



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 65-262

Food and Drug Administration
Rockville MD 20857

JUN 29 2006

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Sr. 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 October 5, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ceftriaxone for Injection USP, packaged in 1 g/100 mL and 2 g/100 mL single-use piggyback bottles. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated November 9, 2004; March 11, July 5, and August 12, 2005; and March 9, May 22, and June 23, 2006.

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 Ceftriaxone for Injection USP, 1 g/100 mL and 2 g/100 mL to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Rocephin® for Injection, 1 g/100 mL, and 2 g/100 mL, respectively, of HLR Technology).

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 with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Gary Buehler" followed by a large, stylized flourish that resembles the letters "S" and "for".

Gary Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research