# Forest Laboratories, Inc.
## Inter-Office Memorandum

**To:** S. Hariharan, S. Mahashabde, I. Green

**From:** Ibrahim A. Munkaila IB

**Subject:** CIT-MD-18

**Date:** March 7, 2000

**CC:** W. Whitney, S. Aygen, M. Jacob, J. Rocchio

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## DEVIATION REPORT

BACKGROUND:
CIT-MD-18 is a multi-center, randomized, double-blind, placebo-controlled, flexible-dose and age stratified study. The study required Citalopram 20mg tablets in bottles of 10's and 40's and Citalopram Placebo tablets in bottles of 10's and 40's.

These were the supplies we used in the study:

| Lot Number | Product/ Strength | Bottle size | Description |
|---|---|---|---|
| P01102 | Citalopram 20 mg Tablets | 10's | Pink Oval trade dress tablets* |
| P01164 | Citalopram Placebo tablets | 10's | White non trade dress tablets |
| P01164 | Citalopram Placebo Tablets | 40's | White non trade dress tablets |
| P02161 | Citalopram 20 mg Tablets | 40's | White non trade dress tablets |

The packaging for this study was performed in November 1999, and Lot P01102 used in packaging was trade dress tablets instead of white non-trade dress tablets.

It was brought to our attention by the Medical Department that; some of the patients enrolled in this study had pink tablets in their bottles. We immediately investigated this matter by opening a bottle each from the above mentioned lot numbers. We discovered Lot number P01102 were the pink oval tablets, with FP/20MG imprints. We were requested by Medical Department to recall all the supplies and repackage them.

Our decision to use this lot was based on the fact that the required strength of Citalopram was available in the desired packaging configuration (10's) in our inventory. This would also save time on our planning towards this study since we did not have to procure this supply through Packaging department.

In preparation for this study, all established procedures of the Clinical Packaging Group were followed. Visual inspection of the contents of the sealed bottles was not performed. The cartons were marked as Citalopram 20mg tablets and the Certificate of Analysis we obtained to support the use of this batch in the study did not provide any descriptive information about the shape, color and size of the tablet. That is the reason we inadvertently packaged the wrong tablets.

To promptly correct this matter, a new lot (P01165) of Citalopram 20mg tablets in bottles of 10's has been selected to replace the pink tablets. 640 bottles of this lot are required. Each bottle has been opened and verified that they all contain white non- trade dress tablets. All the Patient Kits in house were opened and the four bottles (Visits 2-4) replaced with the newly labeled bottles. Visits 5-6 bottles will remain intact in the Kits. The same action will be taken for all Kits returned from the sites.

To prevent a situation like this ever arising again, we are taking the following precautionary measures:

1. Visual inspection of the contents of a few bottles of any lot should be mandatory. This will be included as part of the packaging protocol.

2. The Clinical Packaging Group will request a copy of the Packaging Worksheet from the Packaging Department for any batch we intend to employ in any study. This will also be an attachment to the packaging protocol.

3. Certificates of Analysis for all batches will be a part of the packaging dossier.

4. A color-labeling scheme to differentiate between our trade and non-trade batches will be incorporated. These colored labels will be affixed to our inventory cards and on the product cartons as well. This practice will be extended to include all batches in our possession now and any new inventories.

* This description was not known at the time of packaging.