OFFICE OF PHARMACEUTICAL SCIENCE

Office of Pharmaceutical Science Regulatory and Scientific Briefings

CONTENTS

PURPOSE

- This MAPP describes policies and procedures governing regulatory and scientific briefings in the Office of Pharmaceutical Science (OPS), Center for Drug Evaluation and Research (CDER). These briefings will be used as a forum to discuss difficult regulatory and scientific issues, share information across the office, assist in decision making, provide support for decisions, and address potential problems in a prospective manner.

BACKGROUND

- The OPS mission is to ensure that high quality, safe and effective, new and generic drugs are available to the public by applying sound scientific and regulatory standards. There are many organizations within OPS that are directly involved in carrying out efforts to support this mission. In some cases, these organizations support each other's activities, and in other cases the organizations may be operating in parallel for biotechnology products, new drugs, and generic drugs. Sharing of regulatory and scientific information, issues, policies, and procedures, and participating in crosscutting decision-making and program planning are critical to ensuring that OPS activities are conducted under the highest scientific standards and best practices.

DEFINITIONS

- **Briefing Background Packages:** All the related background materials and presentations to be made during the briefing. This package may include several topic background packages, as well as the agenda.

- **Co-chairs:** Director and Deputy Director, OPS.

- **OPS Regulatory and Scientific Briefing:** The OPS forum to discuss difficult regulatory and scientific issues, share information across the office, assist in decision making, provide support for decisions, and address potential problems in a prospective manner.

- **Participants:** Includes OPS Immediate Office managers, office directors, deputy directors, associate directors, division directors, and other staff as needed.

- **Topic Background Package:** All the related background material and presentations to be made during discussion of a specific topic.

- **Topic Lead:** The person, usually an OPS staff member, responsible for leading and championing the discussion of a briefing topic.

POLICY

- Briefings will be held monthly or as needed.

- The briefings will be scheduled for 2 hours, unless the topic or topics require additional time.

- Participants and co-chairs should attend all meetings, as feasible, and be prepared for in-depth scientific discussions.

RESPONSIBILITIES

- **Co-chairs will:**

    1. Determine the appropriateness of proposed briefing topics.

    2. Preside over the briefing (i.e., guide the discussion, handle controversy, and adhere to appropriate time frames).

- **Participants will:**

  1. Attend as many briefings as feasible.

  2. Come to briefings prepared for in-depth scientific discussions of all issues on the agenda.

  3. Complete briefing evaluation forms (Attachment B).

- **Recorder** (identified on the briefing request form — Attachment A) **will:**

  1. Draft and finalize minutes of briefing.

  2. Forward final minutes of briefing to the Special Assistant to the Director, OPS.

- **Special Assistant to the Director, OPS will:**

  1. Collect the briefing request forms (Attachment A) and discuss the merits of possible briefing topics with the co-chairs.

  2. Inform staff requesting a briefing whether the briefing has been granted or not.

  3. Reserve conference rooms and equipment as needed.

  4. Ensure that all participants and any other desired attendees are scheduled.

  5. Distribute agenda and all background materials to attendees.

  6. Coordinate and distribute minutes of the briefings.

  7. Capture and monitor any action items emanating from the briefings.

  8. Archive all briefing materials (i.e., backgrounders and minutes).

  9. Provide updates and/or summaries to the participants as needed.

  10. Collect and evaluate all completed evaluation forms (Attachment B).

- **Topic Lead will:**

  1. Complete the briefing request form, including agenda (Attachment A).

  2. Prepare the topic background information package.

  3. Lead the topic discussion at the meeting.

PROCEDURES

- Briefing request forms (Attachment A) will be submitted to the Special Assistant to the Director, OPS, as soon as a potential briefing topic is identified.

- Topic background packages will be sent to the Special Assistant to the Director, OPS, at least 2 weeks prior to the briefing.

- Briefing background packages will be sent by the Special Assistant to the Director to the briefing attendees within 24 hours of receiving the last topic background package.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

Attachment A

OPS Scientific and Regulatory Briefing Request Form

Subject of Briefing Topic, including firm, drug, and application number, if applicable:

Purpose of Discussion:

Desired Outcome/Resolution:

Background:

Questions for the Participants:
1.
2.

Options, if applicable:
1.
2.

Recommendation, if applicable:

Application(s) or other due date, if applicable:

Topic Lead:

Proposed Topic Agenda:

- **Overview/Background (name, if other than Topic Lead) ___minutes**
- **Presentation 1 (name, if other than Topic Lead) ___minutes**
- **Presentation 2 (name, if other than Topic Lead) ___minutes**
- **Discussion/Q & A (name, if other than Topic Lead) ___minutes**
- **Summary (including action items) (name, if other than Topic Lead) ___minutes**
- **Next Steps (name, if other than Topic Lead) ___minutes**

List of participants to be invited and their affiliation:

Designated Recorder (i.e., OPS Project Manager, OPS Special Assistant):

Equipment Needs (i.e., LCD projector, overhead projector, laptop):

Attachment B

OPS Scientific and Regulatory Briefing Evaluation Form

Briefing Subject:

Briefing Date:

On a scale of 1-5 (with 5 being the highest) rank the following:

Value of Background Package: ____

Knowledge of presenters: ____

Relevance of presentations: ____

Relevance of discussions: ____

Adequacy of time for presentations: ____

Adequacy of time for discussions: ____

Did the decisions reflect the discussions: ____

Usefulness of briefing: ____

Is further discussion needed: **Yes____** **No____**

Is a follow-up briefing needed: **Yes____** **No____**

If a follow-up briefing is needed, what should the focus be:

Comments:

Name (optional):_____

PLEASE SEND ALL EVALUATION FORMS TO THE SPECIAL ASSISTANT TO THE DIRECTOR, OPS – HFD-003