Lotus cc:Mail for Charles Flicker

Author: Amy Rubin at forest_njo
Date: 03/15/2000 4:23 PM
Normal
Receipt Requested
CC: Paul Tiseo at FOREST_NYC
TO: Charles Flicker at FOREST_NYC
Subject: Re[3]: Letter to FDA for CIT-18
---------- Message Contents

Thanks for the compliement. Part of my job is to create "masterful" euphemisms to protect Medical and Marketing.

Amy

---------- Reply Separator ----------
Subject: Re[2]: Letter to FDA for CIT-18
Author: Charles Flicker at Forest_NYC
Date: 3/14/2000 2:23 PM

Altho "potential to cause bias" is a masterful stroke of euphemism, I would be a little more up front about the fact that the integrity of the blind was unmistakenly violated.

---------- Reply Separator ----------
Subject: Re: Letter to FDA for CIT-18
Author: Amy Rubin at forest_njo
Date: 03/09/2000 8:56 AM

Paul

I have taken the liberty of editing your letter as follows:
Please make any other changes you feel are necessary.

Thanks,

Amy

Dear Dr.Katz,

We are taking this opportunity to notify the Division of a clinical supply packaging error for study CIT-MD-18 (sites -----). 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 safey 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 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 the proper conduct of the study.

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

Sincerely,

Reply Separator

Subject: Letter to FDA for CIT-18
Author: Paul Tiseo at Forest_NYC
Date: 3/8/2000 11:35 AM

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