DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076534

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kimberly Ernst
Associate Director, Global Regulatory Affairs
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 8, 2002, 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 26, May 3, June 23, August 27, and November 30, 2004; July 14, and August 23, 2006; March 26, July 31, and October 12, 2007; May 16, August 4, and August 8, 2008; January 8, April 29, April 30, and May 26, 2009; January 20, and October 12, 2010; and February 24, April 28, August 25, September 14, September 16, and October 20, 2011.

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 Olanzapine Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zyprexa Zydis Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg and 20 mg, respectively, of Eli Lilly and Company (Lilly). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which your ANDA is based, Lilly's Zyprexa Zydis, 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. 6,960,577 (the '577 patent) is scheduled to expire on November 1, 2017. Your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that the '577 patent is a method of use patent, and that this patent does not claim any indication for which you are seeking approval.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as

described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research