



Robert J. West
Special Agent
Nashville Domicile
New Orleans Resident Office
330 Franklin Road, Suite 135A-108
Brentwood, TN 37027

18 November 2002

Subject: FDA Investigation of Dr. Anne Campbell for clinical study: Randomized, Open-label, Multicenter trial of the Safety and Effectiveness of Oral Telithromycin (Ketek) and Amoxicillin/Clavulanic Acid (Augmentin) in Outpatients with Respiratory Tract Infections in usual Care settings.

Dear Mr. West

As per our telephone conversation on 13 November 2002, please find attached a copy of PPD Development's policy regarding PPD employee communication with regulatory agencies. As outlined in the policy, PPD requires employees to notify senior management prior to communication with a regulatory agency. A determination is made at that time as to whether or not a member of management from the Quality Management Systems staff needs to participate in the communication. This policy is not intended to prevent or interfere with any regulatory agency interaction with appropriate PPD employees but is to ensure that senior PPD management is kept informed and that the most appropriate individuals are addressing the inquires from a regulatory agency.

As a point of clarification, it is not PPD's policy that we contact previous employees or try to control and/or restrict any regulatory agency access to these individuals. PPD has been contacted by some of these individuals after the fact regarding communication with your office but again PPD did not initiate this communication with these former employees and we have not directed them on how to respond to your inquires.

The documents that you requested in your 04 Nov 2002 email will be sent on or before 01 Dec 2002.

Please contact me at 919-462-4439 if you have additional questions.

Sincerely

A handwritten signature in black ink that reads 'R.M. McCormick'.

Robert M. McCormick
Vice President, Quality Management Systems
PPD Development, LLC.

CC: FDA Communication File

Regulatory Agency Communication Policy

Policy Scope

This policy applies to all staff of PPD Development worldwide with the exception of those business units for which Regulatory Agencies are currently or have the potential to become a client in the near term. (i.e., Informatics)

Policy

It is the policy of PPD Development, LLC ("PPD") that authorized persons conduct all communication with Regulatory Agencies only and that detailed written documentation be retained of such communications. It is also PPD's policy and commitment to comply with applicable regulations and to correspond with authorities in an honest and professional manner. The responsibility for communication with Regulatory Agencies resides with corporate officers of PPD or their authorized designees. PPD employees are not permitted to initiate and/or engage in communications with Regulatory Agencies on behalf of PPD in an official capacity unless specifically authorized in writing by a corporate officer (i.e., Fred Eshelman, Fred Davenport or Paul Covington) or as specified in this policy under Pre-designated Delegation of Authority

Unanticipated and unsolicited communication from a Regulatory Agency will be referred to a corporate officer or his/her authorized designee. PPD employees shall not volunteer information or respond to any questions until authorized by a corporate officer. For unanticipated and unsolicited telephone contacts from a Regulatory Agency the employee is to document the name and contact number of the Regulatory Agency representative and state that an authorized representative of PPD will return the call. This information must be forwarded immediately to a corporate officer, Vice President of Regulatory and Scientific Affairs and/or Vice President Quality Management Systems.

Pre-Designated Delegation of Authority

Communications to or from Regulatory Agencies which involve issues related to GCPs, cGMPs and GLPs and related ICH guidelines and DEA regulations related to clinical study supply issues will be the responsibility of PPD's Vice President, Quality Management Systems.

Communications to or from Regulatory Agencies which involve studies in support of an IND and NDA (or equivalent), or which are part of the IND and NDA (or equivalent) process or associated regulations and guidelines with respect to which PPD has been transferred obligations, will be the responsibility of PPD's Vice President of Regulatory and Scientific Affairs.

In connection with services provided by PPD to its clients for projects for which PPD's Regulatory and Scientific Affairs Department is not responsible for the IND and/or NDA

submission or maintenance, it is anticipated that there will be PPD contacts with various Regulatory Agencies on behalf of a client. If in such instance a client requests that a PPD employee participate in communications with Regulatory Agencies, the PPD employee shall adhere to the client's SOPs for communicating with Regulatory Agencies. In addition, an authorized representative of the client must either lead or at least participate in every telephone or in-person communication with the Regulatory Agency. The PPD employee shall document the communication with the Regulatory Agency and forward a copy of the communication report to the master study file, to the client when applicable, and to PPD's Regulatory and Scientific Affairs Department.

Documentation of Communication

All communications will be documented in a contact report, which will record the date of contact, the individuals participating in the communication (from the Regulatory Agency, PPD and the client, if applicable), a detailed description of the communication, and a listing of required action points from the communication. The contact report is to be signed by the responsible PPD employee authorized to communicate with the Regulatory Agency and filed with PPD Regulatory Affairs and, if appropriate, the study master file.

Documentation of Delegation of Authority

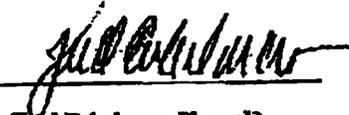
A record of any delegation of authority under this policy shall be forwarded to QMS and maintained by QMS. Senior management of PPD will review a listing of all individuals authorized to communicate with Regulatory agencies quarterly.

Definitions

Communications means any contact (i.e., written, email, telephone, videoconference, in-person) on behalf of PPD or its clients with any member of a Regulatory Agency.

Regulatory Agency means any governmental authority, which has any responsibility for the review and approval of drugs, biologics, medical devices, nutritional supplements, and veterinary products in any country of the world (e.g., FDA and DEA in the U.S.A.; MCA in the UK, EMEA for European Union, MLHW in Japan).

PPD Development, LLC



Fred Eshelman, PharmD

President and CEO

September 25, 2001

