DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078357

Orgenus Pharma, Inc.
U.S. Agent for : Orchid Healthcare
Attention: Diana Wilk
700 Alexander Park, Suite 104
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Desloratadine Tablets, 5 mg.

Reference is also made to the tentative approval letter issued by this office on August 25, 2009, and to your amendments dated September 18, and October 13, 2009.

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 Desloratadine Tablets, 5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clarinex Tablets, 5 mg, of Schering Plough Corporation (Schering). 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, Schering's Clarinex Tablets, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,100,274 (the '274 patent)	January 7, 2020
7,211,582 (the '582 patent)	June 30, 2015
7,214,683 (the '683 patent)	December 30, 2014
7,214,684 (the '684 patent)	December 30, 2014
7,405,223 (the '223 patent)	January 7, 2020

With respect to these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Desloratadine Tablets, 5 mg, under this ANDA. Of the patents listed above, only the ‘274 patent was listed in the Orange Book when your ANDA was received; your paragraph IV certifications to the other patents were submitted in amendments to your ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Orchid Healthcare (Orchid) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications, excluding those submitted in an amendment. You notified the agency that Orchid complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '274 patent (as well as the four other patents) was brought against Orchid in the United States District Court for the Northern District of New Jersey [Schering Corp. v. Orgenus Pharma, Inc., Civil Action Nos. 06-4715(MLC), 07-4623 (MLC), and 08-5623 (MLC)]. You have provided documentation that each of these civil actions was resolved pursuant to signed court orders dated August 14, 2009, and September 9, 2009.

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.

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 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
Division of Drug Marketing, Advertising, and Communications
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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 078357".***

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research