DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 200904

ANDA APPROVAL

Sandoz Inc.
100 College Road West
Princeton, NJ 08540
Attention: Gregory Seitz
Director, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Linezolid Injection, 200 mg/100 mL and 600 mg/300 mL.

Reference is also made to the tentative approval letter issued by this office on May 30, 2014, and to your amendments dated January 9, and April 3, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Linezolid Injection, 200 mg/100 mL and 600 mg/300 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zyvox Injection, 200 mg/100 mL and 600 mg/300 mL, of Pharmacia and Upjohn Company (Pharmacia).

The RLD upon which you have based your ANDA, Pharmacia's Zyvox Injection 200 mg/100 mL and 600 mg/300 mL, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,559,305 (the '305 patent) is scheduled to expire (with pediatric exclusivity added) on July 29, 2021.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Linezolid Injection, 200 mg/100 mL and 600 mg/300 mL, under this ANDA. You have notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Sandoz within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Sandoz was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Linezolid Injection, 200 mg/100 mL. As a first applicant, Sandoz was eligible for 180 days of generic drug exclusivity. The Agency has determined, however, that Sandoz has forfeited its

eligibility for 180-day exclusivity because Sandoz failed to obtain tentative approval within 30 months after the date on which the ANDA was filed.[1] See section 505 (j) (5) (D) (I) (IV) of the FD&C Act.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. You should advise the Office of Generic Drugs of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 via publicly available labeling repositories.

[1] Sandoz's ANDA was received on December 29, 2009. ANDA 200904 was tentatively approved on May 30, 2014. The agency finds that Sandoz's failure to obtain tentative approval within 30 months was not caused by a change in or review of the requirements for approval, nor was a related citizen petition submitted that was subject to section 505(q) of the FD&C Act.

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Gwendolyn Murphy, Project Manager, at (240) 402-9624.

Sincerely yours,

William P. Rickman -S

Digitally signed by William P. Rickman -S
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Date: 2015.07.16 15:42:16 -04'00'

For Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research