NDA 22015/S-040

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Oliwier Nowak, PharmD, RAC
Manager, Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981

Dear Dr. Nowak:

Please refer to your supplemental new drug application (sNDA) dated and received October 30, 2020, 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" supplemental new drug application provides for alternative die lines labeling for all three 1-count sachet labels and changes to the Drug Facts labeling "Directions" section by:

- Adding "[bullet] do not combine with starch-based thickeners used for difficulty swallowing"
- Changing "[bullet] use no more than 7 days" to "[bullet] do not use more than 7 days"
- Revising the order of bulleted direction statements

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and be identical to the labels submitted on March 5, 2021; March 10, 2021; and April 9, 2021 as outlined in the table below.

Submitted Labeling	Date Submitted
1-Count Sachet – Barcode (used in 24-Count Carton Dispenser) (A die line versions)	March 5, 2021
1-Count Sachet – Barcode (used in 24-Count Carton Dispenser) (B die line versions)	March 10, 2021
1-Count Sachet – Not for Individual Sale (used in 10-, 20-Count Carton) (A and B die line versions)	March 5, 2021
1-Count Sachet – Patient Sample Not for Sale (used in 24-Count Sample Carton) (A and B die line versions)	March 5, 2021
7-Dose Bottle	April 9, 2021
14-Dose Bottle	April 9, 2021
30-Dose Bottle	March 5, 2021
36-Dose Bottle	March 5, 2021
45-Dose Bottle	March 5, 2021
34-Dose Bottle for 68-Dose Twin Pack (2 x 34 Dose Bottle)	March 5, 2021
10-Count Carton (A and B die line versions)	March 5, 2021
20-Count Carton (A and B die line versions)	March 5, 2021
24-Count Carton Dispenser	March 5, 2021
24-Count Patient Sample Carton	March 5, 2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22015/S-040**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 Helen Lee, PharmD, Safety Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
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/

VALERIE S PRATT
04/27/2021 05:32:42 PM