DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-578/S-061
NDA 50-634/S-028

SUPPLEMENT APPROVALS

Teligent OÜ
c/o Teligent Pharma, Inc.
Attention: Susan Todd
Director Regulatory Affairs
105 Lincoln Avenue, P.O. Box 697
Buena, NJ 08310

Dear Ms. Todd:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 17, 2016, received November 17, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- **NDA 50-578:** Fortaz (ceftazidime for injection) 500 mg, 1 g, 2 g, and 6 g
- **NDA 50-634:** Fortaz (ceftazidime injection) 1 g and 2 g

These Prior Approval supplemental new drug applications submitted in response to our October 5, 2016, Prior Approval supplement request letter, provide for revisions to the prescribing information and pharmacy bulk packaging in order to mitigate the potential for medication errors and to furnish safe information regarding the use of these drugs.

Specifically, revisions have been made to the **DESCRIPTION, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, DOSAGE AND ADMINISTRATION** sections, **Administration** subsection, **COMPATIBILITY AND STABILITY**, and **HOW SUPPLIED** sections. In addition, the Pharmacy Bulk Package, cartons and containers have been updated as appropriate, to align packaging configurations with these changes.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended and they are 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 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 these NDAs, 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 these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide highlighted or marked-up copies that show all changes, as well as clean Microsoft Word versions. The marked-up copies should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled: *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 50-578/S-061 and NDA 50-634/S-028**." Approval of these submissions by FDA is not required before the labeling is used.

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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES: Prescribing Information - Pharmacy Bulk Package
Prescribing Information - Single Dose Vials and Containers
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
07/28/2017