CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 078009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-009

Zydus Pharmaceuticals USA, Inc.
Attention: G. Srinivas
Senior Director, Drug Regulatory Affairs
210 Carnegie Center, 1st Floor
Princeton, NJ 08540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 29, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lamotrigine Tablets (Chewable, Dispersible), 2 mg, 5 mg, and 25 mg.

Reference is also made to the tentative approval letter dated September 13, 2007, and to your amendments dated October 21, and December 23, 2008; and January 13, 2009.

We have completed the review of this ANDA as amended, 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. Accordingly, the ANDA insofar as it pertains to the 5 mg and 25 mg strengths is approved, effective on the date of this letter. Because of the 180-day generic drug exclusivity issue explained below, we are unable to approve the 2 mg strength at this time. The 2 mg strength remains **tentatively approved** and will not be eligible for final approval until the 180-day generic drug exclusivity issue noted below has been satisfactorily resolved.

The reference listed drug (RLD) upon which you have based your ANDA, Lamictal (Chewable Dispersible) Tablets of GlaxoSmithKline (GSK), 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. 5,698,226 (the '226 patent), is scheduled to expire on July 29, 2012.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '226 patent is

invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lamotrigine Tablets (Chewable, Dispersible), 2 mg, 5 mg and 25 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Zydus Pharmaceuticals USA, Inc. (Zydus) for infringement of the listed '226 patent. You have notified the agency that Zydus complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Zydus within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

I. Approval of Lamotrigine Tablets (Chewable, Dispersible) 5 mg and 25 mg

The Division of Bioequivalence has determined your Lamotrigine Tablets (Chewable, Dispersible), 5 mg and 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, GSK's Lamictal (Chewable Dispersible) Tablets, 5 mg and 25 mg, respectively. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

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.

We 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(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.

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/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence – SPL for Approved ANDA 78-009***".

II. Tentative Approval of the 2 mg strength product

We remain unable at this time to grant final approval to your ANDA insofar as the 2 mg strength because another ANDA for Lamotrigine Tablets (Chewable, Dispersible), 2 mg, containing a paragraph IV certification was received by this office prior to the receipt of your ANDA. This other ANDA, therefore, is eligible for 180-day generic drug exclusivity for Lamotrigine Tablets (Chewable, Dispersible), 2 mg. According, your ANDA will be eligible for final approval on the date that is 180 days after the date the agency receives notice, with respect to the other ANDA, of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act.

Our decision to continue the tentative approval status of your Lamotrigine Tablets (Chewable, Dispersible), 2 mg, is based upon information currently available to the agency, i.e., data in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product. This decision is subject to change on the basis of new information that may come to our attention.

To reactivate your ANDA with respect to the 2 mg strength prior to final approval, please submit a "MINOR SUPPLEMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that this product will be eligible for final approval. Your

supplement must provide a summary of the legal basis upon which you believe the ANDA should be approved, as well as:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this ANDA, or
2. a statement that no such changes have been made to the ANDA since the date of tentative approval.

Any changes in the conditions outlined in this ANDA and the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to Agency review before final approval of your Lamotrigine Tablets (Chewable, Dispersible), 2 mg 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.

In addition to the supplement requested above, the agency may request at any time prior to the final date of approval that you submit an additional supplement containing the requested information. Failure to submit either supplement may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

Your Lamotrigine Tablets (Chewable, Dispersible), 2 mg, may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of a drug before the effective final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, the 2 mg product will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional supplements, please contact Lisa Kwok, PharmD, Project Manager, at 240-276-8494.

Sincerely yours,

{See appended electronic signature page}

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

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
1/22/2009 02:43:09 PM
Deputy Director, for Gary Buehler