NDA 209949/S-006
NDA 209949/S-007

SUPPLEMENT APPROVAL

Xellia Pharmaceuticals, ApS
c/o Xellia Pharmaceuticals USA, LLC
Attention: Mark Kopulos
Senior Director, Regulatory Affairs
2150 E. Lake Cook Road, Suite 1015
Buffalo Grove, IL 60089

Dear Mr. Kopulos:

Please refer to your supplemental new drug applications (sNDAs) dated and received April 4, 2020, for NDA 209949/S-006, and July 22, 2020, for NDA 209949/S-007, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for daptomycin for injection, 350 mg/vial.

We acknowledge receipt of your amendment to supplement 006, dated March 5, 2021, which constituted a complete response to our February 12, 2021, action letter.

Prior approval supplement 006 provides for the addition of pediatric patients (1 to 17 years of age) to the approved indication for the treatment of complicated skin and skin structure infections (cSSSI).

Prior approval supplement 007 provides for the addition of pediatric patients to the indication for the treatment of *Staphylococcus aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).

Specifically, these prior approval supplemental applications provide for revisions to the **INDICATIONS AND USAGE (1)**, **DOSAGE AND ADMINSTRATION (2)**, **ADVERSE REACTIONS (6)**, **CLINICAL PHARMACOLOGY (12)**, and **CLINICAL STUDIES (14)** sections of the prescribing information (PI). Additionally, updates have been made to the **WARNINGS AND PRECAUTIONS (5)** and **ADVERSE REACTIONS (6)**, **Post-Marketing Experience (6.2)** sections of the PI to align with that of the listed drug.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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, 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).

CARTON LABELING

Submit final printed carton labeling that are identical to the enclosed carton labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit the labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton Labeling for approved NDA 209949/S-006 and NDA 209949/S-007**." Approval of these submissions by FDA is not required before the labeling is used.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the

[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.

labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names* and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

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 applications, you are exempt from this requirement.

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 questions, call Sheel Shah, PharmD, Regulatory Project Manager, at 240-402-3968.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
- Carton Labeling

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/

SUMATHI NAMBIAR
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