



ANDA 090681

Accord Healthcare, Inc.  
Attn: Samir Mehta, Ph.D  
President  
1009 Slater Road  
Suite 210-B  
Durham, NC 27703

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 17, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Quetiapine Fumarate Extended-release Tablets, 150 mg (base), 200 mg (base), 300 mg (base), and 400 mg (base).

Reference is also made to your amendments dated April 6, 2009; and March 11, May 10 and 27, June 29, August 16, September 13, 15, and 28, October 15 and 28, November 9, 12, and 17, 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 issues 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). This determination is 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 of Astra Zeneca, 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) expire (with pediatric exclusivity added) on March 26, 2012, and November 28, 2017, respectively.

With respect to the '288 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(iii) of the

Act stating that Accord Healthcare Inc. (Accord) will not market Quetiapine Fumarate Extended-release Tablets, 150 mg, 200 mg, 300 mg, and 400 mg, under this ANDA prior to the expiration of the patent. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the '288 patent has expired (with pediatric exclusivity added) on March 26, 2012.

In addition, with respect to the '437 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Quetiapine Fumarate Extended-release Tablets, 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 Accord for infringement of the patent that was the subject of the paragraph IV certification. You notified the agency that Accord complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of '437 was brought against Accord 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. Accord Healthcare, Inc., Accord Healthcare Ltd., and Intas Pharmaceutical Ltd., CA No. 08-cv-4804 and 09-cv-0619].

Therefore, final approval cannot be granted until the '288 patent has expired and:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),
  - b. the date the court decides<sup>1</sup> that the '437 patent is invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or
  - c. the '437 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 this ANDA prior to final approval, please submit a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. This amendment should be submitted approximately 90 days prior to the date you believe the ANDA will be eligible for final approval. The amendment should state the legal/regulatory basis for approval,

---

<sup>1</sup> 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.

and it should also identify changes, if any, in the conditions under which the product was tentatively approved including updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if no changes have been made to the ANDA. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to this amendment, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above. 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 serve to delay 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 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 upon submitting an amendment to the ANDA, 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  
12/14/2010