NDA 208562/S-006

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 application (sNDA) dated and received May 27, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Voriconazole for injection.

We also refer to our letter dated May 09, 2022, 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 voriconazole. This information pertains to the risk of increased photosensitivity reactions associated with concomitant administration of voriconazole and methotrexate.

This supplemental new drug application provides for revisions to the labeling of Voriconazole for injection.The agreed upon changes to the language included in our May 09, 2022, letter are as follows (additions are noted by double underline and deletions are noted by strikethrough):

FULL PRESCRIBING INFORMATION

5 WARNINGS AND PRECAUTIONS

5.6 Photosensitivity

In addition, Voriconazole for injection has been associated with photosensitivity related skin reactions such as pseudoporphyria, cheilitis, and cutaneous lupus erythematosus, as well as increased risk of skin toxicity with concomitant use of methotrexate, a (b) (4) (b) (4) drug (b) (4) -associated with ultraviolet (UV) reactivation (b) (4) There is the potential for this risk to be observed with other drugs associated with UV reactivation. Patients should avoid strong, direct sunlight during Voriconazole for injection therapy.

Other edits to reflect the changes are included in the following sections/subsections in the attached Prescribing Information (PI): **HIGHLIGHTS OF PRESCRIBING**

INFORMATION, **ADVERSE REACTIONS (6)** section, **Clinical Trials Experience (6.1)**, subsection under **Clinical Trials Experience in Adults,** Dermatological Reactions, **Postmarketing Experience in Adult and Pediatric Patients (6.2)** subsection, and **PATIENT COUNSELING INFORMATION (17)** section.

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.

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).

[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.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Jacquelyn Rosenberger, PharmD, RAC, Regulatory Project Manager, at (301) 796-9179

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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/

PETER W KIM
08/16/2022 08:37:01 AM