DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 21140/S-026

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer, Inc.
McNeil Consumer Healthcare Division
Attention: Cindy Abraham
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2210

Dear Ms. Abraham:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 11, 2018, 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) tablet.

This "Prior Approval" supplemental new drug application provides for:

- Cartons no larger than 24-count and limited to blister packaging only
- After "**Ask a doctor before use if you have**" the bullet "a history of abnormal heart rhythm" has been added to the end of the list
- After "**Ask a doctor or pharmacist before use if you are taking**", the statement "a prescription drug. Loperamide may interact with certain prescription drugs" follows, and "antibiotics" has been removed

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 and with the following minor editorial revision: include copyright dates.

We are approving the submission for packages containing a maximum of 48 mg loperamide, unit-dose packaging, and attendant labeling to changes to support ongoing efforts to ensure the safe use of loperamide hydrochloride.

LABELING

Submit final printed labeling, with the revisions listed above, 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 labeling identified in the below table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
4-count carton (blister)	December 3, 2018
6-count carton (blister)	December 3, 2018
8-count carton (blister)	December 3, 2018
12-count carton (blister)	December 3, 2018
18-count carton (blister)	December 3, 2018
24-count carton (blister)	December 3, 2018
4-count immediate container (blister)	August 10, 2018
6-count immediate container (blister)	August 10, 2018

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21140/S-026**." 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 Janice Adams-King, Safety Regulatory 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

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
12/11/2018