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APPLICATION NUMBER:

ANDA 200154

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200154

Sandoz Inc.
Attention: Gregory Seitz
Associate Director, Regulatory Affairs
One Health Plaza
Bldg. 103, Rm. 246
East Hanover, NJ 07936

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 3, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cisatracurium Besylate Injection, 10 mg (base)/mL packaged in 200 mg (base)/20 mL Single-dose Vials, and 2 mg (base)/mL packaged in 10 mg (base)/5 mL Single-dose Vials (Preservative-Free).

Reference is also made to your amendments dated September 18, and October 21, 2009; May 17, May 27, May 28, October 26, and November 15, 2010; March 25, May 20, June 8, and September 29, 2011; and January 17, January 19, January 23, and January 25, 2012. We also acknowledge receipt of your correspondences dated January 15, and December 16, 2010 addressing the 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 Cisatracurium Besylate Injection, 10 mg (base)/mL and 2 mg (base)/mL (Preservative-Free) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Nimbex Injection, 10 mg (base)/mL and 2 mg (base)/mL, respectively, (Preservative-Free) of Abbott Laboratories (Abbott).

The RLD upon which you have based your ANDA, Abbott's Nimbex Injection, 10 mg (base)/mL and 2 mg (base)/mL (Preservative Free), 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. 5,453,510 (the '510 patent) is scheduled to expire on September 26, 2012.

You ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(VI) of the Act stating that the '510 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Cisatracurium Besylate Injection, 10 mg (base)/mL and 2 mg (base)/mL (Preservative-Free), 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 '510 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Abbott Laboratories v. Sandoz Inc., Civil Action No. 09-cv-00972-UNA]. You have also notified the agency that the litigation was 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 the listed patent. Therefore, with this approval, Sandoz is eligible for 180 days of generic drug exclusivity for Cisatracurium Besylate Injection, 10 mg (base)/mL and 2 mg (base)/mL (Preservative-Free). 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

02/03/2012

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