

NDA 20-822

Forest Laboratories, Inc.
Attention: Kathryn Bishburg, Pharm.D.
Associate Director, Regulatory Affairs
909 Third Avenue
New York, New York 10022-4731

Dear Dr. Bishburg:

Please refer to your New Drug Application dated May 7, 1997, received May 12, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celexa™ (citalopram hydrobromide) 20 mg, 40 mg, and 60 mg Tablets.

Reference is also made to an agency approvable letter dated May 12, 1998.

We acknowledge receipt of your submissions dated May 22, June 15, June 22, July 6, July 16, and July 17, 1998. Your submission dated May 22, and received May 26, 1998 constituted a full response to our May 12, 1998 action letter. The user fee goal date for this application is July 26, 1998.

This new drug application provides for the use of Celexa™ to treat depression.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

Accompanying this letter (ATTACHMENT) is the labeling, including the revisions agreed to, that should be used for marketing this drug product. These revisions are terms of the NDA approval. Marketing the product before making the agreed upon revisions in the product's labeling may render the product misbranded and an unapproved new drug.

Additionally, we note that you do not intend to market, at this time, the 60 mg strength and, as such, references to this strength have been removed from the attached labeling.

We have the following additional comments:

Phase 4 Commitments

We remind you of your Phase 4 commitments specified in your submissions dated May 22, July 6, July 16, and July 17, 1998. These commitments, along with any completion dates agreed upon, are listed below.

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Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR

314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

MANUFACTURING AND CONTROLS

1. Expiration Date

As requested in your correspondence dated May 22, 1998, the Agency is approving an initial 24-month expiration dating period based upon your currently available 18-month data.

2. Nomenclature

We again note that the established name, citalopram hydrobromide, has not been adopted by the USAN Council. We acknowledge your commitment to submit a copy of the USAN approval letter to the Agency when granted.

3. Methods Validation

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

BIOPHARMACEUTICS

We note your agreement to the following dissolution method and specification for all tablet strengths:

Apparatus:	USP Apparatus 1 (basket)
Speed:	100 RPM
Medium:	800(b)(4)ffer (pH = 1.5) at 37 °C
Specification:	Q =(CC)--t 30 minutes

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-822." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane

Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ATTACHMENT