DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20606/S-017

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer, Inc.
McNeil Consumer Healthcare Division
Attention: Timothy Kline, Ph.D., RAC
Senior Associate, Regulatory
7050 Camp Hill Road
Fort Washington, PA 19034-2210

Dear Dr. Kline:

Please refer to your Supplemental New Drug Application (sNDA) dated January 19, 2017, received January 19, 2017, 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) chewable tablet.

This "Changes Being Effected" sNDA provides for the addition of the "Heart Alert" in accordance with the "Changes Being Effected" (CBE-0) Request Letter from the Agency dated August 12, 2016; and, revision of pediatric dosing as requested by the Agency on December 15, 2016.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the Imodium® Multi-Symptom Relief (loperamide hydrochloride 2 mg, simethicone 125 mg) chewable tablet (loperamide hydrochloride) chewable tablet, 2mg 18-count carton (blister) submitted on January 19, 2017, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 20606/S-017**." 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 CAPT Janice Adams-King, Safety Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
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/

VALERIE S PRATT
04/12/2017