

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-458

APPROVAL LETTER

ANDA 76-458

MAY 14 2004

Par Pharmaceutical, Inc.
Attention: Julie Szozda
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 15, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluoxetine Oral Solution USP, 20 mg(base)/5 mL.

Reference is also made to your amendments dated December 31, 2003, and January 28, and April 28, 2004.

The listed drug product referenced in your application, Prozac Liquid of Eli Lilly & Co., is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,626,549 (the '549 patent) is scheduled to expire on June 2, 2004. Your application contains a patent statement under section 505(j)(2)(A)(viii) of the Act indicating that this patent does not claim any of the proposed indications for which you are seeking approval under this ANDA. In addition, the labeling for this drug product incorporates language to inform health care practitioners that the reference listed drug has been approved for pediatric use. This language is acceptable under the Best Pharmaceuticals for Children Act (BCPA).

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Fluoxetine Oral Solution USP, 20 mg(base)/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug [Prozac[®] Liquid (Oral Solution) of Eli Lilly & Co.].

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

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,



Gary Buehler 5/14/04

Director

Office of Generic Drugs

Center for Drug Evaluation and Research

cc: ANDA 76-458
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-92

Endorsements:

HFD-647/L.Tang/ *U.V. Venkataram for*
HFD-647/U.Venkataram/ *U.V. Venkataram 5/5/04*
HFD-617/S.Shepperson/ *Shepperson 5-5-04*
HFD-613/A.Vezza/ *A.Vezza 5/5/04*
HFD-613/L.Golson/ *John Bal 5/6/04* *R. C. Adams 5/13/04*

Robert Lee Sext
5/14/2004

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F/T by rad5/3/04

APPROVAL