

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 18-936/S-054

CHEMISTRY REVIEW

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DEC 15 1998

CHEMIST REVIEW
OF SUPPLEMENT

1. ORGANIZATION:	HFD-120
2. NDA:	18-936
3. SUPPLEMENT NUMBERS/DATES:	SCF SEM-054
letter date:	17-JUN-1998
stamp date:	18-JUN-1998
4. AMENDMENT:	
5. RECEIVED BY CHEMIST:	22-JUN-1998
6. APPLICANT NAME & ADDRESS:	Lilly Research Laboratories Lilly Corporate Center Indianapolis, Indiana 46285
7. NAME OF DRUG:	Prozac [®] Pulvules [®]
8. NONPROPRIETARY NAME:	Fluoxetine Capsules, USP
9. CHEMICAL NAME/STRUCTURE:	see USP
10. DOSAGE FORM(S):	Pulvules (capsules)
11. POTENCY:	40 and 60 mg
12. PHARMACOLOGICAL CATEGORY:	anti-depressant
13. HOW DISPENSED:	<input checked="" type="checkbox"/> (Rx) <input type="checkbox"/> (OTC)
14. RECORDS & REPORTS CURRENT:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
15. RELATED IND/NDA/DMF:	

16. SUPPLEMENT PROVIDES FOR: addition of two new strengths: 40 and 60 mg.

17. COMMENTS: This NDA currently is approved for doses of up to 80 mg/day. The sponsor states that the proposed new strengths would provide additional prescribing options.

18. CONCLUSIONS & RECOMMENDATIONS: The supplement may be approved when the sponsor has adequately addressed the issues raised in the draft letter.

19. REVIEWER NAME

SIGNATURE

DATE COMPLETED

Robert H. Seevers
Chemistry Team Leader

[Handwritten Signature]

12/15/98

cc:

Original NDA 18-936

NDA 18-936 Division File
HFD-120/CSO/David
HFD-120/Chemist/Seevers

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