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APPLICATION NUMBER:

ANDA 090999

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090999

Sandoz Inc.
Attention: William Kwok
Director, Regulatory Affairs
One Health Plaza
Bldg. 103, Rm. 245
East Hanover, NJ 07936

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 31, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Aprepitant Capsules, 40 mg, 80 mg, and 125 mg.

Reference is also made to your amendments dated March 10, March 18, March 19, and June 3, 2009; March 1, April 28, May 18, June 22, October 14, and December 9, 2010; February 7, February 25, March 1, March 4, March 11, April 21, April 27, May 2, and May 20, 2011; and March 13, June 4, July 16, and August 3, 2012.

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 Aprepitant Capsules, 40 mg, 80 mg, and 125 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Emend Capsules, 40 mg, 80 mg and 125 mg, respectively, of Merck and Company, Inc. (Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Merck's Emend Capsules, is subject to periods of patent protection. The following unexpired patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,538,982 (the '982 patent)	July 23, 2013
5,719,147 (the '147 patent)	April 17, 2015
6,096,742 (the '742 patent)	July 1, 2018

With respect to each of these patents, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Aprepitant Capsules, 40 mg, 80 mg, and 125 mg, 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 '147 and '742 patents in the United States District Court for the District of New Jersey, [Merck & Co., Inc., v. Sandoz Inc., Civil Action No. 3:09-cv-00890-MLC-LHG]. 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 for Aprepitant Capsules, 40 mg, 80 mg, and 125 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Sandoz may be eligible for 180 days of generic drug exclusivity for Aprepitant Capsules, 40 mg, 80 mg, and 125 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Sandoz failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Sandoz's eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Sandoz begins commercial marketing of Aprepitant Capsules, 40 mg, 80 mg, and 125 mg, or (b) at any time prior to the expiration of the '742 patent if Sandoz has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
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

09/24/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.