



NDA 22015/S-047

## SUPPLEMENT APPROVAL

Bayer HealthCare LLC  
Attention: Meriem Karimi, MPH  
Manager, Regulatory Affairs  
100 Bayer Boulevard

Dear Meriem Karimi:

Please refer to your supplemental new drug application (sNDA) dated and received January 20, 2023, 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 a new accordion-style (i.e., fold-out) Drug Facts label (DFL) for the 7-count stand-alone bottle presentation.

### **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:

<b>Submitted Labeling</b>	<b>Date Submitted</b>
Drug Facts Label (DFL) for 7-Count Immediate Container (Bottle)	July 26, 2023

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 22015/S-047.**” Approval of this submission by FDA is not required before the labeling is used.

In order to provide adequate directions for use, ensure that future labels allocate sufficient space for all required labeling statements and indices.

## **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.<sup>2</sup> 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).

---

<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, call Cynthia Kim, Senior 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  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

---

CYNTHIA N KIM  
07/27/2023 11:39:42 AM

NUSHIN F TODD  
07/27/2023 12:17:30 PM