March 20, 2000

Russell Katz, M.D., Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation and Research I
Center for Drug Evaluation and Research
HFD-120, Woodmont II
Document Control Room, 4th Floor
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852

CENTER FOR DRUG EVALUATION
AND RESEARCH

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RECEIVED HFD-120

Re: **IND 22,368/Serial No. 217 – General Correspondence**
Product: **Citalopram Hydrobromide Tablets 10 mg, 20 mg and 40 mg**

Dear Dr. Katz:

We are taking this opportunity to notify the Division of a clinical supply packaging error for study CIT-MD-18 (site #2 – Dr. Busner and site #16 – Dr. Wagner). Due to this error, medication was dispensed to eight (8) randomized patients in a fashion that had the potential to cause patient bias. At no time was patient safety an issue. Upon notification of this error, Forest immediately requested that all study drug be accounted for, and shipped back to Forest facilities. Upon receipt, the drug was correctly packaged and resent to the sites. Additionally, a fax was sent to the sites explaining the error, the corrective measures taken, and suggesting that although this was not a safety issue, that their IRBs be notified.

A full complement of 160 patients will be enrolled under standard double-blind conditions.

For reporting purposes, the primary efficacy analysis will exclude the eight potentially unblinded patients, with a secondary analysis including them also to be conducted. All patients will be included in all safety analyses.

We want to reassure you that this issue has been resolved and all appropriate measures taken to insure that proper conduct of the study.

If you have any questions or require additional information, please do not hesitate to call Tracey Varner at 201-386-2124.

Sincerely,

Tracey Varner
Manager, Regulatory Affairs
Forest Laboratories, Inc.

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                               PLAZA THREE, SUITE 602**