



NDA 022015/S-006

SUPPLEMENT APPROVAL

Schering-Plough HealthCare Products, Inc.
Attention: William Cochran
Senior Manager, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Mr. Cochran:

Please refer to your April 14, 2009 supplemental new drug application, received April 15, 2009, 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 submissions dated July 14, October 7, October 27, and November 4, 2009 and April 20, 2010.

Your submission of November 4, 2009 constituted a complete response to our October 15, 2009 action letter.

This "Prior Approval" supplemental new drug application provides for the addition of a 10-count carton with the trademarked name "NeatPAX", the text "Travel Size" underneath with an illustration of a single packet being poured into a glass filled with liquid on the principal display panel (PDP); an illustration of a glass filled with liquid and a cup filled with a hot beverage on the right side panel and an illustration of a single packet in the opening of a purse with the text "Travel Size" and "10 Pre-Measured, Single Doses" on the left side panel. In addition, the supplement provides for the addition of the trademarked name "NeatPAX" and the text "Travel Size" on the PDP of the single dose packet. The supplement also provides for the addition of the descriptor "Osmotic" before the word Laxative on the statement of identity; the addition of "(Irregularity)" to the bullet text "Relieves Occasional Constipation" on the PDP to read "Relieves Occasional Constipation (Irregularity), and the additional statement "Sugar Free" outside the Drug Facts box for all packages (7-, 14- and 30-dose bottles, 10-count single dose carton and single dose packet).

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 labeling (1-count immediate container (single dose packet) label submitted April 20, 2010, the 7-, 14- and 30-dose

immediate container (bottle) labels submitted October 27, 2009 and the 10-count carton label submitted April 20, 2010), 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 (October 2005)*. 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-006.**” Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

Sincerely,

{See appended electronic signature page}

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

Enclosure

Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22015	SUPPL-6	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	MIRALAX

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
05/05/2010