



NDA 22015/S-043

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 January 11, 2022, 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 the addition of "Easy to Open & Pour" on the labeling and associated update in count size for MiraLAX (polyethylene glycol 3350) powder for solution.

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 identical to the following:

Submitted Labeling	Date Submitted
1-Count Sachet – Barcode (used in 24-Count Sample Carton) (A and B die line versions)	June 24, 2022
1-Count Sachet – Not for Individual Sale (used in 10, 20 Count Sample Carton) (A and B die line versions)	June 24, 2022
1-Count Sachet – Patient Sample Not for Sale (used in 24-Count Sample Carton) (A and B die line versions)	June 24, 2022
10-Count Carton (A and B die line versions)	June 24, 2022
20-Count Carton (A and B die line versions)	June 24, 2022
24-Count Carton	June 24, 2022
24-Count Patient Sample Carton	June 24, 2022

Submitted Labeling	Date Submitted
20-Count Patient Sample Carton	June 24, 2022
1-Count Sachet – Patient Sample Not for Sale (used in 20-Count Sample Carton)	June 24, 2022

In addition, to maintain the “#1 doctor recommended” claim, during future survey data collection, we recommend updating the data collection methods. For instance, ensure that the physicians are recommending MiraLAX for the OTC indication and not for Rx indication. We also recommend adding a disclaimer that links (using an asterisk) the “#1 doctor recommended” statement with the data source. The disclaimer should state how the “#1 doctor recommended” statement is validated by the data. Lastly, remove the term “NEW!” from the promotional statement “NEW! Easy to Open & Pour” statement after 6 months.

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-043.**” 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.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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>

If you have any questions, call Cynthia Kim, PharmD, BCPS, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton 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/

NUSHIN F TODD
07/05/2022 11:24:47 AM