DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 203683

APPROVAL LETTER

Watson Laboratories, Inc.
400 Interpace Parkway
Parsippany, New Jersey 07054
Attention: Joyce Anne DelGaudio
Executive Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 17, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg.

Reference is also made to your amendments dated March 5, September 9, and November 5, 2015. The March 5, 2015 submission constituted a complete response to our January 16, 2015 action 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 Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Bystolic Tablets, of Forest Laboratories, Inc. (Forest). 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, Forest's Bystolic Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, 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. 6,545,040 (the '040 patent), is scheduled to expire on December 17, 2021.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the '040 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, 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 FD&C Act, and that litigation was initiated against Watson for infringement of the '040 patent within the statutory 45-day period in the United States District Court Delaware [Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Janssen Pharmaceutica N.V. v. Torrent Pharmaceuticals LTD, Watson

Laboratories, Inc.(NV), Watson Laboratories, Inc.(DE), Watson Laboratories, Inc.(NY), Watson Laboratories, Inc.(CT), Watson Pharma, Inc., and Watson Pharmaceuticals Inc., et al., Civil Action No. 12-cv-5026]. You have notified the agency that the litigation was dismissed and therefore, under section 505(j)(5)(B)(iii) of the FD&C Act your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Watson was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg. Therefore, with this approval, Watson may be eligible for 180 days of shared generic drug exclusivity for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg. The agency notes that Watson failed to timely obtain tentative approval of this ANDA under section 505(j)(5)(D)(i)(IV) of the FD&C Act (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.

At least one first applicant remains eligible for 180 days of generic drug exclusivity for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

Under section 506A of the FD&C 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 FD&C 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(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,

Carol A. Holquist -S

Digitally signed by Carol A. Holquist -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052464, cn=Carol A. Holquist -S
Date: 2015.11.27 13:08:34 -05'00'

Carol A. Holquist, RPh
Acting Deputy Director
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