DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-606/S-014
NDA 21-140/S-011

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 applications dated December 28, 2006, received December 29, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium Advanced (2 mg loperamide HCl and 125 mg simethicone) chewable tablets (NDA 20-606) and caplets (NDA 21-140).

We acknowledge receipt of your submissions dated October 16, 25 and 30, 2007, and March 28 and April 22, 2008.

The October 30, 2007 submissions constituted a complete response to our October 29, 2007 action letter.

These supplemental new drug applications propose to change the trade name of Imodium Advanced to Imodium Multi-Symptom Relief and associated labeling changes.

We have completed our review of the applications, as amended. The applications are approved, effective on the date of this letter, for use as recommended in the agreed upon labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (2-count caplet sample pouch, 1-count blister backing label for 6-count caplet blister card, 30- and 42-count caplet bottle labels, 12-, 18-, 30-, and 42-count caplet outer carton labels, 1-count blister backing label for 6-count chewable tablet blister card, and 18-count chewable tablet outer carton label submitted on April 22, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL for each NDA 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 these submissions as "**FPL for approved supplement**

NDA 20-606/S-014" and **"FPL for approved supplement NDA 21-140/S-011**." Approval of these submissions by FDA is not required before the labeling is used.

We remind you of our commitment to allow you to use the already-printed labels that contain these minor editorial differences from the agreed upon labeling:

1. The indication statement in the Drug Facts labeling reads "controls symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas" rather than "relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas."

2. The statement on the principal display panel (PDP) reads "Relief of diarrhea plus: Gas · Cramps · Pressure · Bloating" instead of "Relief of diarrhea plus: Gas · Cramps and Pressure · Bloating."

3. The font size of the PDP flag "INTRODUCING Formerly Imodium Advanced" is smaller.

4. The statement of identity, "Loperamide HCl, 2 mg/…Simethicone, 125 mg… Antidiarrheal/Anti-Gas," on the PDP is printed in a smaller font and appears in a less conspicuous location.

We remind you of your April 22, 2008 commitment not to print additional copies of the originally-printed labeling. All further printing of labels for these products must be identical to the agreed upon labeling referenced above.

We also remind you to remove the statement "INTRODUCING Formerly Imodium Advanced" from the principal display panel 6 months after the first label is introduced to the OTC marketplace.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs 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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
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
4/30/2008 08:36:47 AM