DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19487/S-028

SUPPLEMENT APPROVAL

Johnson & Johnson Consumer Inc.
Attention: Jennifer Norman, R.Ph.
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Norman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 5, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imodium® A-D (loperamide hydrochloride) solution, 1 mg per 7.5 mL.

This sNDA provides for the following labeling revisions:

- Change the dosage formulation statement on the Principal Display Panel from *Liquid* to *Oral Solution.*
- Change *Directions* in Drug Facts label (DFL) to include only metric units.
- Update to include the current distributor information.

LABELING

Submit final printed labeling (FPL) identical to the 120-count label submitted on January 27, 2016:

- 4 fluid ounces (fl oz) immediate container (bottle) *version 1*
- 4 fluid ounces (fl oz) immediate container (bottle) *version 2*
- 4 fluid ounces (fl oz) immediate container (bottle)
  For ages 6 years & up, version 1
- 4 fluid ounces (fl oz) immediate container (bottle)
  For ages 6 years & up, version 2
- 8 fluid ounces (fl oz) immediate container (bottle) *version 1*
- 8 fluid ounces (fl oz) immediate container (bottle) *version 2*
- Dosing cup representation

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 19487/S-028**." 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 Dan Brum, Chief of the Project Management Staff, at (301) 796-0578.

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
04/05/2016