Lotus cc:Mail for Charles Flicker

Author: Paul Tiseo at Forest_NYC
Date: 03/02/2000 12:24 PM
Normal
TO: Joan Barton, Keith Curley at FOREST_CMK, Charles Flicker, Ivan Gergel, Shankar Hariharan at FOREST_INW, Joan Howard, Shashank Mahashabde, Lawrence Olanoff
CC: Tracey Varner at FOREST_NJO
TO: Amy Rubin at FOREST_NJO, Edward Lakatos, Anjana Bose
CC: Carlos Cobles
Subject: CIT-18 FAX to Investigational sites
---------- Message Contents

Dear all,

For your information, a copy of the FAX that went out to all CIT-MD-18 Pediatric Investigational sites this morning is attached. All sites have also been contacted by telephone and given verbal instructions on how to proceed with both drug shipment as well as their patients who have been Screened and/or randomized.

I would also like to thank everyone involved in this process for their input and their assistance in rectifying this situation in such a timely manner.

If you have any questions, please do not hesitate to contact me.

Best regards,

Paul

Forest Laboratories, Inc.

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FAX TRANSMISSION COVER SHEET

**** *URGENT MESSAGE* ****

Date: *March 2, 2000*

To:

Fax:

Re: *CIT-MD-18 Citalopram Pediatric Depression Study*

Sender: ***Paul J. Tiseo, PhD***
Associate Medical Director
CNS Development Group

YOU SHOULD RECEIVE 4 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL THE ABOVE NUMBER.

It has come to our attention that an error was made during the packaging of the clinical supplies for the above-noted study. 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. As a result, dispensing these tablets would automatically unblind the study. This medication needs to be replaced with the appropriate white tablets immediately to maintain the study blind.

For those sites that have already randomized patients, please be advised that this error in packaging *does not affect the safety of your patients in any way*. The medication used in both the white and the pink tablets is exactly the same. Only the color of the tablets is different.

In order to correct this mistake, we are asking each site to return their study medication to Forest Laboratories using the instructions on the following page. For those sites who have already randomized patients or who have patients in Screen, instructions are also provided.

Return of medication

Please return all patient kits (each kit containing 6 bottles of medication) to our facility in Commack, NY at the address given below. All bottles containing the pink tablets will be replaced with the correct white tablets and returned to you within 48 hours of receiving it from your site. *Please note that the box containing the bottles of placebo lead-in medication does not need to be returned.* (Sites with randomized patients are discussed below).

Send the drug to:

Keith Curley

Forest Laboratories

500 Commack Road

Commack, NY 11725

Phone: 516-493-4490

Please send the drug via Fed Ex using Account No. 1316 77 278. In addition, we would ask that you also fill out the *"Study Supply Return Shipment Form"* that is contained in your Regulatory Binders. This is the form that you would normally use at the end of a study to return unused medication. Please note that you will only be sending back "Unused units". For patients who have already been randomized, you will keep those drug units at your site. This is discussed in more detail below.

What to do with your patients.....

Patients already randomized: *This packaging error will not affect these patients.* These patients will proceed through the study normally and will continue on into the extension study if they so desire. All scheduled efficacy and safety assessments will be conducted. DO NOT ship their remaining drug back to Forest. Keep all of their drug at your site and continue to use it as you would ordinarily. Return only the units of drug for your non-randomized patients.

Patients in Screening: All sites who have patients in the placebo lead-in period have already been contacted directly. The screening period for these patients will be expanded to allow the medication to be re-packaged prior to randomization. *Medication that is shipped from these sites on Thursday, March 2nd will returned by Tuesday morning, March 7th.* Also - any additional placebo medication that is used during this time period will be resupplied.

Patients scheduled for Screening: If you presently have patients scheduled for Screening, you may proceed and initiate Screening activities such as the K-SADS-PL and/or labs, etc. Under NO circumstances, however, should these patients be dispensed single-blind placebo medication until you have your re-packaged medication returned to you. As the turnaround for re-packaging will be only a few days, this should not result in any significant delays.

IRB

Although this is not a patient safety issue, we recommend that you inform your IRB of the mistake in packaging. A brief letter is attached for your use, explaining in detail the reason for the medication recall.

On behalf of Joan Barton and the rest of the Forest Pediatric Team, I would like to thank all of you for your understanding and assistance with this situation, and we apologize for any inconvenience that we may have caused you. If you should have any questions about any of these procedures, please do not hesitate to contact me.

Best regards,

Paul J. Tiseo

Paul J. Tiseo, PhD
Associate Medical Director
CNS Development Group

To:

Date:

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

We have been informed by Forest Laboratories, Inc., the sponsor of the above-noted study, that an error was made during the packaging of clinical supplies. 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. As a result, dispensing these tablets would automatically unblind the study. This medication will now be replaced with the appropriate white tablets to maintain the study blind.

We have been advised that this error in packaging does not affect the safety of our patients in any way. The medication used in both the investigational white tablets and the commercial pink tablets is exactly the same. Only the color of the tablets is different.

We have been instructed by Forest Laboratories to return all study medication to their packaging facility in Commack, NY. All bottles containing the incorrect tablets will be replaced and returned to our site within several days.

Patients currently enrolled in the study will not be affected by this and will proceed through the study without interruption.