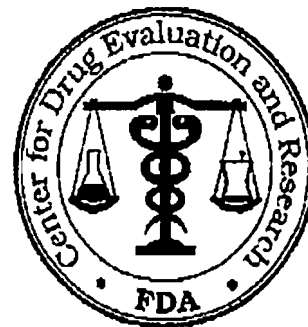


ANDA 091415



OFFICE OF GENERIC DRUGS

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville, MD 20855
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Torrent Pharmaceuticals Limited TEL. (269) 544-2299
ATTN: Dawn Chitty FAX: (269) 544-2334
FROM: Leigh Ann Sears FDA CONTACT PHONE: (240) 276-8453

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated March 11, 2009, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Olanzapine Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 mg.

We are pleased to inform you that this application is APPROVED!

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091415

Torrent Pharmaceuticals Inc. USA
U.S. Agent for: Torrent Pharmaceuticals Limited
Attention: Dawn Chitty
Director, Regulatory Affairs
5380 Holiday Terrace, Suite 40
Kalamazoo, MI 49009

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 11, 2009, 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 September 9, 2009; August 20, 2010; and February 8, April 28, June 17, August 9, August 25, September 15, September 19, September 29, October 19, and two amendments dated October 24, 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 product (RLD), Zyprexa Zydis Tablets, 5 mg, 10 mg, 15 mg, and 20 mg, respectively, of Eli Lilly and Company. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD referenced in your application, Zyprexa Zydis Tablets, 5 mg, 10 mg, 15 mg, and 20 mg, of Eli Lilly and 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. 6,960,577 (the '577 patent) is scheduled to expire on November 1, 2017.

With respect to the '577 patent, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that this patent does not claim any indication for which you are seeking approval under your ANDA.

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/StructuredProductLab>

eling/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/UCM072392.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

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

/s/

ROBERT L WEST

10/25/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.