



ANDA 090482

Handa Pharmaceuticals, LLC
Attention: Maggie Chang, Ph.D.
Executive Vice President, Quality Affairs
39465 Paseo Padre Parkway
Suite 2600
Fremont, CA 94538

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 11, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Quetiapine Fumarate Extended-release Tablets, 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg.

Reference is made to your amendments dated February 9, February 10, March 9, and November 11, 2009; and June 2, July 6, July 12, September 9, September 13, September 17, October 1, October 15, October 28, November 4, November 9, November 18, and November 19, 2010.

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 reference listed drug (RLD) upon which you have based your ANDA, Seroquel XR Extended-release Tablets, 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg of AstraZeneca UK Limited, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,879,288 (the '288 patent) and 5,948,437 (the '437 patent) are scheduled to expire (with pediatric exclusivity added) on March 26, 2012, and November 28, 2017, respectively.

With respect to each of these patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that these are method of use patents (U-601 and U-839 use codes) that do not claim any indication for which you are seeking approval under your ANDA.

Your ANDA also contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Quetiapine Fumarate Extended-release Tablets, 50 mg, 150 mg, 200 mg, 300 mg, and 400 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 Handa Pharmaceuticals, LLC (Handa) for infringement of one or more of the patents that were the subject of the paragraph IV certifications. You notified the agency that Handa complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '288 and '437 patents was brought against Handa within the statutory 45-day period in the United States District Court for the District of New Jersey [AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited v. Handa Pharmaceuticals, LLC and John Doe Entity, Civil Action No. 08-cv-5328 and 08-cv-5997].

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),
 - b. the date the court decides¹ that the patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or
 - c. the listed patents have 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 approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if

¹ 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.

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 significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the application 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 301 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 application, or prior to submitting additional amendments, please contact Sarah Nguyen, Project Manager, at (240) 276-8467.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

KEITH O WEBBER
12/09/2010