



NDA 022015/S-012

SUPPLEMENT APPROVAL

Merck Consumer Care, Inc.
Attention: Ms. Verna Mecadon
Associate Director, Regulatory Affairs
556 Morris Avenue
Summit, NJ 07901

Dear Ms. Mecadon:

Please refer to your Supplemental New Drug Application (sNDA) dated March 4, 2011, received March 7, 2011 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 amendments dated August 12 and 31, and September 2, 6 and 20, 2011.

The September 20, 2011 submission constituted a complete response to our September 7, 2011 action letter.

This "Prior Approval" supplemental new drug application proposes the addition of a "POWDER dot" graphic to the Principle Display Panel with the following claims:

1. Unflavored
2. POWDER
3. Grit Free

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed 1-count immediate container (packet) label, the 10-count carton label, and the 7-, 14-, and 30-dose immediate container (bottle) labels submitted on September 20, 2011, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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 22015/S-012.**” 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.

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 any questions, call Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
Office of Drug Evaluation IV
Division of Nonprescription Clinical Evaluation
Center for Drug Evaluation and Research

Enclosures: 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/

ANDREA LEONARD SEGAL
03/15/2012