



NDA 50-578/S-064

**SUPPLEMENT APPROVAL**

Teligent OÜ  
c/o: Teligent Pharma, Inc.  
Attention: Susan Todd  
Director, Regulatory Affairs  
105 Lincoln Avenue  
P.O. Box 687  
Buena, NJ 08310

Dear Ms. Todd:

Please refer to your Supplemental New Drug Application (sNDA) dated March 22, 2019, received March 22, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fortaz (ceftazidime for injection) for Intravenous, 500 mg, 1 g, 2 g, and 6 g.

This Prior Approval supplemental new drug application was submitted in response to the Agency's Prior Approval Supplement Request Letter dated February 26, 2019, and provides for revisions to the **PRECAUTIONS** section, **Drug Interactions** subsection. Specifically, information regarding the use of ceftazidime and the effect on gut flora and the reduced efficacy when used in combination with oral estrogen, has been removed.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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, with the minor editorial revision described above and 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 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).

### **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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infectives  
Office of Infectious Diseases  
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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**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.**  
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/s/  
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DMITRI IARIKOV  
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