NDA 216578/S-004

SUPPLEMENT APPROVAL

Astellas Pharma US, Inc.
Attention: Sanja Kurtagic-Kadunic
Associate Director, Regulatory Affairs
Astellas Pharma Global Development, Inc.
2375 Waterview Drive
Northbrook, IL 60062

Dear Sanja Kurtagic-Kadunic:

Refer to your supplemental new drug application (sNDA) dated and received, November 15, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Veozah (fezolinetant) oral tablet.

We also refer to our letter dated October 17, 2024, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for Veozah. This information pertains to the risk of symptomatic hepatotoxicity.

This supplemental new drug application provides for revisions to the labeling for Veozah consistent with our October 17, 2024, letter.

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.

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 (text for the Prescribing Information, Patient Package Insert), 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.

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

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental 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 Meredith Hillig, MS, Safety Regulatory Project Manager, at Meredith.hillig@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Christina Chang, M.D., M.P.H.
Division Director
Division of Urologic, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

[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.

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/

CHRISTINA Y CHANG
12/16/2024 06:44:01 PM