

---

# Manual of Standard Operating Procedures and Policies

---

## Regulatory - Communication

### Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants

**SOPP 8101.1**

**Version #4**

**Date: May 18, 2007**

---

#### 1. Purpose

The purpose of this document is to describe the procedures involved in the scheduling and conduct of regulatory meetings between individuals in the Center for Biologics Evaluation and Research (CBER) and representatives of the regulated industry (including sponsors/applicants of PDUFA related products) and/or individual investigators to address issues relating to product development. This SOPP identifies types of meetings and describes actions and responsibilities of CBER personnel for each type.

#### 2. Definitions

Meetings described in section 119(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (1) are between CBER and a sponsor or applicant for drugs under section 505(b) of Food, Drug and Cosmetic (FD&C) Act or section 351 of the Public Health Service (PHS) Act that are held for the purpose of reaching agreement on the design and size of clinical trials that are intended to form the primary basis of an effectiveness claim in a marketing application or for validating efficacy under accelerated approval provisions (see 21 CFR 314 Subpart H and 601 Subpart E).

In the enclosure to a letter from the Secretary, Health and Human Services, Donna Shalala, to Senator James M. Jeffords, dated November 12, 1997 (Prescription Drug User Fee Act [PDUFA 2] goals letter), three types of meetings were identified, with specific performance goals associated with each. With each subsequent PDUFA negotiation, performance goals may change and therefore this SOPP should be followed with the current applicable goals in mind (2). The conduct of these meetings is further described in the "Guidance for Industry- Formal Meetings with Sponsors and Applicants for PDUFA Products" (3).

To the extent that section 119(a) of FDAMA requires FDA to meet with a sponsor or applicant with regard to a drug that is not a PDUFA product, the procedures, but not the time frames or performance goals, described in this document will apply to any such meeting.

These meetings may either be face-to-face or electronic, i.e., by teleconference or videoconference.

#### **Type A Meeting**

A meeting which is necessary for an otherwise stalled drug development program to proceed (e.g., to

address an issue that has resulted in a clinical hold or refuse to file, dispute resolution meetings, special protocol assessment meetings requested by the sponsor/applicant after FDA's evaluation of protocols in assessment letters).

### **Type B Meeting**

Type B meetings include the following: Pre-IND, End of Phase 1, End of Phase 2/Pre-Phase 3, or a Pre-BLA/NDA meeting. Each sponsor/applicant should usually request only one of each of these Type B meetings for each potential application.

- **Pre-IND meeting:**

Prior to the submission of an initial Investigational New Drug Application (IND), the sponsor/applicant may request a meeting with FDA to review and reach agreement on the format for the IND, the scope and design of planned Phase 1 clinical studies, design of animal studies needed to support human clinical testing and product characterization issues. Note that a meeting to discuss the general development of a drug may take place without an IND, and would be considered a Type C meeting.

- **End of Phase 1 meeting:**

A sponsor/applicant of a product being developed under 21 CFR 312 Subpart E, 21 CFR 314 Subpart H, 21 CFR 601 Subpart E, or of a similar product may request a meeting with CBER after completion of early Phase 1 studies to review the Phase 1 data and reach agreement on plans for the Phase 2 program.

- **End of Phase 2/Pre-Phase 3 meeting:**

The purpose of this meeting is to review the Phase 2 data to determine whether it is safe to proceed to Phase 3, to evaluate plans for the Phase 3 program and protocols, plans to assess pediatric safety and effectiveness and to identify any additional information necessary to support a marketing application for the uses under investigation.

- **Pre-BLA/NDA meeting:**

The pre-BLA/NDA meeting is held to describe for CBER reviewers the general information that will be submitted in the marketing application, to discuss preliminary efficacy results derived from studies conducted to support the Biologic License Application (BLA)/ New Drug Application (NDA) and appropriate methods for final statistical analysis, to discuss the proposed format for data in the planned marketing application, to identify the studies that the sponsor/applicant will rely on as adequate and well-controlled, plans to assess pediatric safety and effectiveness, to discuss submission of an incomplete application under section 506 of FD&C Act, and to discuss any major outstanding issues. A pre-BLA/NDA meeting may take place without an IND when the entire development of the drug has been outside the U.S. and there will be no studies conducted under IND in the application.

### **Type C Meeting**

Any other type of meeting (e.g., cost recovery, facility design, and general product issues meeting).

## **3. Background**

Meetings with industry and investigators provide a forum for the Agency to provide guidance to firms during product development and facility design, and to facilitate their compliance with the regulations governing development and post-approval marketing of products. Generally, these meetings are scheduled at the request of a pharmaceutical firm or investigator with a stated purpose. Occasionally, the Agency will suggest such a meeting be scheduled. Meetings should serve a useful purpose, i.e., should not be premature or clearly unnecessary.

## **4. Policy**

It is CBER's policy that meeting requests be evaluated promptly, meetings including appropriate review staff be scheduled and held, and that these meetings be properly documented. Further it is CBER's policy that for products covered by PDUFA, the performance goals established in the most current PDUFA letter will be met (Appendix 1). For products not covered by PDUFA, the procedures set forth in this document will be used; however, the performance goals will not apply. CBER will make every effort to respond to meeting requests and meet with sponsor/applicants of non-PDUFA products as expeditiously as possible.

The Pediatric Research Equity Act of 2003 (PREA; amendment to FD&C Act, section 505 and 351 of PHS Act) requires that before and during the investigational process of a new drug or biological product, FDA will meet at appropriate times with the sponsor to discuss the sponsor's plans and timelines for pediatric studies or any planned request by the sponsor for waiver or deferral of pediatric studies. To assure that the statutory requirements are met in a timely manner, industry representatives should be advised (at the time the meeting is scheduled) that CBER will be requesting their pediatric development plan (or deferral or waiver request) at the meeting. The status is then to be recorded in the meeting minutes. This request should be made for all relevant meetings under this SOPP until the sponsor/applicant satisfies requirements under PREA. Relevant meetings would include any meeting where clinical development plans are discussed, such as end of Phase 2/pre-Phase 3, pre-BLA/NDA meetings (4).

## 5. Responsibilities and Procedures

### Meeting Requests

All meeting requests should be forwarded immediately to the Application Division or Regulatory Management Staff of the appropriate Office, according to the list below, for coordination according to Office-specific SOPPs.

- Office of Blood Research and Review, Division of Blood Applications
- Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality
- Office of Vaccines Research and Review, Division of Vaccines and Related Products Applications
- Office of Cellular, Tissue, and Gene Therapies, Regulatory Management Staff

An individual in the Applications Division, or other Division as specified in Office-specific SOPPs, will be identified as the point of contact (POC) for the request. The POC will be responsible for coordinating the meeting including:

- ensuring that the necessary information is entered into the CBER Regulatory Meetings Tracking System (CRMTS)
- evaluating the initial request,
- acting as the contact person between the Agency and the outside sponsor/applicant,
- notifying and coordinating with other staff, as needed,
- following through to ensure that the meeting is scheduled,
- scheduling the internal pre-meeting to finalize responses to the sponsor/applicant, and
- ensuring that the meeting is properly documented and documentation promptly submitted to the administrative record

The initial request or proposal for a meeting should be immediately evaluated for completeness. To be considered a complete request, and one that qualifies as a PDUFA product for the performance goals, the submission should be in writing (letter or fax) and include:

- the product name and application number if already assigned
- chemical name and structure (if appropriate).
- proposed indication
- type of meeting being requested (Type A, B or C)
- a brief statement of the purpose of the meeting

- this should include a description of the types of studies or data that the sponsor/applicant intends to discuss at the meeting
- for new products this should include a description and the developmental status of the product
- a listing of the specific objectives or outcomes that the sponsor/applicant expects
- a proposed agenda, including estimated times needed for each agenda item
- a list of specific questions (grouped by discipline)
- a list of planned external non-FDA attendees
- a list of requested participants or disciplines to be represented from the Center
- the approximate time that an information package for the meeting will be sent to the Center (i.e., x weeks prior to the meeting). For Type A meetings, this should be at least two weeks in advance of the meeting and for Type B or C meetings at least one month in advance of the meeting. (Refer to Cancellation section of this SOPP.)
- suggested dates for the meeting

If the request is not complete, the POC will inform the sponsor/applicant what is necessary to initiate the process of scheduling a meeting. If the request concerns a PDUFA product, the sponsor/applicant should also be informed that the request, as submitted, does not qualify for the performance goals.

The POC will ensure that a decision regarding the need for the meeting is reached. The internal scheduling of a meeting by the POC is initiated within five working days of the decision that a meeting is needed.

### **Tracking the Meeting**

When a meeting request is received by the Office, the required information must be entered into the CBER Regulatory Meetings Tracking System (CRMTS) as per CRMTS User Guide (5). CRMTS will automatically create a unique MEETING ID. If the meeting request is a pre-application submission, ensure that the relevant information is completed in the Pre-application Tracking System (PTS) database.

If a meeting is canceled, either by CBER or the sponsor/applicant, the STATUS field is updated, and the record is closed. A new record must be entered if the meeting is subsequently rescheduled. If the meeting is postponed, a new current schedule date is entered and the meeting status is changed to "postponed."

The required data should be entered into the system as they become available to ensure the quality of CRMTS data reports. Quality control procedures, as established by each Office, will be followed to assure the accuracy of the data entered.

### **Scheduling the Meeting**

If the meeting request is complete,

- The POC will identify appropriate persons to attend, according to Office-specific procedures. FDA attendees may include reviewers, Division Directors, Associate Directors for Policy, statistician(s), representatives from the Office of Compliance and Biologics Quality as well as experts from other Centers. When possible the POC should schedule time following the formal meeting for clarification of outstanding issues.
- The POC will ensure that necessary personnel are notified that a meeting is being scheduled, and that meeting arrangements are made in conformance with Office-specific SOPPs.
- The POC will contact the sponsor/applicant to obtain sufficient copies of the information package for all proposed Agency attendees.

A meeting date will be set and the POC will communicate the date and time of the meeting, the meeting format (e.g., face-to-face, teleconference), as well as a list of proposed Agency attendees, to the

sponsor/applicant, in writing (letter or fax; Meeting Scheduling Memorandum Template, Appendix 2), within the identified timeframe as outline in the PDUFA performance goals for the type of requested meeting (Appendix 1) based on the receipt of an adequate request. The meeting date should reflect the next available date on which all applicable Center personnel are able to attend, consistent with the Center's other business and the performance goal for that type of meeting. If the sponsor/applicant specifies a date later than that established in the performance goals, the meeting date should be within 14 days of the requested date.

When scheduling the meeting, the POC, reviewers, and managers also should consider other important timing issues in the meeting process such as drafting and reviewing meeting minutes. The POC should schedule time to draft the minutes within five business days following the formal meeting. A Meeting Tracking Tool has been developed and may be used by FDA meeting participants (see CBER Meeting Management Tool in CBER's Meeting Minutes Training Module). The tracking tool lists the meeting process activities, the timetable for completion of each activity, the responsible party, and indication of progress toward completion of each activity. Communication should occur among all FDA team members to ensure that they are in agreement regarding the meeting timeline.

Emergency meetings will be scheduled upon evaluation of the request by the primary reviewer with supervisory concurrence according to Office-specific SOPPs. Any request for an emergency meeting should justify the urgency.

Separate meetings for manufacturing, clinical, and/or establishment issues are encouraged if the proposed agenda includes extensive discussion of more than one of these topics. This will provide for the most efficient use of reviewer time. These meetings should be consecutive but separated by 5 - 10 minutes to allow for non-disruptive exit and entrance of persons attending the meetings. Any person scheduled for one of the meetings should have the option of attending all of the meetings. Of note, it is expected that the scheduled times would be respected, therefore if the allotted meeting time is exceeded, additional discussion should be tabled until another time.

### **Post-Scheduling Coordination / Follow Up**

The information package should be prepared by the sponsor/applicant and submitted to the POC. The information package should provide summary information relevant to the product(s), plus supplementary information to enable the development of responses to issues raised by the sponsor/applicant or reviewing division. The content of the information package should support the intended objectives of the formal meeting with FDA. If the content of the information package is not sufficient to provide the basis for a meaningful discussion (e.g., critical data have not been generated or analyzed or have not been included in the package), the Agency may elect to cancel the meeting.

The POC ensures all proposed attendees receive meeting announcements and that the meeting materials are received/distributed to the attendees in sufficient time for an adequate review. The sponsor/applicant should align the information package with the agenda for the formal meeting and should clearly organize the contents to facilitate CBER's review. As such, a fully paginated document with a table of contents including appropriate indexes, appendices, and cross-references is recommended. While the data included in the information package will vary depending on the product, indication, phase of drug development, and issues to be discussed, information packages generally should include the following:

- Product name
- Chemical name and structure (if appropriate)
- Proposed indication(s)
- Dosage form, route of administration and dosing regimen (frequency and duration)
- Clinical data summary
- Preclinical data summary
- Chemistry, manufacturing and controls summary

In the "Guidance for Industry - Formal Meetings with Sponsors and Applicants for PDUFA Products" (3), sponsors or applicants wishing specific guidance regarding contents of the information package are directed to request such information from the POC or the Applications Division or Regulatory Management Staff in the CBER Office with product responsibility.

The information package should be received in CBER not less than two weeks prior to a Type A or one month for a Type B or C meeting. As a guide, the information package for each of the main meeting types should include the following:

- Pre-IND meeting - a summary of manufacturing information including completed or proposed testing and specifications; any pre-clinical studies completed or proposed; any known experience with the product in humans; the proposed eventual clinical use with rationale; a reasonably complete protocol or protocol synopsis; and information on any unique characteristics which differentiate the product from other similar entities.
- End of Phase 2/Pre-Phase 3 meeting - a synopsis of data from studies completed to date and proposed Phase 3 protocol(s) including detailed statistical plan. Outlines of any contractual arrangements for product manufacture and details of the characterization of the product to be used in the studies should also be submitted. If the Phase 3 product is not the same as the product intended for the market, proposals for studies to determine the comparability of the products are necessary. CBER will request the sponsor/applicant's pediatric development plan (or deferral or waiver request) at the meeting to satisfy the requirements under PREA, the status of which is recorded in the meeting minutes.

Note: At PDUFA-related meetings, the sponsor/applicant should be reminded of the benefits of requesting a Special Protocol Assessment, if appropriate, in accordance with published FDA "Guidance for Industry-Special Protocol Assessment" (6).

- Pre-BLA/NDA meeting - a summary of the data from the pivotal studies completed; the proposed indication; proposed format of the submission, manufacturing information on the products used in the study(ies) and product intended for distribution if different; outlines of any contractual arrangements for product manufacture, proposed format of the submission and a timeline for submission. CBER will request a status update of the manufacturer's pediatric development plan (or deferral or waiver request) at the meeting to satisfy the requirements under PREA, the status of which is recorded in the meeting minutes (PREA Compliance Checklist, Appendix 3).
- Establishment issues meeting - identification of the product(s) produced with a brief description of the manufacturing process; a production process flow chart; floor plans with manufacturing process, personnel flow, water system, HVAC system, air pressure differentials, and air qualities described; a brief description of water and HVAC systems; changeover procedures and product/personnel separation information for multi-use facilities; a brief description of validation procedures including the validation master plan; and any unique issues pertinent to the facility.
- BLA/NDA (pending application) meeting - adequate information upon which FDA staff may determine answers to the questions posed.

The POC will ensure that the date and pertinent information are added to the Office calendar. Should an individual find he/she will not be able to attend a meeting after it is scheduled he/she is responsible for designating an appropriate individual to attend on his/her behalf.

The POC should encourage the sponsor/applicant to limit formal presentations to focus on the questions to be addressed. This will allow more time for discussion and facilitate a more productive meeting. The POC should remind the industry representative that for relevant meetings, an update of their pediatric development plan (or intent to request deferral or waive) will be required.

## **Related Considerations**

Telephone or video conferences may be held in lieu of face-to-face meetings, when possible. The POC, in consultation with the review team, should determine when a telephone or video conference is appropriate.

If CBER wishes non-FDA, U.S. Government HHS employees to participate in the meeting, the POC should ensure that they are aware of the statutory restrictions for protection of confidential information. The POC will notify the Scientific Advisors and Consultants Staff (SACS), HFM-71, to ensure that the appropriate procedures are followed. If CBER wishes either non-HHS government employees or non-Government employees to participate in the meeting, the POC must either:

- obtain permission from the requestor for the presence of those specific individuals or
- appoint the individuals as Special Government Employees. (The procedure for this may be obtained from SACS.)

## **Cancellation**

The POC must clearly convey to the requestor that all pre-read meeting materials should be received not less than two weeks prior to the scheduled meeting date for Type A meetings and one month for Type B and C meetings. The sponsor/applicant should be notified that failure to submit adequate meeting materials by the appropriate date could result in meeting cancellation. If the meeting is cancelled, the requestor should be notified by telephone or other rapid means of communication and a cancellation notice will be generated to be conveyed immediately to all Agency attendees by electronic mail. The cancellation notice should be forwarded to the requestor by fax or mail.

## **Internal Pre-meetings**

Pre-Meetings: An internal meeting prior to any meeting with a sponsor/applicant will also be scheduled, if deemed appropriate. This pre-meeting should include all of those persons invited to attend the meeting with the sponsor/applicant. The pre-meeting is an opportunity for the FDA to formulate a consensus on its responses to the sponsor/applicant's questions and to identify additional issues or comments to share with the sponsor/applicant. Reviewers should draft their responses to the sponsor/applicant's questions and submit them to the POC within 24 hours prior to the pre-meeting. If reviewers will require additional collaboration outside of the pre-meeting to develop the FDA responses, the review staff should engage in communications among themselves to develop their responses prior to the pre-meeting. The POC will bring FDA responses to the pre-meeting to be discussed and resolved. During the pre-meeting the team should agree upon specific assignments and define roles and responsibilities for FDA staff during the formal meeting. The sponsor/applicant's questions and FDA responses occur in advance of the formal meeting and make up the bulk of the agenda and form the basis for the FDA meeting minutes.

Prior to any meeting, and in conformance with Office-specific SOPPs, a CBER staff person should be identified to lead the meeting. Normally this would be the reviewer who is primarily involved with the issues being discussed. Reviewers should be assigned to address questions related to their discipline during the formal meeting. The POC ensures someone is assigned to moderate the meeting, as well as record a summary of discussions, agreements, and action items that occur during the meeting.

## **FDA Communication to Sponsor/Applicant Prior to Formal Meeting**

Communicating relevant issues with the sponsor/applicant prior to the scheduled meeting (e.g., by fax) can focus the discussions during the formal meeting, eliminate the need for further discussion on topics where the sponsor/applicant is satisfied with FDA responses, and in some cases results in the meeting being canceled by the sponsor/applicant.

If sending preliminary responses to the sponsor/applicant, FDA should clarify that the responses are not

final until the FDA and sponsor/applicant agree that no further discussion is needed. Preliminary responses should be sent to the requestor 24 to 48 hours before the formal meeting using the CBER Meeting Response Memorandum Template (Appendix 4).

Following written confirmation from the sponsor/applicant that the meeting can be cancelled; the POC will complete the remaining fields in CRMTS and send the FDA-sponsor/applicant communications to the administrative record. If the sponsor/applicant requests the meeting still be held following receipt of the FDA preliminary responses, FDA should provide notification that a summary of discussions, agreements, and action items will be provided after the meeting.

Also, FDA should notify the requestor that if additional questions arise during the meeting, FDA may not be able to respond to those questions during the formal meeting.

### **Meeting and Post-Meeting**

The POC should ensure that a clear agenda and adequate materials are available for the meeting with the sponsor/applicant. The agenda for the sponsor/applicant meeting usually consists of the sponsor/applicant's questions and FDA responses as generated in the FDA internal pre-meeting. The availability of the meeting room and any necessary equipment should be re-confirmed in the week prior to the meeting.

CBER personnel must escort representatives of the sponsor/applicant to the conference room. The meeting will begin with introductions. The meeting leader will keep the meeting to the agenda with attention to time allotted and summarize the issues and/or agreements reached at the conclusion of the meeting. In order to decrease misunderstandings, it is strongly recommended that the last 5 - 10 minutes of the meeting be used to summarize agreements reached, advice provided, action items, and unresolved issues.

The POC will record the minutes of the meeting, or assure that another person is recording the minutes, and obtain a list of all persons attending. It is essential that the staff member recording the minutes be at the meeting for its entirety. When product and clinical meetings are scheduled consecutively, there may be different persons recording minutes for the different meetings.

The POC will ensure that a meeting summary is drafted, reviewed and finalized. This meeting summary will constitute the official minutes of the meeting. The meeting summary will clearly outline the important agreements reached, any unresolved issues remaining, issues for further discussion and action items. These may be included in bulleted form and need not be in great detail (Official Meeting Summary Template, Appendix 5). The record of the summarization in the last 5 - 10 minutes of the meeting should facilitate the preparation of this document for the administrative record.

- The minutes should include the following information:
  1. Header information
    - a. Meeting ID # (generated by CRMTS)
    - b. Application type and number (if applicable)
    - c. Product name (if applicable)
    - d. Sponsor (sponsor/applicant)
    - e. Meeting type (A, B, C)
    - f. Meeting category (e.g., Pre-IND, End-of Phase 2, Protocol Discussion)
    - g. Meeting date & time
    - h. Meeting format (e.g., face-to-face, teleconference)
    - i. Meeting Chair/leader
    - j. Meeting Recorder
  2. Attendees (sponsor/applicant & FDA), titles, affiliations

3. Background and Objectives- a background section that includes the following:
  - a. Purpose of the meeting
  - b. Brief history of events leading up to the meeting, if applicable
  - c. Context of product development
  - d. Cite who requested the meeting (FDA or sponsor/applicant)
  - e. Identify past action items or key agreements, if applicable
  - f. Identify if protocols or standards changed since the last meeting that could affect the current responses
  - g. Reference the meeting request and information package submission by date
4. Discussion
  - a. Sponsor/applicant questions
  - b. FDA responses with rationale
  - c. Key discussion points
    - i. Summary of discussion points
    - ii. Indicate owner of comments (FDA or sponsor/applicant)
    - iii. If no discussion is needed, the minutes should clearly indicate that there was no discussion of the topic by FDA or the sponsor/applicant
  - d. Discussion of pediatric plan (or deferral/waiver request with rationale) including timeline for conducting pediatric studies, study design, pediatric populations to be evaluated and pediatric formulation to be studied, if applicable
5. Decisions/agreements reached  
Agreements and disagreements should be noted regardless of length of discussion
6. Issues requiring further discussion
7. Action items
  - a. Description of action
  - b. Ownership (FDA or sponsor/applicant)
  - c. Due date or timeline
8. Attachments/Handouts (for administrative record only)  
Copy of materials (e.g. slides) used during discussion at the meeting  
PREA Compliance Checklist

When writing about agreements, disagreements, issues for further discussion, and action items, ownership should be acknowledged not as "he said, she said" but as whether the item was raised by FDA or sponsor/applicant in general. Action items also should include dates for follow-up. There should be a record of when discussions occurred and when there was no discussion.

The POC should follow a review process to finalize draft minutes. After the draft minutes have gone through the review process and are finalized, the template for the cover letter is to be used to submit the final minutes to the requestor (Appendix 6).

- Sponsor/applicants may identify the critical outcomes they believe should be included in the meeting documentation and may submit draft meeting minutes to the POC. Drafts of meeting minutes prepared by the sponsor/applicant are not the official minutes of the meeting, but may be considered during the preparation or review of the official minutes and sent to the administrative record.
- Sponsor/applicants are responsible for notifying CBER of any significant differences in their understanding of the meeting outcomes (as reflected in the official minutes). The POC should notify the sponsor/applicant of this responsibility in the cover letter accompanying the minutes.

- The Division Director (in consultation with the meeting chair, if appropriate) should resolve differences identified by the sponsor/applicant between the FDA minutes and its understanding of the meeting outcomes. This negotiation may at times be accomplished by the POC, but the Division Director has ultimate responsibility for a successful resolution. If policy issues or requirements related to a particular application that emerge during or after a formal meeting cannot be resolved at the level of the component that held the meeting, the dispute resolution process may be invoked by the sponsor/applicant (7).
- All substantive correspondence regarding meeting minutes, including internal FDA correspondence that impact the FDA responses to the sponsor/applicant, should be submitted to the administrative record.

The POC will ensure that the finalized meeting summary is sent to reviewers, the administrative record and to the sponsor/applicant within 30 calendar days of the meeting. The meeting summary may be transmitted to the company by mail or fax using the template cover letter (Appendix 6).

In accordance with 21 CFR 10.65(f), the sponsor/applicant, or other meeting participant, may prepare and submit to CBER a memorandum summarizing their understanding of issues discussed at the meeting. This memorandum should be included along with CBER's summary in the administrative record.

In the event that the sponsor/applicant wishes clarification of items in the official minutes, the POC will coordinate the appropriate response (e.g., guidance on a course of action or arranging a teleconference).

## 6. Effective Date

May 18, 2007

## 7. Appendices

[Appendix 1: PDUFA Meeting Performance Goals Table](#)

[Appendix 2: Meeting Scheduling Memorandum Template \(PDF - 15 KB\)](#)

[Appendix 3: PREA Compliance Checklist \(PDF - 14 KB\)](#)

[Appendix 4: CBER Meeting Response Memorandum Template \(PDF - 20 KB\)](#)

[Appendix 5: Official Meeting Summary Template \(PDF - 18 KB\)](#)

[Appendix 6: Cover Letter Used for Distributing the Official Meeting Summary Template \(PDF 13 KB\)](#)

## 8. References

1. [Food and Drug Administration Modernization Act of 1997](#);
2. [Prescription Drug User Fee Act \(PDUFA\) 3 letter](#);
3. [Guidance for Industry- Formal Meetings With Sponsors and Applicants for PDUFA Products](#);
4. [Guidance for Industry- How to Comply with the Pediatric Research Equity Act](#);
5. CBER Regulatory Meetings Tracking System Database (CRMTS) User Guide
6. [Guidance for Industry- Special Protocol Assessment](#);
7. [SOPP 8005: Major Dispute Resolution Process](#);

## 9. History

Written/Revised	Approved	Approval Date	Version Number	Comment

Leonard Wilson/ Lydia Falk	Robert, Yetter, PhD	May 4, 2007	4	Update to include updating the status of PREA studies and Quality System implementation
Leonard Wilson	Robert Yetter, PhD	12/23/2002	3	Updated mail code and appendix 1; added references to PDUFA 3
Robert Yetter, PhD	Robert Yetter, PhD	08/15/2002	2	Add reminder for sponsors to use Special Protocol Assessment (SPA); add link as appendix; revise appendices numbering
RMCC	Rebecca Devine	02/11/1999	1	Original Document

Updated: May 8, 2007