DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021140/S-020

SUPPLEMENT APPROVAL

McNeil Consumer Health Care
Attention: Victoria Wagner-Weber
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your Supplemental New Drug Application (sNDA) dated September 18, 2014, received on September 18, 2014, submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imodium Multi Symptom Relief Caplets (loperamide hydrochloride 2 mg and simethicone 125 mg).

We acknowledge receipt of your amendment dated March 5, 2015.

This "Prior Approval" sNDA provides for the following labeling revisions:

- increases graphic sizes, adds a new flag and text on the principle display panel, and new warning and direction statements in the Drug Facts labeling
- changes to the opening mechanism for the blister card and the accompanying graphics and text directions for opening the blister.

We have completed our review of this application, as amended. 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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling submitted on March 5, 2015 and must be in the Drug Facts labeling format (21 CFR 201.66), where applicable:

Outer Carton Labeling

- 12-count blister carton,
- 18-count blister carton
- 24-count (18 + 6) bonus blister carton
- 30-count bottle carton,
- 42-count bottle carton
- 54-count (42 + 12) bonus bottle carton

Immediate Container Label

- 30-count bottle,
- 42-count bottle
- 54-count bottle
- 6-count blister card label

Your submission dated March 5, 2015, notified us that the 12-count blister carton labeling is intended to represent the 18-count blister carton labeling, the 30-count bottle carton labeling is intended to represent the 42-count bottle carton labeling, and the 30-count bottle (immediate container) label is intended to represent the 42-, and 52-count bottle (immediate container) labels, as representative package sizes. Any changes approved for the submitted representative labeling will be incorporated onto the labeling of the represented package sizes, which are identical to the submitted respective representative labeling, with the exception of the count size.

The FPL 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-020."** 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. Because none of these criteria apply to your application, you are exempt from this requirement.

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 Daniel Reed, Regulatory Project Manager, at (301) 796-2220.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

THERESA M MICHELE
03/18/2015