DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206940-S005

SUPPLEMENT APPROVAL

Allergan Holdings Unlimited Company
Attention: Kerri Kaplan, Pharm.D.
Director, Regulatory Affairs
Harborside Financial Center, Plaza V
Jersey City, NJ 07311

Dear Dr. Kaplan:

Please refer to your Supplemental New Drug Application (sNDA) dated October 12, 2017, received under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viberzi (eluxadoline) Tablets, 75mg and 100 mg.

We also refer to our letter dated September 14, 2017, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Viberzi (eluxadoline). This information pertains to the risk of anaphylaxis and hypersensitivity.

This supplemental new drug application provides for revisions to the labeling for Viberzi (eluxadoline). The agreed upon changes to the language included in our September 14, 2017, letter are as follows (additions are noted by underline and deletion are noted by ~~strikethrough~~).

Highlights

----------CONTRAINDICATIONS----------

- **patients with a known hypersensitivity reaction to VIBERZI (4, 5.3)**

----------ADVERSE REACTIONS----------

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1- 800-~~433~~678-~~8871~~1605or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

5 WARNINGS AND PRECAUTIONS

5.3 Hypersensitivity Reactions

In postmarketing experience, serious hypersensitivity reactions (including anaphylaxis) (b) (4) ; have been reported following VIBERZI administration. Some of these reactions occurred after the first one or two doses of VIBERZI *[see Adverse Reactions (6.2)]*.

6.2 Postmarketing Experience

Hypersensitivity: (b) (4) anaphylaxis, angioedema (e.g. swollen face and throat), dyspnea, throat tightness, and chest pain/tightness *[see Warnings and Precautions (5.3)]*. (b) (4)

Medication Guide

What is the most important information I should know about VIBERZI?
VIBERZI can cause serious side effects, including:

- Serious allergic reactions. Serious allergic reactions have happened in some people after taking 1 or 2 doses of VIBERZI. Stop taking VIBERZI right away and get emergency medical care if you have signs or symptoms of an allergic reaction, including:
  - swelling of your face, lips, mouth or tongue
  - shortness of breath or other breathing problems
  - ~~fainting, dizziness, feeling lightheaded (low blood pressure)~~
  - itching
  - rash
  - hives

APPROVAL & LABELING

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

We note that your October 12, 2017, submission includes final printed labeling (FPL) for your package insert, Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, 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 titled "SPL Standard for Content of Labeling Technical Qs and As"

at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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

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 Evangela Covert, Regulatory Project Manager, at (301) 796-4075.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Prescribing Information
Medication Guide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
11/08/2017