NDA 021518/S-017

SUPPLEMENT APPROVAL

Astellas Pharma US, Inc.
Attention: Jennifer M. LaMora
Associate Director, Regulatory Affairs
1 Astellas Way
Northbrook, IL 60062

Dear Ms. LaMora:

Please refer to your supplemental new drug application (sNDA) dated and received March 3, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VESIcare (solifenacin succinate) tablets.

We acknowledge receipt of your amendment dated November 27, 2019, which constituted a complete response to our August 28, 2017, action letter.

This Prior Approval supplemental new drug application provides for:

- Updates to the **USE IN SPECIFIC POPULATIONS** section to align with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) and to revise the **Pediatric Use** subsection to indicate that the safety and effectiveness of VESIcare Tablets have not been established in pediatric patients

- Addition of “adults” to the indication statement in the **INDICATIONS AND USAGE** section

- Addition of “dizziness”, “urinary retention” and “vomiting” in the **ADVERSE REACTIONS**, **Post-Marketing Experience** section

- Editorial changes to **DOSAGE AND ADMINISTRATION, DOSAGE FORMS AND STRENGTHS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, DRUG INTERACTIONS, CLINICAL PHARMACOLOGY, NONCLINICAL TOXICOLOGY, CLINICAL STUDIES, and PATIENT COUNSELING INFORMATION** sections for consistency across labels for the different dosage forms of solifenacin succinate.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, and 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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).

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

[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.

the claimed indication 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.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated March 3, 2017, containing the final reports for the following postmarketing requirement listed in theMay 28, 2014, postmarketing requirement letter.

> 353-3 Pediatric studies under PREA for the treatment of overactive bladder in pediatric patients for ages five to 11 years old and adolescents for ages 12 to 17 years old.

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes your postmarketing requirement acknowledged in our May 28, 2014, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, please call Nenita Crisostomo, Regulatory Health Project Manager, at 301-796-0875.

Sincerely,

{See appended electronic signature page}

Christine P. Nguyen, M.D.
Director (Acting)
Division of Urology, Obstetrics, and Gynecology
Office of Rare Disease, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

CHRISTINE P NGUYEN
05/26/2020 04:58:21 PM