DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-844

SEP 19 2005

Roxane Laboratories, Inc.
Attention: Elizabeth A. Ernst
Associate Director, DRA-Multisource Products
1809 Wilson Road
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 18, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Zidovudine Tablets USP, 300 mg.

Reference is also made to the tentative approval letter issued by this office on July 27, 2005, and to your amendments dated September 10, and November 4, 2004; and July 29, 2005.

The listed drug product (RLD) referenced in your application, Retrovir Tablets of GlaxoSmithKline, has been subject to periods of patent protection. The following patents are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", for this drug product:

U.S. Patent Number	Expiration Date
4,724,232	September 17, 2005
4,818,538	September 17, 2005
4,828,838	September 17, 2005
4,833,130	September 17, 2005
4,837,208	September 17, 2005

With the expiration of each of the above listed patents, we have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Zidovudine Tablets USP, 300 mg, to be

bioequivalent and therapeutically equivalent to the listed drug (Retrovir® Tablets, 300 mg, of GlaxoSmithKline). 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 abbreviated application require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this abbreviated application 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 20705-1266

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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