Lotus cc:Mail for Charles Flicker

Author: Paul Tiseo at Forest_NYC
Date: 03/08/2000 11:35 AM
Normal
TO: Lawrence Olanoff, Ivan Gergel, Amy Rubin at FOREST_NJO
CC: Tracey Varner at FOREST_NJO, Julie Kilbane, Charles Flicker
TO: Anjana Bose
Subject: Letter to FDA for CIT-18
---------- Message Contents

Dear all,

Attached please find the letter that Charlie and I put together for the purpose of informing the FDA of our packaging mishap in the citalopram pediatric study.

Please review and send your comments back to me within the next few days. I will compile the corrections here and then send the final letter to NJO for final Regulatory review.

If you have any questions, give me a call.

Paul

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 due to a clinical supplies packaging error for the above-referenced trial, eight randomized patients at two investigational sites were dispensed medication that could have potentially unblinded the study. The drug for this study has since been repackaged and 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.

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