DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 65-386

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 27, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Piperacillin and Tazobactam for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial.

Reference is also made to your amendments dated November 1, November 7, and November 17, 2007; January 28, and January 31, 2008; and May 15, June 25, July 2, July 21, and August 25, 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 Piperacillin and Tazobactam for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zosyn for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial, respectively, of Wyeth Pharmaceuticals Inc. (Wyeth).

The RLD upon which you have based your ANDA, Wyeth's Zosyn for Injection, 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. 6,900,184 (the '184 patent) expires on April 14, 2023.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '184 patent is invalid , unenforceable, or will not be infringed by your manufacture, use, or sale of Piperacillin and Tazobactam for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial, under this ANDA. You have notified the agency that Orchid Healthcare (Orchid) complied with the requirements of section 505(j)(2)(B) of the Act and that no action for infringement of the '184 patent was brought against Orchid.

With respect to 180-day generic drug exclusivity, we note that Orchid, by virtue of its timely submission to a substantially complete ANDA of an amendment containing a paragraph IV certification to the '184 patent, is a "first applicant" with respect to its ANDA for Piperacillin and Tazobactam for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial.[1] Therefore, with this approval, Orchid is eligible for 180 days of generic drug exclusivity for Piperacillin and Tazobactam for Injection, 2 g (base)/250 mg (base) per vial, 3 g (base)/375 mg (base) per vial, and 4 g (base)/500 mg (base) per vial. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, runs from the date of commercial marketing by a first applicant.

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.

We 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.

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[1] See part (b) of section 4 of the QI Supplemental Funding Act of 2008 (QI Act). These Transitional Rules provide that, with respect to patent information filed with the Secretary within the 60-day period after enactment of the QI Act --

> "each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the enactment of this Act, a substantially complete application … to contain a [paragraph IV certification] with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)."

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
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/oc/datacouncil/spl.html, 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 65-386".***

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-65386	ORIG-1	ORCHID HEALTHCARE	PIPERACILLIN AND TAZOBACTAM

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/s/

GARY J BUEHLER
09/15/2009