DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-448/S-004

McNeil Consumer Healthcare
Attention: Hina S. Harlow, Pharm.D
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated February 28, 2006, received March 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium A-D (2 mg loperamide HCL) chewable tablets.

We acknowledge receipt of your submissions dated June 27, and September 8, 2006, and January 3, 2007.

Your submission of September 8, 2006 constituted a complete response to our June 30, 2006 action letter.

This supplemental new drug application provides for a new formulation, a new manufacturing facility, and a new tradename "Imodium A-D EZ Chews" for the Imodium A-D chewable tablets.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (20-count bottle label and 20-count carton label submitted January 3, 2007) and submitted labeling (40 and 60-count bottle and carton label submitted January 3, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66.

We remind you to remove the flag "New!" from the principal display panel six months after introduction into the marketplace.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-448/S-004**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joel Schiffenbauer

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