DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-565

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Senior Director, Global Regulatory Affairs
3600 Arco Corporate Drive, Suite 310
Charlotte, NC 28273-7104

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 7, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base).

Reference is also made to your amendments dated June 26, November 3, and November 17, 2006; and May 14, July 8, August 4, August 13, September 2, October 17, October 24, and November 25, 2008. We also acknowledge receipt of your correspondence dated August 4, and December 9, 2008, addressing the patent issues associated with this ANDA.

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 manufacture 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, Geodon Capsules of Pfizer, Inc., is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

| U.S. Patent Number | Expiration Date |
|---|---|
| 4,831,031 (the '031 patent) | March 2, 2012 |
| 5,312,925 (the '925 patent) | September 1, 2012 |
| 6,150,366 (the '366 patent) | May 27, 2019 |
| 6,245,766 (the '766 patent) | December 18, 2018 |

With respect to the '766 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that this is a method of use patent, and that this patent does not claim any indication for which you are seeking approval under this ANDA.

With respect to the '925 and '366 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base), under this ANDA. You have notified the agency that Dr. Reddy's Laboratories Limited (DRL) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '925 or '366 patents was brought against DRL 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).

With respect to the '031 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that DRL will not market Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base) prior to the expiration of this patent. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until expiration of the '031 patent, currently March 2, 2012.

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 it should also identify changes, if any, in the conditions under which the product 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. This amendment 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 current good manufacturing practices (cGMPs) are subject to agency review before final approval of the ANDA will be made. Such changes should be submitted as an amendment to the ANDA and categorized as representing either "major" or "minor" changes. The amendment will be reviewed according to OGD policy in effect at the time of receipt. Your submission of multiple amendments prior to final approval may also lead to 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 approved for marketing under section 505 of the Act and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to March 2, 2012, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Esther Chuh, Project Manager, at (240)276-8530.

Sincerely yours,

*{See appended electronic signature page}*

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/
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Robert L. West
12/29/2008 09:59:01 AM
Deputy Director, for Gary Buehler