DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-140/S-012

McNeil Consumer Healthcare
Attention: Anne Marie O'Connell
Director, Global Technical Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. O'Connell:

Please refer to your supplemental new drug application dated May 11, 2007, received May 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium Advance (2 mg loperamide HCl and 125 mg simethicone) caplets.

We acknowledge receipt of your submissions dated September 4, 7, and 13, 2007.

This supplemental new drug application provides for a reformulation of the caplet that will replace the currently marketed product and revisions to the carton Drug Facts label and bottle labels for the 18- and 30-count sizes. According to your September 7, 2007 submission, the labeling for the 18- and 30-count package sizes is representative of the 12- and 42-count package sizes, respectively, with the only difference being the count size. In addition, according to your September 13, 2007 submission, no changes have been made to the blister backing for the 18-count (representative of the 12-count) package size.

We have completed our review of this application, as amended. This application is approved for the 18- and 30-count (representative of 12- and 42-count) package sizes, 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 (text for the 18- and 30-count carton label with Drug Facts (representative of the 12- and 42-count), and 30-count bottle label (representative 42-count) submitted on September 7, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for all represented stock keeping units 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 21-140/S-012**." 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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