CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 090862

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090862

Sandoz Inc.
Attention: Jean Domenico
Associate Director, Regulatory Affairs
2555 W. Midway Blvd.
Broomfield, CO 80038

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 11, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Voriconazole for Injection, packaged in 200 mg Single-use Vials.

Reference is also made to the tentative approval letter issued by this office on May 5, 2010, and to your amendments dated June 3, 2011; and February 16, February 24, April 18, May 3, and May 4, 2012. We also acknowledge receipt of your correspondences dated November 24, and December 1, 2010; February 3, February 8, 2011; and February 24, 2012, addressing patent issues associated with this ANDA.

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 Voriconazole for Injection, 200 mg/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Vfend I.V. for Injection, 200 mg/vial, of Pfizer Inc.

The RLD upon which you have based your ANDA, Vfend I.V. for Injection, 200 mg/vial of Pfizer Inc. (Pfizer), is subject to unexpired periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,567,817 (the '817 patent) and 6,632,803 (the '803 patent) expire on May 24, 2016, and June 2, 2018, respectively.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Voriconazole for Injection, packaged in 200 mg Single-use Vials, under this ANDA. You have notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and no action was brought against Sandoz for infringement of the '817 patent, and litigation for infringement of the '803 patent was brought against Sandoz outside the statutory 45-day period in the United States District Court for the District of Delaware [Pfizer Inc., Pfizer Limited, Pfizer Ireland Pharmaceuticals and C.P. Pharmaceuticals International C.V., v. Sandoz Inc., Civil Action No. 1:11-CV-00023-UNA]. You have also notified the agency that this litigation has been dismissed.

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 to one or more of the patents listed for Vfend I.V. for Injection, packaged in 200 mg Single-use Vials. Therefore, with this approval, Sandoz is eligible for 180-days of generic drug exclusivity for Voriconazole for Injection, packaged in 200 mg Single-use Vials. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the 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 Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised 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/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

05/30/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.