



NDA 022015/S-023

SUPPLEMENT APPROVAL

Bayer HealthCare, LLC
Consumer Care
Attention: Joanna Fleming
Senior Manager, Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated April 28, 2015, received April 29, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MiraLAX (polyethylene glycol 3350) powder for solution, 17 g.

We acknowledge receipt of your amendment dated October 5, 2015.

This sNDA provides for labeling to reflect ownership by Bayer HealthCare, LLC and other additions and revisions to labeling as listed below:

Adds 24-count carton and 50-count *sample* carton

Revises 10-count carton

Revises 7-dose and 14-dose bottles

Revises 30-, 36-, and 45-dose bottles

Adds two different co-packaged retail configurations

- A co-package containing two identical 45-dose bottles packaged as a *twin pack*
- A co-package containing two different bottle sizes, a 45-dose bottle and a 14-dose *travel* bottle

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 in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the following labels submitted on April 28, 2015:

- 1-dose immediate container (sachet)
- 1-dose “Not For Individual Sale” immediate container (sachet)
- 1-dose “Sample – Not for Sale” immediate container (sachet)

- 10- and 24-count carton
- 36- and 45-dose bottle
- 45- plus 14-dose “Travel Size” package
- Two identical 45-dose bottles *twin pack* package

and identical to the following labels submitted on October 5, 2015:

- 50-count *Sample* carton
- 7-, 14- and 30-dose bottle

In addition, note that our approval of the 45-dose twin pack and 45 plus 14 dose “Travel Size” bottle labeling does not represent approval of all possible MiraLAX products that could be packaged together. Other configurations and larger total count package sizes will require review, as they may have clinical, consumer use, safety and/or quality implications (such as stability and expiratory issues) unique to each drug product.

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-023.**” 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 questions, contact Jeffrey Buchanan, Regulatory Health Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD
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
10/29/2015