DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022015/S-035

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Joanna Fleming
Associate Director, Regulatory Affairs
100 Bayer Boulevard
PO Box 915
Whippany, NJ 07981-0915

Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 12, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MiraLAX (polyethylene glycol 3350) powder for solution, 17 g per dose.

This "Prior Approval" sNDA provides for the following:

- addition of "#1 Doctor Recommended Brand" icon on the principal display panel (PDP)
- addition of two bulleted statements in the Directions section of the drug facts label (DFL):
  - "ensure that the powder is fully dissolved before drinking"
  - "do not drink if there are any clumps"

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 below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission date(s)
Cartons	
1x17 g (single-dose) immediate container (sachet) for use in 24-ct carton	June 12, 2018
1x17 g (single-dose) "Sample – Not for Sale" immediate container (sachet) for use in 24-ct "Sample" carton	June 12, 2018
1x17 g (single-dose) "Not For Individual Sale" immediate container (sachet) for use in 3-, 10- , 20-ct cartons and "2 Free Mix-In PAX Single Dose Packets" + 14- dose immediate container (bottle) presentation	June 12, 2018
3-count carton	June 12, 2018
10-ct carton (alternative Die line A presentation)	September 21, 2018
10-ct carton (alternative Die line B presentation)	September 21, 2018
20-count carton (alternative Die line A presentation)	June 12, 2018
20-count carton (alternative Die line A presentation)	June 12, 2018
24-count carton	June 12, 2018
24-count "Sample" carton	June 12, 2018
40-ct "Twin Pack" outer carton (holds two 20-count cartons)	November 8, 2018
Bottles	
7-dose bottle, front/back label	June 12, 2018
14-dose bottle, front/back label	June 12, 2018
30-dose bottle, front/back label	June 12, 2018
36-dose bottle, front/back label	June 12, 2018
45-dose bottle, front/back label	June 12, 2018
34-dose bottle, front/back label	June 12, 2018
34-dose bottle, front/back label with "Twin Pack!" flag	June 12, 2018
2x34-dose bottle Twin Pack bottles, presentation front/back	June 12, 2018
14-dose bottle with 2 free sachets with a shrink wrap package presentation	June 12, 2018

The FPL 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 022015/S-035**." 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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
06/03/2019 02:44:03 PM

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