DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-124

February 21, 2007

Actavis Mid Atlantic LLC
Attention: Elizabeth Trowbrige, R.A.C.
Associate Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, New Jersey 07207

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 28, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL.

Reference is also made to your amendments dated July 16, 2001; August 12, 2004; and May 26, July 13, September 26, and December 11, 2006.

We have completed the review of this ANDA 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 is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Ranitidine Oral Solution USP, 15 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zantac Syrup, 15 mg/mL, of GlaxoSmithKline (GSK).

The RLD upon which you have based your ANDA, GSK's Zantac Syrup, 15 mg/mL, 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. 5,068,249 (the '249 patent), is scheduled to expire (with pediatric exclusivity added) on May 26, 2009.

Your ANDA contains a paragraph IV certification to the '249 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ranitidine Oral Solution USP, 15 mg/mL, 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 was brought against Actavis Mid Atlantic LLC (Actavis - formerly Alpharma) for infringement of the listed '249 patent. You have notified the agency that Actavis complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Actavis within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Actavis was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '249 patent for this drug product. Therefore, with this approval Actavis is eligible for 180-days of generic drug exclusivity for Ranitidine Oral Solution USP, 15 mg/mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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 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

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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,

{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
2/21/2007 03:29:43 PM
for Gary Buehler