DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208562/S-002

SUPPLEMENT APPROVAL

Xellia Pharmaceuticals USA, LLC
Attention: Edward Eichmann
US Regulatory Affairs Director
8900 Capital Boulevard
Raleigh, NC 27616

Dear Mr. Eichmann:

Please refer to your Supplemental New Drug Application (sNDA) dated September 27, 2017, received September 27, 2017, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Voriconazole for Injection, 200 mg/vial.

We also refer to our approval letter dated March 26, 2018 which contained an error in the NDA and supplement number.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 26, 2018, the date of the original approval letter.

This Changes Being Effected supplemental new drug application provides for changes to the following sections:

- **DOSAGE AND ADMINISTRATION** (2) section, **Recommended Dosing in Adults** (2.3) and **Use in Patients with Hepatic Impairment** (2.6) subsections;
- **WARNINGS AND PRECAUTIONS** (5) section, **Embryo-Fetal Toxicity** (5.4) and **Patients with Hepatic Impairment (**5.8) subsections;
- **DRUG INTERACTIONS** (7) section;
- **USE IN SPECIFIC POPULATIONS** (8)
- **Pregnancy** (8.1), **Lactation** (8.2), **Females and Males of Reproductive Potential** (8.3), and **Pediatric Use** (8.4) subsections;
- **CLINICAL PHARMACOLOGY** (12) section, **Pharmacodynamics** (12.2), **Pharmacokinetics** (12.3), **Microbiology** (12.4), Pharmacogenomics subsections;

- **NON CLINICAL TOXICOLOGY** (13) section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection;
- and to the **REFERENCES** (15) and **PATIENT COUNSELING INFORMATION (17)** sections, of the prescribing information.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the 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.

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 date(s).

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 Naseya Minor, Regulatory Project Manager, at (301) 796-0756.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Acting Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling