SOPP 8104: Documentation of Telephone Contacts with Regulated Industry

Version #4

Effective Date: August 3, 2010

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1. Purpose

The purpose of this document is to describe the procedures that the Center for Biologics Evaluation and Research (CBER) staff should routinely follow regarding telephone conversations with sponsors/applicants of investigational and marketing submissions to safeguard the proprietary information in such submissions and to assure that the administrative record is complete. The same procedures also apply to contacts with regulated industry and other non-FDA persons regarding issues related to pre-application submissions and meetings, import and export requests, promotional labeling, inspections, investigations, or other regulatory actions.

2. Background

Contacts are initiated by sponsors/applicants or their representatives to check on the status of submissions [i.e., Investigational New Drug Applications (INDs), Biologics License Applications and supplements (BLAs/BLSs), Master Files (MFs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Investigational Device Exemptions (IDEs), 510Ks, Premarket Approvals (PMAs), and Product Development Protocols (PDPs)], to request information or guidance, or to inquire about other regulatory activities such as inspections or investigations, and enforcement actions. FDA may contact a sponsor/applicant to clarify or advise on issues in submissions, to request information, or to notify the sponsor/applicant of a regulatory action. While CBER staff have a responsibility to accommodate reasonable inquiries, these inquiries should not be allowed to disrupt operations.

In the past, unauthorized individuals, representing themselves as members of a sponsor/applicant firm or as agents for the firm, have attempted to obtain information from various Centers within the FDA for their own advantage or personal financial gain. Additionally, some callers have made inquiries of CBER staff during ongoing inspections without full disclosure of their identity or purpose. CBER staff have an obligation to prevent disclosure of proprietary information to unauthorized persons and not to interfere with any ongoing regulatory action.

CBER staff must adequately and promptly document telephone conversations in the official record to assure that the administrative file is inclusive of all telephone communication, and that the status of the application as reflected in the CBER regulatory database is complete and accurate.

3. Policy

CBER staff members should follow procedures described herein to prevent the inadvertent disclosure of information to unauthorized individuals and/or interference with ongoing regulatory actions, and to minimize the number of unnecessary telephone conferences with sponsor/applicant firms. All substantive teleconferences with non-FDA persons are to be documented in writing, signed, recorded in the appropriate CBER regulatory database and imported into the Electronic Document Room (EDR).

Substantive teleconferences are those which add new information or change old information in a submission. These communications include discussions involving clarification or resolution of an issue or one that was the basis of a decision. All CBER requests for information are substantive teleconferences.

Examples of substantive teleconferences are:

- Discussion that changes the status of an application, for example, placement or removal of a clinical hold.
- Discussion with a sponsor/applicant regarding protocols

Examples of non-substantive teleconferences are:

- Confirmation of meeting time and location with no discussion of meeting topics
- Confirmation of receipt of submission/data with no discussion of contents of the submission/data.

Whenever possible, there should be more than one CBER staff person on a teleconference.

4. Procedures

Confirming the Caller's Identity

All callers should be confirmed as either an authorized contact or agent of the sponsor/applicant firm. When a caller's identity is questioned, the caller should be advised that a designated contact at the sponsor's/applicant's organization should initiate the call or the CBER contact should attempt to return the call utilizing recognized contacts and phone numbers.

A written authorization from the sponsor/applicant to the file designating a representative agent must be obtained prior to communication. The authorization should list the agent's name, telephone numbers (including FAX), address, and the nature of the information that may be disclosed to the agent. Copies of the agent authorizations must be supplied to each relevant application.

Points of Contact within CBER

Whenever possible, the Regulatory Project Manager (RPM) will be the initial point of contact for industry representatives requesting filing requirements, application status, or the appropriate contact for a technical issue. Technical inquiries related to submissions may be

handled by the appropriate IND reviewer, application chairperson or their designee with notification to the RPM.

CBER Personnel Contacting Sponsors/Applicants

CBER personnel may also contact sponsors/applicants (or their designated agents) to clarify issues of immediate need or of a time-dependent nature, or to notify them of a regulatory decision. This communication should be handled through the RPM or a copy/electronic notification of the conversation record should be forwarded to the RPM. In order to make a teleconference more efficient, the review committee should communicate prior to the call to have consensus on what will be asked/requested from the sponsor/applicant. The prior communication will help eliminate numerous calls from the review committee.

Some examples of this type of communication include:

- a request for information to clarify a submission, or to request additional information
- a decision to place an IND on clinical hold, or notification that a clinical hold has been removed
- an effort to resolve minor deficiencies prior to approval of a BLA, NDA, PMA, or a supplement or prior to clearance of a 510(k) submission
- a critical need situation to maintain a sole source, therapeutically important drug
- a decision to suspend a license

CBER staff may discuss deficiencies found in the applications in accordance with the definition of an Information Request found in "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act." CBER staff should keep in mind that a discussion of minor deficiencies could elicit a submission from the firm and, depending on the regulatory pathway, may change a milestone. Therefore, letters should be utilized to convey major deficiencies.

Documenting Changes in IND/IDE Regulatory Status

If the regulatory status of an IND or IDE (e.g., clinical hold, partial hold, remove hold, disapproval) is changed during a telephone conversation, the lead CBER participant must enter the communication in CBER's Biologics IND and Related Applications Management System (BIRAMS) no later than close of business the same day with the correct communication type so that the status in BIRAMS is changed automatically and the RPM notified. The narrative summary of the conversation should be entered by the lead CBER participant within five working days. Refer to the BIRAMS User Guide for instructions on documenting telephone conversations in BIRAMS.

Sensitive Information

In instances where sensitive information or controversial issues regarding an application will be discussed at least two CBER representatives familiar with the issue(s) should participate in the call. All CBER participants should concur with the final written telecon summary.

Inquiries Involving OCBQ

The appropriate branch in the Office of Compliance and Biologics Quality (OCBQ) will handle inquiries regarding promotional labeling, facilities, inspections, or compliance issues (including import/export issues and enforcement actions). The appropriate RPM should be notified of all communications.

Inquiries Made during Ongoing Inspections

If the call is related to an ongoing inspection or investigation, refer to SOPP 8103, "Headquarters Contacts with Regulated Manufacturers During Agency Inspections"

Documentation of Conversations

All substantive telephone conversations should be documented in writing by the RPM or the technical contact and the memorandum should be included in the permanent administrative file. The memorandum of the conversation should include:

- the date and time of the teleconference,
- names of all FDA and sponsor/applicant participants,
- the subject,
- a clear and concise summary of advice,
- decisions,
- policy or actions,
- action items, and
- the signature of the preparer.

If a sponsor/applicant mentions another product while on a teleconference, a separate teleconference communication record is required for each product file if the discussion regards substantially different issues or information.

The record of the teleconference should be entered into the appropriate CBER regulatory database by the lead CBER participant as soon as possible, preferably within five working days. The memorandum must be imported into the EDR. **If a teleconference memorandum pertains to more than one file, a communication record must be entered in the appropriate regulatory database and a memorandum must be placed in each file.**

A teleconference memorandum should not be embedded as part of another document, for example, a review memo. Each document type (review memorandum, teleconference memorandum) must be entered into the appropriate CBER regulatory database separately. If appropriate, a teleconference can be referenced in another document type, but the teleconference must be entered separately.

If there is more than one teleconference held during the course of a day, each teleconference must be entered as a separate teleconference record.

The date to be entered in the CBER regulatory database is the date of the teleconference and not the date the memorandum was prepared. If there were several people on the teleconference and minutes are distributed for review and/or revision prior to submission in the database, a history line can be included on the memorandum. However, a concurrence page is not necessary.

If a non-substantive teleconference previously not documented is mentioned in a sponsor's letter, that teleconference must be entered into the appropriate CBER regulatory database. The memorandum may be generated from the notes taken by the reviewer or the RPM during the teleconference. Each reviewer is encouraged to take notes of all teleconferences for which he/she participates.

If a member of the review committee needs to contact the sponsor/applicant (or designee), the RPM should be present on the call to ensure proper documentation and to address regulatory issues. If the RPM is not present for the call, the lead CBER participant will enter the communication in the appropriate regulatory database and import the teleconference memo into the EDR or forward to the RPM for inclusion in the submission's administrative file.

5. Effective Date

August 3, 2010

6. References

A. References below are located on CBER's internet Web Page

FDA Staff Manual Guide 2126.2

BIRAMS Read Only and Telecon Access Quick Guide [Available from the CBER Regulatory Information Management Staff (RIMS)]

B. Web links to the references below can be found in the list following the History Section

Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act, November 2001

SOPP 8103: Headquarters Contacts with Regulated Manufacturers During Agency Inspections

7. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Dixon	Robert A.	July 29, 2010	4	Revised for consistency

Written/Revised	Approved	Approval Date	Version Number	Comment
	Yetter, PhD			with new SOPPs
RMCC	Robert A. Yetter, PhD	May 4, 2007	3	Revised procedures on documentation
K Schneider Glen Jones, PhD	Robert A. Yetter, PhD	August 17, 2001	2	Additional details and appendices/references added
M. Beatrice	M. Beatrice	January 31, 1994	1	Reissued as SOPP 8104. No change to content

8. References

- Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act, November 2001 (PDF - 27KB)
- SOPP 8103: Headquarters Contacts With Regulated Manufacturers During Agency Inspections