

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 65-089

APPROVAL LETTER

MAY 25 2004

TEVA Pharmaceuticals USA
Attention: Vincent Andolina
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 12, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/28.5 mg (base)/5 mL and 400 mg/57 mg (base)/5 mL. 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 February 24, April 2, and April 23, 2004.

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 Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/28.5 mg (base)/5 mL, and 400 mg/57 mg (base)/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Augmentin®-200 for Oral Suspension, 200 mg/28.5 mg (base)/5 mL, and Augmentin®-400 for Oral Suspension, 400 mg/57 mg (base)/5 mL, respectively, of GlaxoSmithKline). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

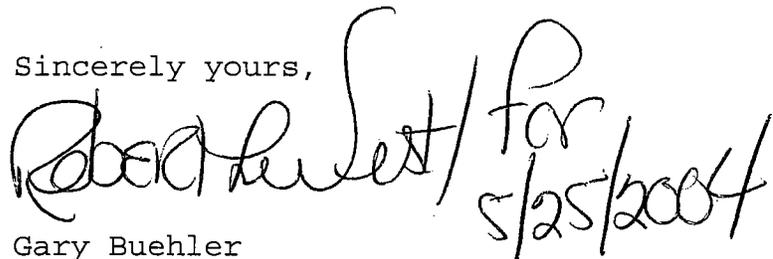
Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler", followed by a vertical slash and the date "5/25/2004".

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

cc: ANDA 65-089
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205

Endorsements:

HFD-623/Y.Pan/5/14/04 *Yap Pn 5/14/04*
HFD-643/M.S.Furness/5/14/04 *S.M. Furness 5/14/04*
HFD-617/M.Anderson/5/14/04 *M Anderson 5/17/04*
HFD-613/J.Council/5/14/04 *J. Council 5/17/04*
HFD-613/L.Golson/5/14/04 *M. Golson for Lillie Colson*

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F/T by: mda/5/14/04

*Robert West
5/25/04*

*one satisfactory
Alayda Kayan
5/18/04*

APPROVAL