PHARMACEUTICAL SCIENCE

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS (CPB) BRIEFING CRITERIA AND ATTENDANCE POLICIES

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PURPOSE This MAPP establishes a process to determine when CPB briefings should be held, who should attend, and what procedures should be followed.

BACKGROUND

A CPB briefing is an interactive meeting in which the Office of Clinical Pharmacology and Biopharmaceutics (OCPB) reviewers of a new drug application (NDA) present to and discuss with OCPB staff and other invited or interested FDA guests important information, data, and issues related to his/her NDA review.

OCPB holds CPB briefings to:

- Lend consistency in policy to reviews across OCPB divisions
- Ensure high scientific quality of OCPB reviews
- Identify scientific needs for new OCPB policy development
- Provide valuable information to OCPB staff, medical officers and other ODE staff who are in attendance
- Promote consensus decisions and teamwork
- Provide reviewers and OCPB managers the opportunity to interact and allow speaking practice

- Provide a forum for early management involvement in preparation for FDA Advisory Committee meetings

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POLICY **Criteria For Holding CPB Briefings and Attendance**

OCPB Division Directors can escalate briefing levels if they deem it necessary. The CPB briefing should be scheduled with the overall NDA review plan and timetable as decided upon in the ODE division/review team, so that the CPB briefing process does not interfere with meeting PDUFA goals.

- ***Required*** **OCPB Office Level CPB Briefings;** Office level CPB briefings are *required* if any of the following conditions apply:

  1. Unique scientific and/or potential new office policy issues (to be identified by the host OCPB division)

  2. All NDAs whose drugs are to go to Advisory Committee Meetings and have potentially controversial clinical pharmacology and/or biopharmaceutics issues

  3. New molecular entities (NMEs) that are first in a pharmaceutical or therapeutic class

  4. All NDAs that OCPB intends to recommend nonapproval due to clinical pharmacology and/or biopharmaceutic issues

Attendees

Expected to Attend from OCPB:

1. Office Director
2. Special Asst to Office Director
3. Division directors and/or deputy directors, plus pharmacometrics staff representative
4. Team leader
5. Primary reviewer

Invited to Attend:

1. Selected ODE division staff [e.g., director, review team members]
2. Office of Pharmaceutical Science (OPS) staff who have requested notification
3. OCPB deputy director, other designated OCPB staff, & staff from three OCPB divisions

- ***Required* OCPB Inter-Division Level CPB Briefings**

  Inter-division level CPB Briefings are *required* in the following situations:

  1. All NDAs for which the pivotal bioequivalence study(ies) fail to meet established criteria to document the bioequivalence of the clinical dosage form and the to-be-marketed dosage form.

  2. Immediate release to controlled/extended release, or new/novel dosage forms

Attendees

Expected to Attend from OCPB:

1. Division directors and/or deputy directors, plus pharmacometrics staff representative
2. Team leader
3. Primary reviewer

Invited to Attend:

1. Selected ODE division staff
2. OPS staff who have requested notification
3. OCPB Director and deputy director, other designated OCPB staff, and staff from three OCPB divisions

- ***Optional* OCPB Inter-Division and Intra-Division Level CPB Briefings**

  (Note: Need for these types of CPB briefings is to be determined by the OCPB division director responsible for the NDA review.)

  Optional inter-division level CPB briefings may be held in any of the following situations:

  1. NDAs whose drugs are to go to Advisory Committee Meetings and have *no* controversial clinical pharmacology and/or biopharmaceutic issues

  2. NMEs that are not first in a pharmaceutical or therapeutic class

  3. New routes of administration

Attendees

Expected to Attend from OCPB:

1. Division directors and/or deputy directors, plus pharmacometrics staff representative
2. Team leader
3. Primary reviewer

Invited to Attend:

1. Selected ODE division staff
2. OPS staff who have requested notification
3. OCPB director and deputy director, other designated OCPB staff, and staff from three OCPB divisions

Optional intra-division level CPB briefings may be held for all NDAs or supplements related to the following:

1. Waivers of bioavailability and/or bioequivalence
2. Most topical drugs/dosage forms
3. Combination products
4. Formulation changes
5. New indications or patient populations
6. Any of the situations identified under optional inter-division level where the inter-division briefings are not held

Attendees

Expected to Attend from OCPB:

1. Division director and/or deputy director
2. Team leader
3. Primary reviewer

Invited to Attend:

1. Selected ODE division staff
2. OPS staff who have requested Notification
3. OCPB director and deputy director, other designated OCPB staff, and staff from three OCPB divisions

PROCEDURES

Distribution of Information for a CPB Briefing

***Required* Office CPB Briefing**
Hard copies (n=7) to OCPB Staff:

Office Director -	1 copy
Special Asst to Offc Dir-	1 copy
Division Directors -	1 copy ea.
Pharmacometrics -	1 copy
Team Leader -	1 copy

***Required* Inter-Division CPB Briefing**
Hard copies (n=7)

Office Director-	1 copy
Special Asst to Offc Dir-	1 copy
Division Directors-	1 copy ea.
Pharmacometrics-	1 copy
Team Leader-	1 copy

***Optional* Inter-Division CPB Briefing**
(Only if held.)
Hard copies (n=7):

Office Director-	1 copy
Special Asst to Offc Dir-	1 copy
Division Directors -	1 copy ea.
Pharmacometrics -	1 copy
Team Leader -	1 copy

***Optional* Intra-Division CPB Briefing**
(Only if held.)
Hard copies (n=4):

Office Director-	1 copy
Special Asst to Offc Dir-	1 copy
Division Director -	1 copy
Team Leader -	1 copy

- Additional copies will be distributed on an as-needed basis or upon request.

- Hard copies will include:

  1. Cover sheet identifying the names of the reviewer and team leader, the ODE division, NDA, drug name, CPB briefing date, time and location, plus a brief description of the specific scientific and/or policy issue(s) to be discussed (if none so state).

  2. Filled out OCPB NDA survey form (v:\io\cpbform2.xls).

  3. The NDA review's synopsis/summary section (i.e., front portion without appendices), and a copy of the labeling/package insert.

  4. If appropriate, any relevant information/data from the review's appendices that relate to the specific issue(s) that will be discussed at the CPB briefing.

  Ideally, the primary reviewer should bring to the CPB briefing a copy of the review's appendices in case questions arise for which the information can be disseminated to interested participants.

- At the time the CPB briefing hard copy package is to be distributed (*ideally at least one week before the scheduled CPB briefing)*, the reviewer should also post the review's synopsis/summary section (i.e., front portion without the appendices) and, if feasible, the proposed labeling/package insert on the X drive in the directory X:\OFFICES\OPS\OCPB\REVIEWS. The reviews should be filed in PDF format (PDF instructions are located in v:\pdf\pdf.txt). The reviewer should then send an E-mail notification indicating the document's common drive location to:

    1. Selected OCPB staff and OPS staff who have requested special notification, using the distribution list “CPBBRIEFING”

    2. Director, OPS if the CPB briefing is office level

    3. Those outside OPS identified as "invited attendees" as determined by the reviewer/team leader (e.g., selected ODE division staff)

- The E-mail notification should also indicate:

    1. The team leader, ODE division, NDA and drug name

    2. The CPB briefing date, time, location, and seating capacity

    3. A brief description of the specific scientific and/or policy issue(s) to be discussed at the CPB briefing (if none so state)

    4. The word processing package and version used for the NDA review

    Note: For a review that is put in the X:\OFFICES\OPS\OCPB\ REVIEWS directory where tables and/or graphs are not electronically incorporated, OCPB staff who would like to have a copy of the missing information should contact the review author. Alternatively, staff in an OCPB division might want to obtain a copy of the missing information from his/her Division Director's hard copy package.

For NDA Reviews not Having a CPB Briefing

For all NDA reviews that are covered under the category of *optional* inter-division and intra-division level CPB briefings, where a CPB briefing is NOT to be held, each completed NDA review (i.e., review's synopsis/summary section without appendices) should still be put in the X:\OFFICES\OPS\OCPB\REVIEWS directory and an E-mail message sent to OCPB staff. The e-mail should include indicating:

1. The NDA and drug name

2. The name of the NDA review file in the X:\OFFICES\OPS\OCPB\ REVIEWS directory

3. Information on the word processing package and version used.

An NDA review will automatically be deleted thirty days after it is put in the X:\OFFICES\OPS\OCPB\REVIEWS directory. A hard copy file and electronic version will be available.

Setting up a CPB Briefing

- **The following procedures are recommended for setting up a CPB briefing.**

  1. The primary reviewer for a CPB briefing should contact his/her division secretary and provide preferred dates, times, and location (ideally in the building where the relevant ODE division staff reside, except if held on Tuesdays) where he/she would like to hold the CPB briefing. The primary reviewer should also inform the secretary if this is a *required office CPB briefing*, an *inter-division CPB briefing*, or an *intra-division CPB briefing* and provide the NDA number and drug name. Briefings may be held on the designated days and times below. The primary reviewer must inform the secretary if the briefing is for a large and/or complicated NDA review that will require more than one hour, e.g., 1.5 to 2 hours.

Tuesday	2 - 4 pm (in WOC-II after OCPB Senior Staff Meeting)
Thursday	10 - 12 Noon
Friday	10 - 12 Noon

Note: If the primary reviewer wishes to have specific ODE division staff present (e.g., review team, etc.), it is suggested that he/she check the availability of the ODE staff for the preferred dates/times before those dates/times are given to the division secretary.

2. The division secretary should, ideally within a day or two, get back to the primary reviewer with a confirmed/scheduled CPB briefing date, time, location plus information on the conference room seating capacity. The secretary should have checked and scheduled the following attendees, as appropriate, via Teamlinks/Russell Calendar Manager.

   Required office CPB briefing (N = 8):
   - Office Director
   - Special Asst to Office Director
   - Three division directors
   - Pharmacometrics team leader
   - Team leader
   - Primary reviewer
   - OCPB calendar

   Inter-division CPB briefing (N = 7):
   - Special Asst to Office Director
   - Three division directors
   - Pharmacometrics group supervisor
   - Team leader
   - Primary reviewer
   - OCPB calendar

   Intra-division CPB briefing (N = 3):
   - Primary reviewer's division director
   - Team leader
   - Primary reviewer
   - OCPB calendar

   (1) If there are OCPB staff other than those noted above, OPS staff, or others who need to attend a given CPB briefing, their names also should be given to the division secretary so their availability can be checked and they can be scheduled. (2) If any of the required attendees are unable to attend a scheduled CPB briefing, they are

responsible for having a designee attend for him/her; the same applies for the pharmacometrics group.

3. Once the primary reviewer has been notified by the division secretary that a date, time, etc., have been confirmed/scheduled for a CPB briefing and the CPB briefing hard copy package is ready to be distributed, the primary reviewer should send out an E-mail message announcing the briefing as covered above.

   The OCPB director, OPS staff who have requested special notification, other designated office staff, and invited attendees from the three OCPB divisions should contact the primary reviewer ASAP to let him/her know of their attendance at the CPB briefing for seating accommodation purposes; otherwise seating will be on a first-come basis.

- **How Long Should a CPB Briefing Be**

  A CPB briefing need not last more than one hour for small straightforward NDA reviews that have no complicated scientific and/or policy issues. Longer meetings should be scheduled for large and/or complicated NDA reviews (i.e., up to 2 hours). The presenter's team leader will serve as timekeeper and note taker.

- **What Is Expected to be Discussed at a CPB Briefing?**

  Essential attendees are expected to have read the CPB briefing package in advance. The following topics should be addressed at the CPB briefings:

  1. Brief summary of background and general information, including an inventory of the NDA studies (OCPB NDA survey report form)

  2. Brief summary of ODE Division's clinical perspective/position, concerns related to the NDA

  3. Key clinical pharmacology and/or biopharmaceutics science and/or policy issue(s)

  4. Package insert recommendations

  5. Overall summary/consensus of discussed issues before meeting adjourns.

6. For issues in dispute or decisions requiring follow-up action, the reviewer and team leader are responsible for e-mailing a summary of resolutions discussed in the briefing and any needed follow-up, to the attendees, the Office Director, and the division directors.

EFFECTIVE DATE

This MAPP is effective upon date of publication.