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APPLICATION NUMBER:

ANDA 079003

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079003

Watson Laboratories Inc.
Attention: Joyce Anne DelGaudio
Executive Director, Regulatory Affairs
380 Mount Kimble Ave
Morristown, NJ 07962

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 16, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly).

Reference is made to the tentative approval letter issued by this office on March 15, 2011; and to your amendments dated February 27, March 13, March 14, March 15, March 16, March 19, and March 20, 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 Ibandronate Sodium Tablets, 150 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Boniva Tablets, 150 mg (base) of Hoffman-La Roche Inc. (HLR). 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, HLR's Boniva Tablets 150 mg (base), 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
6,294,196 (the '196 patent)	October 7, 2019
7,192,938 (the '938 patent)	May 6, 2023
7,410,957 (the '957 patent)	May 6, 2023
7,718,634 (the '634 patent)	May 6, 2023

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 Ibandronate Sodium Tablets, 150 mg (base), under this ANDA. You have notified the agency that Watson Laboratories Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '814, '196, '634 and '938 patents was initiated against Watson within the statutory 45-day period in the United States District Court for the District of New Jersey [Hoffman-La Roche Inc. v. Watson Laboratories Inc., Civil Action No. 07-4539 (SRC)]. Litigation was also brought for infringement of the '957 patent.[1] Claims with respect to the '196 and '938 patents were later dismissed.

With respect to 180-day generic drug exclusivity, we note that Watson was one of the first ANDA applicants for Ibandronate Sodium Tablets, 150 mg (base) to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Watson may be eligible for 180 days of generic drug exclusivity for Ibandronate Sodium Tablets, 150 mg (base). 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 by a first applicant identified in section 505(j)(5)(B)(iv). The agency notes that Watson 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 Watson's eligibility for 180-day generic drug exclusivity. It will do so only if an application submitted by an applicant other than a first applicant becomes eligible for full approval within 180 days after a first applicant begins commercial marketing of Ibandronate Sodium Tablets, 150 mg (base). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

[1] We note that the '957 and '634 patents were listed in the Orange Book after receipt of your ANDA.

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.

We 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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide additional tablet film coat formulation information, along with applicable executed batch records, finished drug product release data and a biowaiver request with the appropriate dissolution profile data (f2 calculation) in a "Changes Being Effected in 30 Days (CBE-30)" supplement after the ANDA has been approved, and prior to distribution of the uncoated and the coated product. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "CHANGES BEING EFFECTED IN 30 DAYS - POST APPROVAL COMMITMENT RESPONSE."

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

03/20/2012

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