DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-053

DEC 5 2005

TEVA Pharmaceuticals USA
Attention: Philip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 22, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ribavirin Tablets, 200 mg.

Reference is also made to the tentative approval letter issued by this office on September 15, 2005, and to your amendment dated October 10, 2005.

The listed drug product (RLD) referenced in your application, Copegus Tablets, 200 mg, of Hoffmann LaRoche, Inc., was subject to a period of new product (NP) market exclusivity. As noted in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", this exclusivity expired on December 3, 2005.

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 Ribavirin Tablets, 200 mg, to be bioequivalent and therapeutically equivalent to the listed drug (Copegus Tablets, 200 mg of Hoffmann LaRoche, Inc.). 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

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.

Sincerely yours,

Robert Lumpkin for

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