DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021140/S-016

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Division of McNeil-PPC, Inc.
Attention: John F. Hauser
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Mr. Hauser:

Please refer to your Supplemental New Drug Application (sNDA) dated November 14, 2011 and received November 14, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imodium® Multi-Symptom Relief (loperamide hydrochloride, 2 mg/simethicone, 125 mg) tablets (capsule-shaped).

This "Prior Approval" supplemental new drug application provides for two "bonus" package sizes of Imodium® Multi-Symptom Relief (loperamide hydrochloride, 2 mg/simethicone, 125 mg) tablets (capsule-shaped) in the following count sizes: 24-count (18 + 6 free tablets) and 54-count (42 + 12 free tablets).

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

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (except as noted below) submitted on November 14, 2011, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

- Imodium® Multi Symptom Relief
  - 24-count (18 + 6 free tablets) carton label
  - 54-count (42 + 12 free tablets) carton label
  - 54-count (42 + 12 free tablets) immediate container (bottle) label

The 54-count carton PDP label and the 54-count bottle PDP label need to be made consistent with the 24-count carton PDP label by reversing the order of the words "[bullet] Gas and [bullet] Bloating" as in the following to read: "Diarrhea PLUS [bullet] Cramps & Pressure [bullet] Bloating [bullet] Gas". This change may be considered to be a minor editorial change and can be submitted with the final printed labeling. Submit these labels as part of the FPL for this

supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

Even though no revisions were made to the blister card (immediate container), submit the immediate container (blister card for the 24-count carton) as part of the FPL for this supplement in order to maintain a record of the complete labeling being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021140/S-016**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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 Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures: Carton and Container Labeling

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
05/03/2012