DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 203689

CONVERSION TO ANDA TENTATIVE APPROVAL

Watson Laboratories, Inc.
425 Privet Road
Horsham, PA 19044
Attention: Rich Leone
Senior Director, Regulatory Affairs, US Generics

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (base), approved on April 22, 2015, pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We are writing to inform you that, consistent with the Amended Final Judgment Order issued on June 9, 2016, the Agency hereby converts the final approval of ANDA 203689 to a tentative approval, and considers that this conversion occurred on the date of that decision. Thus, FDA regards ANDA 203689, as having been tentatively approved as of June 9, 2016. This action conforms the ANDA's status to the court's final judgment, as described in detail below.

The reference listed drug (RLD) upon which you have based your ANDA, Staxyn Orally Disintegrating Tablets, 10 mg, of Bayer Healthcare Pharmaceuticals, Inc., is subject to periods of patent protection. As noted in the in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") the following patents and expiration dates are currently listed:

U.S. Patent Number	Expiration Date
6,362,178 (the '178 patent)	October 31, 2018
7,696,206 (the '206 patent)	October 31, 2018
8,613,950 (the '950 patent)	December 23, 2028

Your ANDA contained paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the '178, '206 and '950[1] patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (base), under this ANDA. As noted in your April 22, 2015 approval letter, you 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 '178 and '206 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Bayer Pharma AG, Bayer Intellectual Property GMBH, and Bayer Healthcare Pharmaceuticals Inc., v. Watson Pharmaceuticals, Inc., Watson Laboratories Inc., and Watson Pharma, Inc., Civil Action No. 1:12-cv-00517-UNA].

[1] The agency notes that the '950 patent was submitted to the agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

Subsequent to this approval action, the United States District Court for the District of Delaware issued an Amended Final Judgment Order in Civil Action No. 1:12-cv-00517 holding that certain claims of the '178, '206 and '950 patents are not invalid, and that Watson's drug product that is the subject of ANDA 203689 infringed certain claims of these patents. The court ordered that "[p]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Watson's ANDA No. 203689 shall be a date not earlier than the latest of the expiration of the '178 patent (October 31, 2018), the '206 patent (October 31, 2018), and the '950 patent (December 23, 2028), as well as any extensions thereto."[2]

Section 505(j) of the FD&C Act does not expressly provide for a change in approval status when the patent litigation results in a finding that one or more listed patents is infringed; however, when a court orders that the approval of an ANDA is not effective before a certain date pursuant to 35 U.S.C.§ 271(e)(4)(A), FDA may convert an approved ANDA to tentative approval status to reflect the court's order.[3]

Therefore, after consideration of the district court's June 9, 2016 Amended Final Judgment Order that the effective date of approval for ANDA 203689 be reset to be a date not earlier than December 23, 2028, FDA is converting the April 22, 2015, final approval of Watson's ANDA 203689 for Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (base), to a tentative approval.

Please be aware that any approved Supplemental ANDAs filed to this ANDA since April 23, 2015, are considered tentatively approved. Any unapproved Supplemental ANDAs and any Annual Report Changes filed to this ANDA are considered WITHDRAWN and should be re-submitted in full as either a "MINOR/MAJOR Amendment to the Original," or as a new Supplemental ANDA once full approval has been obtained again. We note that this is an administrative conversion only and does not reflect any review of the ANDA subsequent to its original approval or approval of any supplements.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 90 days for Agency review. Accordingly, such a request for final approval should be submitted no later than 90 days

[2] Amended Final Judgment Order, *Bayer Pharma AG, Bayer Intellectual Property GMBH, and Bayer Healthcare Phamraceuticals Inc. v. Watson Laboratories, Inc., et al.*, Civil Action No. 1:12-cv-00517-GMS, at 5 (June 9, 2016).
[3] *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004)

prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.
This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book. Should you believe that there are grounds for issuing the final approval letter prior to December 23, 2028, you should amend your ANDA accordingly.

ANNUAL FACILITY FEES

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.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

Additionally, we note that the failure of any facility referenced in the application to self-identify and pay applicable fees means that FDA will not consider the GDUFA application review goal dates to apply to that application.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Chad Snuggerud, Regulatory Project Manager, at 240-402-5852.

Sincerely yours,

{See appended electronic signature page}

Edward M. Sherwood
Director
Office of Regulatory Operations
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/

EDWARD M SHERWOOD
07/12/2017
Ted signed