DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022015/S-026

SUPPLEMENT APPROVAL

Bayer Healthcare LLC
Attention: Joanna Fleming
Associate Director, Regulatory Affairs
100 Bayer Blvd
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated April 28, 2016, received Apri1 29, 2016, and your amendment submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MiraLAX (polyethylene glycol 3350), powder for solution.

This "Prior Approval" supplement provides for the following changes:

- Updates the flag shape and colors on the front labels for the 30-, 36- and 45-dose bottle presentations.
- Adds Instant Rebate Coupons for the 14-, 30-, and 45-dose bottles.
- Removes the website link from the Drug Facts labeling for the 7-, 14-, 30-, 34- (for the 34-plus 34-dose "Twin Pack!" bottle label), 36-, and 45-dose bottles.

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 minor editorial revision below:

Submit final printed labeling (FPL) identical to the following labels received on April 29, 2016:

- 30-, 36- and 45-dose front bottle labels
- Hang Tag Instant Redeemable Coupons listed below

Hang Tag Coupon Value	SKU
Save $5	30, 45 Dose Bottles
Save $4	30, 45 Dose Bottles
Save $3	30, 45 Dose Bottles
Save $2	14, 30, 45 Dose Bottles
Save $1	14, 30, 45 Dose Bottles

and identical to the following labels received on August 30, 2016:

- 7- and 14-dose front and back bottle labels
- 30-, 36- and 45-dose back bottle labels

- 34-dose front and back bottle labels (for the 34-plus 34-dose "Twin Pack!" bottle label)

LABELING

Submit final printed labeling (FPL) identical to the following labels received on August 29, 2016.

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 022015/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.

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}

Karen Murry Mahoney, MD, FACE
Deputy 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/

KAREN M MAHONEY
10/21/2016