NDA 018983-S51

SUPPLEMENT APPROVAL

Mylan Specialty, L.P.
Attention: Robert Barto
Senior Director, Regulatory Affairs
781 Chestnut Ridge Rd.
P.O. Box 4310
Morgantown, WV 26504

Dear Mr. Barto:

Please refer to your supplemental new drug application (sNDA) dated and received on February 10, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Colyte with Flavor Packs (peg-3350 & electrolytes for oral solution).

We also refer to our letter dated February 1, 2021 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for polyethylene glycol (PEG) 3350 containing products. This information pertains to the risk of aspiration when mixed with starch-base thickener for patients with dysphasia.

This supplemental new drug application provides for revisions to the labeling for Colyte with Flavor Packs, consistent with our February 1,2021.

APPROVAL & LABELING

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

We note that your April 19, 2021, submission includes final printed labeling (FPL) for your Prescribing Information, Instruction For Use, and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (Prescribing Information, Instruction For Use and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Anum Shami, PharmD, Regulatory Project Manager, at (301) 837-7103.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instruction For Use

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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/

JOYCE A KORVICK
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