Dear Ms. Fleming:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 13, 2017, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MiraLAX (polyethylene glycol 3350) powder for solution.

This “Prior Approval” sNDA provides for the following:

- Replacement of the 50-count sample carton with a new 24-count sample carton
- Addition of the text “Patient Samples Not for Sale” to the principal display panel and side panels
- Removal of flag “24 Single Doses” in the upper left corner of the principal display panel
- Removal of the bar code

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 identical to the 24-count outer carton (sample) submitted on April 13, 2017, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable. Although no revisions were made to the 24-count immediate container (sachet) label, submit this as part of the FPL for this supplement in order to maintain a record of complete labeling.
The FPL should be submitted electronically according to the guidance for industry titled
Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical
Product Applications and Related Submissions Using the eCTD Specifications (May 2015,
Revision 3). For administrative purposes, designate this submission “Final Printed Labeling
for approved NDA 022015/S-027.” 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
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
CM072392.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 any questions, call Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton 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
10/04/2017