



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

ANDA 200926

Sandoz Inc.  
Attention: Jean Domenico  
Regulatory Affairs, Associate Director  
2555 W. Midway Blvd.  
P.O. Box 446  
Broomfield, CO 80038

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 23, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Doxercalciferol Injection, 2 mcg/mL, packaged in 4 mcg/2 mL Single-dose Vials).

Reference is also made to the Complete Response letter issued by this office on October 9, 2012, and to your amendments dated February 13, and December 12, 2013; and January 13, January 15, and January 23, 2014.

We also refer to our approval letter dated February 4, 2014, which contained the following error: As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,602,116 (the '116 patent), is scheduled to expire on February 11, 2104. The correct date of the patent expiry should be February 11, 2014. This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 4, 2014, the date of the original approval letter.

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 Doxercalciferol Injection, 2 mcg/mL packaged in 4 mcg/2 mL single-dose vials to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Hectorol Injection, 2 mcg/mL packaged in 4 mcg/2 mL single-dose ampules of Genzyme Corporation (Genzyme).

The RLD upon which you have based your ANDA, Genzyme's Hectorol Injection, 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. 5,602,116 (the '116 patent), is scheduled to expire on February 11, 2014.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '116 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Doxercalciferol Injection, 2 mcg/mL packaged in 4 mcg/2 mL single-dose 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 that litigation was initiated against Sandoz for infringement of the '116 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Genzyme Corporation v. Sandoz Inc., Civil Action No. 1:10-cv-00429-UNA]. You have also notified the agency that this case was dismissed.

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.

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(s) 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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee

amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

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.

Sincerely yours,

*{See appended electronic signature page}*

Kathleen Uhl, M.D.  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT L WEST

02/04/2014

Deputy Director, Office of Generic Drugs, for  
Kathleen Uhl, M.D.