DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077431

Roxane Laboratories, Inc.
Attention: Elizabeth A. Ernst
Director, Regulatory and Medical Affairs
1809 Wilson Road
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 8, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Exemestane Tablets, 25 mg.

Reference is also made to the tentative approval letter issued by this office on June 7, 2006, and to your amendments dated April 27, April 29, and October 7, 2005; December 15, 2010; and February 8, and March 30, 2011.

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 Exemestane Tablets, 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Aromasin Tablets, 25 mg, of Pharmacia and Upjohn Co. (Pharmacia & Upjohn). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The agency approved a revision to the labeling of the RLD within 60 days of the expiration of the '616 patent. This revision to the labeling of the RLD does not include a change to the WARNINGS section of the package insert, and the agency has not determined that the continued presence of the labeling in effect before the revision will adversely impact the safe use of the drug. The agency has also determined that your ANDA meets the applicable standards for approval under section 505(j), and was

otherwise eligible for approval but for expiration of the '616 patent. Therefore, under section 505(j)(10) of the Act, the agency has concluded that your ANDA is eligible for approval with labeling that differs from that of the RLD. You are hereby notified that you are required to change the labeling of your product to contain the revision that was approved on March 25, 2011, for the RLD. Acceptance of this letter constitutes your agreement to submit a "Supplement – Changes Being Effected" containing such revised labeling no later than 60 days from the date of the notification.

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 505-1(i).

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.

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/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

ROBERT L WEST

04/01/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.