DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077732

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 31, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg.

Reference is also made to the tentative approval letter issued by this office on May 14, 2009, and to your amendments dated July 6, 2006; and January 21, March 8, and March 26, 2010.

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. However, because of an exclusivity issue explained below, we are unable to approve your Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg, at this time. Therefore, only your Losartan Potassium and Hydrochlorothiazide Tablets, 100 mg/12.5 mg, is deemed as approved. Your Losartan Potassium and Hydrochlorothiazide Tablets 50 mg/12.5 mg and 100 mg/25 mg strengths remain tentatively approved and will not be eligible for final approval until the 180-day generic drug exclusivity issue noted below as been satisfactorily resolved.

Final Approval:

The Division of Bioequivalence has determined your Losartan Potassium and Hydrochlorothiazide Tablets, 100 mg/12.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Hyzaar Tablets, 100 mg/12.5 mg, of Merck and Co., Inc. (Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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. For administrative purposes, please designate this submission as "***Labeling/SPL Final for Approved ANDA 077732***".

Tentative Approval:

The RLD upon which you have based your ANDA, Merck's Hyzaar Tablets, 50 mg/12.5 mg and 100 mg/25 mg, 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. 5,608,075 (the '075 patent) expired on September 4, 2009 (with pediatric exclusivity added).

However, we are unable at this time to grant final approval to your ANDA for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg. Prior to the submission of your ANDA, another applicant submitted an ANDA providing for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg, and containing a paragraph IV certification to the '075 patent. Your ANDA will be eligible for final approval upon the expiration of the other applicant's 180-day exclusivity identified in section 505(j)(5)(B)(iv) of the Act, or that exclusivity is otherwise resolved.

To reactivate your ANDA prior to final approval, please submit a "SUPPLEMENTAL APPLICATION – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This supplemental application should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This supplemental application should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a SUPPLEMENTAL APPLICATION – FINAL APPROVAL REQUESTED.

In addition to the supplemental application requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed 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 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this application, or prior to submitting additional amendments, please contact Dat Doan, Project Manager, at 240-276-8573.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77732	ORIG-1	ROXANE LABORATORIES INC	LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

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

04/06/2010

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