DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-243

NOV 8 2006

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director of Regulatory Affairs
223 Quaker Road
P.O. Box 2900
Pomona, NY 10970

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 18, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Olanzapine Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 mg.

Reference is also made to your amendments dated April 20, and August 12, 2005; and February 15, April 20, September 25, and October 3, 2006.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved.** This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The referenced listed drug (RLD) upon which you have based your ANDA, Zyprexa Zydis Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 mg of Eli Lilly Company, 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. 5,229,382 (the '382 patent), is scheduled to expire on April 23, 2011.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '382 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Olanzapine Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 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 Barr Laboratories, Inc. (Barr) for infringement of the '382 patent. This action must have been brought against Barr prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of '382 was brought against Barr in the United States District Court for the United States District Court of Indiana [Eli Lilly and Company and Lilly Industries Limited v. Barr Laboratories, Inc., Civil Action No. 1:04-CV-1957_SEB-VSS]. This litigation is pending.

Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii)[1] or such shorter or longer period as the court may have ordered, or,

   b. the date the court decides[2] that the '382 patent is invalid or not infringed. See sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act, or,

   c. the '382 patent has expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final

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[1] Because information on the '382 patent was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

approval. This amendment should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the ANDA 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. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to

submitting additional amendments, please contact Jeanne Skanchy, Project Manager, at 301-827-9275.

Sincerely yours,

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