



ANDA 078572

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Sr. Director, Global Regulatory Affairs
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 30, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluoxetine Delayed-release Capsules USP, 90 mg (Once-Weekly).

Reference is made to your amendments dated February 9, May 4, July 12, and November 20, 2007; November 5, and December 31, 2009; and February 23, 2010. Reference is also made to the tentative approval letter issued by this office on December 18, 2008.

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 Fluoxetine Delayed-release Capsules USP, 90 mg (Once-Weekly) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Prozac Weekly Delayed-release Capsules, 90 mg, of Eli Lilly and Company (Lilly).

Your dissolution testing should be incorporated into the stability and quality control program using the same USP method proposed in your ANDA. The "interim" dissolution specifications should be conducted as follows:

Medium 1: 250 mL 0.1 N HCl for 2 hours.

Medium 2: Then, 250 mL Phosphate Buffer at pH 6.8 at 37°C for 45 minutes.

Apparatus: III (Reciprocating Cylinder) @ 12 dpm

The test products should meet the following "interim" specifications:

Acid Medium - NMT 10% is dissolved in 120 minutes.

Buffer Medium - NLT 75% is dissolved in 45 minutes.

These "interim" dissolution tests and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Lilly's Prozac Weekly Delayed-release Capsules, 90 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,910,319 (the '319 patent)	May 29, 2017
5,985,322 (the '322 patent)	May 29, 2017
RE39030 (the '030 patent)	May 29, 2017

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fluoxetine Delayed-release Capsules USP, 90 mg (Once-Weekly), 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 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). You have further notified the agency that DRL brought a declaratory judgment

action against Lilly in the United States District Court for the District of New Jersey [Civil Action No. CV-09-1392]. On September 21, 2009, the court ruled that the '319, '322, and '030 patents are not infringed by DRL and this decision was not appealed by Lilly.

Prior to the submission of your ANDA, another applicant submitted an ANDA providing for Fluoxetine Hydrochloride Delayed-release Capsules USP, 90 mg (base) (Once Weekly), and containing a paragraph IV certification to the patents listed above. This ANDA was entitled to 180-day generic drug exclusivity under section 505(j)(5)(B)(iv) of the Act. Because the other ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, the 180-day exclusivity provisions in effect prior to December 8, 2003, apply. See MMA § 1102(b)(1). Under section 505(j)(5)(B)(iv)(II) as then in effect, a court decision finding the patents to be invalid or not infringed can begin the period of 180-day generic drug exclusivity. The district court's September 21, 2009 finding that the '319, '322, and '030 patents are not infringed by DRL, therefore, began the other applicant's 180-day generic drug exclusivity period. The expiration of this period on March 20, 2010, means your ANDA is eligible for 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 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] 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. For administrative purposes, please designate this submission as "**LABELING/SPL FINAL for Approved ANDA 078572**".

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- ANDA-78572	----- ORIG-1	----- DR REDDYS LABORATORIES LTD	----- FLUOXETINE HYDROCHLORIDE

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
03/22/2010
Deputy Director, for Gary Buehler