products, and that C.B. Fleet is the only company that markets such a product.

FDA is granting and denying your petition for the following reasons. We have reviewed the mineral oil enema dosage recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel) (40 FR 12902 at 12940). The Panel recommended a 120 mL rectal dose for adults and 60 mL for children 3 years and older. The labeling for your client's mineral oil enema product that was submitted to the Panel bears a dose of 4 fluid ounces (fl. oz.) for adults and 2 fl. oz. for children. The Panel converted the fl. oz. doses to the metric system using a conversion factor of 30 mL/fl. oz. and obtained the 120 mL (adult) and 60 mL (children) doses. The more exact measure of 118 mL and 59 mL, respectively, is obtained by using the specific scientific conversion factor of 29.57 mL/fl. oz.

All of the pertinent dosing data for this mineral oil enema are already in the administrative record. Therefore, there is no need to reopen the administrative record at this time, and we are denying this part of your petition. However, FDA will make the dosing changes that you requested (i.e., change 120 mL to 118 mL and 60 mL to 59 mL) in the Laxative FM for the reasons stated in this letter. Accordingly, we are granting that part of your petition.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries (3 copies) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John M. Taylor, III".

John M. Taylor, III  
Associate Commissioner  
for Regulatory Affairs