DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 204065

ANDA APPROVAL

Actavis Laboratories FL, Inc.
2945 West Corporate Lakes Blvd.
Suite B
Weston, FL 33331
Attention: Janet Vaughn
Director of Regulatory Affairs

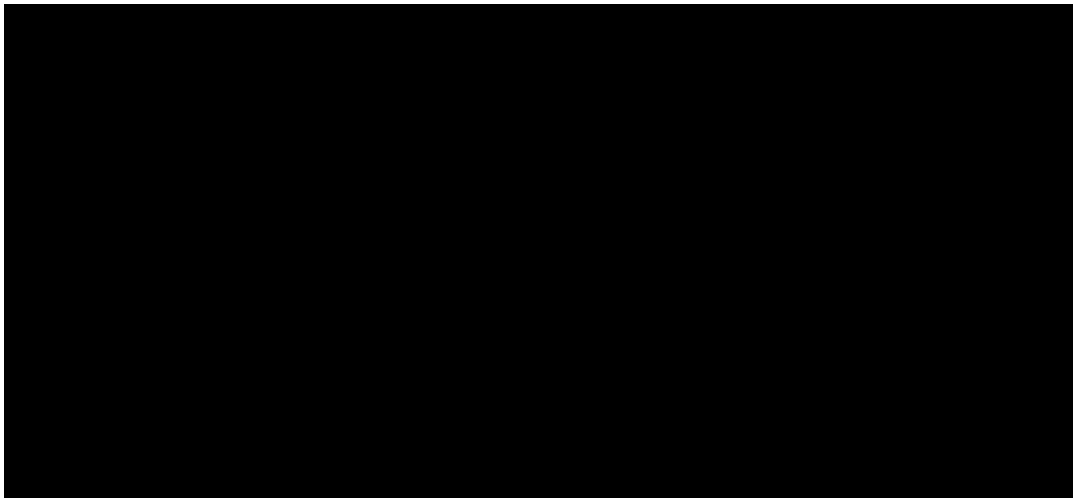
Dear Madam:

This is in reference to your abbreviated new drug application (ANDA), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Desvenlafaxine Succinate Extended-Release Tablets, 25 mg, 50 mg, and 100 mg.

Reference is also made to the complete response letter issued by this office on May 9, 2014 and to your amendments dated May 8, July 16, August 28, and December 23, 2015; January 12, January 19, February 26, and April 20, 2016.

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 Office of Bioequivalence has determined your Desvenlafaxine Succinate Extended-Release Tablets, 25 mg, 50 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pristiq Extended-Release Tablets, 25 mg, 50 mg, and 100 mg, of Wyeth Pharmaceuticals Inc. (Wyeth).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The “interim” dissolution specifications are as follows:



The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Wyeth's Pristiq Extended-Release Tablets, 25 mg, 50 mg, and 100 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,673,838 (the '838 patent) and 8,269,040 (the '040 patent) are scheduled to expire on March 1, 2022 and July 5, 2027, respectively.

Your ANDA contains paragraph IV certifications to each of the patents[1] under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Desvenlafaxine Succinate Extended-Release Tablets, 25 mg, 50 mg, and 100 mg, under this ANDA. With respect to the 50 mg and 100 mg strengths, you have notified the agency that Actavis Laboratories FL, Inc. (Actavis) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Actavis for infringement of the '838 and '040 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Pfizer, Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., PF Prism C.V. v. Actavis Laboratories FL, Inc., consolidated Civil Action No. 12-808] and in the United States District Court for the Southern District of Florida [Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. v. Watson Laboratories, Inc. – Florida, Andrx Corp., Watson Laboratories Inc., Watson Pharma Inc. and Watson Pharmaceuticals Inc., Civil Action No. 12-61268]. You have also notified the agency that these cases were dismissed. With respect to the 25 mg strength, you have notified the agency that Actavis complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Actavis within the statutory 45-day period.

[1] The agency notes that the '040 patent was submitted to the agency after submission of your ANDA for the 50 mg and 100 mg strengths. Litigation, if any, with respect to this patent would not create a statutory stay of approval for these strengths.

With respect to 180-day generic drug exclusivity for your 50 mg and 100 mg strengths, we note that Actavis was one of the first ANDA applicants for Desvenlafaxine Succinate Extended-Release Tablets, 50 mg, and 100 mg, to submit to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Actavis may be eligible for 180 days of shared generic drug exclusivity for Desvenlafaxine Succinate Extended-Release Tablets, 50 mg and 100 mg. The agency notes that Actavis failed to obtain tentative approval of the 50 mg and 100 mg strengths within 36[2] months after the date on which the ANDA was filed. See 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 Actavis' eligibility for 180-day exclusivity for the 50 mg and 100 mg strengths.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Desvenlafaxine Succinate Extended-Release Tablets, 50 mg and 100 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.

With respect to 180-day generic drug exclusivity for your 25 mg strength, we note that Actavis was the first ANDA applicant for Desvenlafaxine Succinate Extended-Release Tablets, 25 mg, to submit to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Actavis is eligible for 180 days of generic drug exclusivity for Desvenlafaxine Succinate Extended-Release Tablets, 25 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 commercial marketing 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.

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[2] This ANDA for Desvenlafaxine Succinate Extended-Release Tablets, 50 mg and 100 mg, was submitted on February 29, 2012. For applications submitted between January 9, 2010, and July 9, 2012 containing a Paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on July 9, 2012, and ending on September 30, 2015, section 1133 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144) extends this period to 40 months. For applications submitted between January 9, 2010, and July 9, 2012 (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on October 1, 2015, and ending on September 30, 2016, section 1133 of FDASIA extends this period to 36 months. In addition, if an application was submitted between January 9, 2010, and July 9, 2012 containing a Paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and FDA has not approved or tentatively approved the application but must consider whether the applicant has forfeited exclusivity because a potentially blocked application is ready for approval, FDA will apply the 36-month period if it makes the forfeiture determination between the period of time beginning on October 1, 2015, and ending on September 30, 2016. For all other applications, the 30-month period set forth in FD&C Act section 505(j)(5)(D)(i)(IV) applies.

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,

{See appended electronic signature page}

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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