CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 18-936/S-052
20-101/S-024

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
317 276 2000

NDA SUPP AMEND

NDA NO. 18-936 REF NO. SLR-052 (AF)
NDA SUPPL FOR Labeling

September 16, 1999 ORIGINAL **FINAL PRINTED LABELING**

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological
Drug Products, HFD-120
Attn.: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857-1706

Re: NDA 18-936/S-052, Prozac® (fluoxetine hydrochloride) - Pulvule®
NDA 20-101/S-024, Prozac® (fluoxetine hydrochloride) - Liquid

Please refer to Lilly's supplemental new drug application submitted to NDA 18-936 on May 11, 1998; the approvable letter from FDA concerning this supplemental application dated August 11, 1999; and a follow-up phone conversation between Mr. Paul David, FDA, and Dr. David W. Johnson, Lilly, on August 31, 1999. In that phone conversation, FDA acknowledged agreement with a Lilly suggested change to the FDA proposed revisions to this labeling, that is to add the phrase "As with other SSRIs" on the beginning of the sentence in the Geriatric Use section that concerns hyponatremia. With acceptance of this change, Lilly agrees to the other labeling revisions in the approvable letter.

Thus, Lilly is herewith submitting revised labeling in final printed form for the referenced products. For your convenience, the changes are highlighted. Enclosed are twenty copies of the revised final printed labeling (identified as **PV 3312 DPP**), ten of which are individually mounted on heavy weight paper or similar material. The labeling is dated August 11, 1999. Lilly will begin utilizing these changes once the approval letter is received from FDA.

Please call Dr. David W. Johnson at (317) 277-1806 or me at (317) 277-3799 if there are any questions. Thank you for your continued cooperation and assistance.

Sincerely,

ELI LILLY AND COMPANY

Gregory T. Brophy, Ph.D.
Director
U.S. Regulatory Affairs

cc: Mr. Paul David

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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NDA 18-936/S-052

Eli Lilly & Co.
Lilly Corporate Center
Indianapolis, IN 46285

MAY 20 1998

Attention: Gregory T. Brophy, Director

DearL Dr. Brophy

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Prozac

NDA Number: 18-936

Supplement Number: S-052

Date of Supplement: May 11, 1998

Date of Receipt: May 12, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on July 11, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Office of Drug Evaluation I
Attention: Document Control Room 4008
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

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John S. Purvis
Chief, Project Management Staff
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA 18-936/052
HFD-120/Div. Files
HFD-120/CSO/David

filename: C:\WPWIN61\TEMPLATE\FDA\18-936.052

SUPPLEMENT ACKNOWLEDGEMENT

Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-2000

May 11, 1998

GERIATRIC LABELING SUPPLEMENT

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological
Drug Products, HFD-120
Attn.: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857-1706

Re: NDA 18-936, Prozac® (fluoxetine hydrochloride) - Pulvule®

In compliance with the FDA final rule issued August 27, 1997 concerning the addition of a "Geriatric Use" Subsection in the Labeling, Lilly is submitting the attached Geriatric Labeling Supplement to NDA 18-936. A cross reference letter for this submission is being sent to NDA 20-101.

Please call Dr. David W. Johnson at (317) 277-1806 or me at (317) 277-3799 if there are any questions. Thank you for your continued cooperation and assistance.

Sincerely,

ELI LILLY AND COMPANY

Gregory T. Brophy, Ph.D.
Director
U.S. Regulatory Affairs

cc: Mr. Paul David (Cover Letter and Volume I)

ATTACHMENT B.
DRAFT LABELING.

4 page(s) of revised draft labeling has been redacted from this portion of the review.