If reconsider NO letter
otherwise I recommend much less narrative, more concise:
Due to a packaging error, 8 randomized patients at 3 investigational sites had access to potentially unblinding information. Drug has been repackaged, and a full complement of 160 additional patients will be enrolled under standard double-blind conditions.
For reporting purposes, the primary efficacy analysis will exclude the potentially unblinded patients, and a secondary analysis including them will also be conducted. These patients will be included in all safety analyses.

Letter to the FDA – **DRAFT**

March 8, 2000

Re: clinical supplies for the Pediatric Depression Study CIT-MD-18

Re: CIT-MD-18; *A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Citalopram in Children and Adolescents with Depression.*

Dear Dr. Katz,

The purpose of this letter is to inform the agency that an error was made during the packaging of the clinical supplies for the above-noted study. This error came to our attention following enrollment of the first few patients into the study. Two of our investigational sites called in to report that some of their patients were receiving white tablets and others were receiving pink tablets. These reports were passed onto Forest Clinical Packaging where it was discovered that a number of bottles of "active" medication were mistakenly packed with the pink-colored commercial Celexa® tablets instead of the standard white citalopram tablets used for blinded clinical studies.

On March 2nd, all sites were notified of this error by telephone and by fax. In addition, the sites were instructed to return their clinical supplies to the Forest manufacturing and packaging facility in Commack, NY. Following receipt of the medication in Commack, all bottles of medication containing trade dress tablets were replaced with bottles containing the investigational white tablets and returned to the sites within 24-48 hours. Replacement bottles and labels were identical to those that were replaced. The randomization code for this study has not been changed.

As only 8 of 160 patients had been randomized at the time this error was discovered, the impact upon the integrity of the study is suggested to be minimal. In addition, these eight patients were restricted to only two investigational sites (a total of 19 sites are involved).

If you should have any questions or require any additional information, please do not hesitate to contact me.