DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204150

TENTATIVE APPROVAL

Alembic Pharmaceuticals Limited
Attention: Hari Nagaradona, Ph.D.
Director, Regulatory Affairs
INC Research, LLC
7361 Calhoun Place, Suite 500
Rockville, MD 20855

Dear Dr. Nagaradona:

Please refer to your New Drug Application (NDA) dated and received February 29, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Desvenlafaxine Extended-Release Tablets 50 mg and 100 mg.

We acknowledge receipt of your amendments dated:

March 12, 2012	July 12, 2012	October 19, 2012	November 27, 2012
May 14, 2012	July 30, 2012	October 26, 2012	November 29, 2012
June 8, 2012	August 27, 2012	October 31, 2012	December 14, 2012
June 21, 2012	August 27, 2012	October 31, 2012	December 20, 2012
July 3, 2012	October 4, 2012	November 5, 2012	

This NDA provides for the use of Desvenlafaxine Extended-Release Tablets for the treatment of Major Depressive Disorder (MDD).

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert, Medication Guide, and immediate container labels**).** This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired. If you have questions as to when this date will be, please contact the Agency at the information provided below.

To obtain final approval of this application, submit an amendment no sooner than two or six months prior to either (1) the expiration of the exclusivity protection or (2) the date you believe that your NDA will be eligible for final approval, as appropriate. You should determine the timing of your amendment by referring to the resubmissions classifications and the associated FDA review timelines described in the Guidance for Industry: Classifying Resubmissions in Response to Actions Letters (http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093430.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=resubmissions%20guidance&utm_content=3). If you believe that there are grounds for issuing the final approval letters before the expiration of exclusivity protection, you should amend your application accordingly.

In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and Risk Evaluation and Mitigation Strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 6 years old in the treatment of major depressive disorder, because studies are highly impractical due to the low prevalence of this disorder in this age range.

We are deferring submission of your pediatric studies for ages 7 to 17 years old in the treatment of major depressive disorder, because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. These required studies are listed below.

1993-1 Deferred pediatric study under PREA for the treatment of major depressive disorder in pediatric patients aged 7 to 17. Conduct a study to obtain data on the efficacy and safety of desvenlafaxine in the relevant pediatric population.

Final Protocol Submission Date: December 2014
Study Completion Date: September 2018
Final Report Submission: March 2019

Submit final reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment(s).**"

If you have any questions, contact CDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301)796-4158 or email: Kofi.Ansah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell Mathis, M.D.
CAPT USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
12/21/2012