BIOPHARMACEUTICAL SCIENCES

Management of CDER Biopharmaceutics Coordinating Committee

CONTENTS

PURPOSE

This MAPP describes the role and responsibilities of the Biopharmaceutics Coordinating Committee (BCC), the procedures to be used for establishing Biopharmaceutics-related technical committees and workgroups, the structure and function of technical committees and workgroups, and the procedures to be used in designating members to serve.

BACKGROUND

Technical committees and workgroups to address various biopharmaceutics issues perform most effectively if the objectives and the responsibilities of its members are clearly defined. Each technical committee and workgroup should effectively communicate its work product both within and outside of CDER. Coordination of functions is desirable to ensure effective use of staff resources and to establish and maintain consistent biopharmaceutics policy across all review and other relevant divisions. To achieve these various objectives, CDER has established the BCC. Since its establishment, the BCC has restructured and delineated the roles and responsibilities of the CDER biopharmaceutic technical committees and workgroups.

ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There will be some fluctuation in the implementation as necessary, given membership and workload demands.

- **BCC**

    1. **Oversight** - CDER oversight for BCC is provided by the Deputy Center Director for Pharmaceutical Science (DCDPS).

    2. **Chair** - The BCC chair is appointed by the DCDPS.

    3. **Executive Secretary -** The BCC chair shall designate an Executive Secretary.

    4. **Members** - The voting BCC members include the following: The Office Director of OCPB; division directors of the Divisions of Pharmaceutical Evaluation, OCPB, and Bioequivalence, OGD; the OGD Division of Bioequivalence team leaders; one representative each from the Office of Medical Policy, Division of Scientific Investigations; the Office of Testing and Research, Division of Product Quality Research; the Immediate Office of OPS; and any others as deemed necessary by the chair. Three rotating members are selected from the team leaders of DPE I, DPE II, and DPE III as follows: the DPE division directors each name one rotating member to serve as a voting member for a 6-month term. If possible, these appointments should be staggered so that all three such members are not appointed at the same time.

    5. **Alternates** - Voting members may send an alternate if they are not able to attend a meeting.

    6. **Observers** - Various units of the Agency that have an interest in, but would not be directly affected by BCC, may nominate observers to attend BCC meetings. The observers are approved by the BCC.

- **Technical Committees and Workgroups**

    1. **Committee Chairs and Co-Chairs**. The BCC will select a chair or co-chairs for each technical committee and workgroup, taking into account expertise and interest in the subject matter, workload, and organizational and management skills. Chairs and co-chairs should be distributed with the goal of achieving broad representation between OCPB and OGD, with the chair from one Office, and the co-chair from

the other, when possible.

Each chair may serve for a 2-year term. The BCC may, however, evaluate a chair's position near the end of the term and may decide to extend the term as appropriate.

2. **Membership.** Members should be chosen based on qualifications, expertise, and interest in the subject matter, workload, and the demands on time caused by membership. Membership should be kept small (up to six members if possible) on technical committees to facilitate efficient operation.

   Membership should normally be rotated periodically. Generally, no member, other than the chair, should serve for longer than 3 years. When needed, a member's term may be extended.

   The terms of the members will be staggered, if possible, as determined by the chair and co-chair, so that some members will be replaced each year.

   To facilitate productivity of the committees, the use of smaller, short-term *ad hoc* workgroups to address specific issues is encouraged. With BCC approval, committees may create workgroups on specific issues bringing in additional expertise as necessary.

RESPONSIBILITIES

- **BCC is responsible for:**

  1. Establishing policies and procedures that govern bioavailability and bioequivalence (BA/BE) reviews in the OCPB and OGD biopharmaceutic reviewing divisions to ensure high quality scientific reviews and promote consistency. Examples of specific issues that might be addressed by the BCC are:
     - General BA/BE recommendations
     - Biopharmaceutic Classification System
     - Locally acting drug products, including topical, oral inhalation, and nasal inhalation
     - Food effects
     - Other

2. Serving as a forum for dispute resolution for biopharmaceutic issues that arise in the divisions or in one of the technical committees. The chair(s) of the BCC are responsible for bringing upper management perspective to resolution of disputes involving biopharmaceutic issues.

3. Coordinating, facilitating, and monitoring the efforts of the CDER biopharmaceutic guidance committees and workgroups including:

   - Providing structure, function, and membership;
   - Assigning topics;
   - Reviewing and approving final guidance products before transmission to CDER management for sign-off;
   - Serving as facilitators or resource staff for advice or problem solving as necessary.

4. Promoting and coordinating research, professional development, workshops, and training activities related to biopharmaceutic issues.

5. Providing assistance to the Biopharmaceutics Technical Committee of the Product Quality Research Institute.

6. Providing expertise on the topic of BA/BE for FDA international activities when requested.

7. Providing oversight and concurrence for policy issues discussed in meetings of the four biopharmaceutics division directors.

- **Executive Secretary is responsible for:**

1. Arranging and organizing meetings; distributing documents; and maintaining files of BCC activities.

2. Preparing the agenda for and summary minutes of each BCC meeting. Meeting minutes will be made available to CDER staff on the X: drive

3. X:\COORCOMM\BCC\MEET\YEAR\MONTH\DAY

   (Example: BCC\MEET\97-04-14).

4. Issues to be brought before the BCC may be directed to the attention of the

Executive Secretary who will attempt to schedule them in consultation with the chair(s) of the BCC.

- **Technical Committees and Workgroups are responsible for:**

    1. Serving as a source of advice and assistance to BCC in responding to CDER staff on matters pertaining to biopharmaceutic reviews.

    2. Developing guidances, policies, and procedures as needed. New guidances, policies, and procedures developed by the technical committees and workgroups should be circulated for comment widely within the Center to obtain the input of all who may be affected by them, and BCC concurrence shall be obtained before the policies and procedures are submitted to management for final signature.

    3. Responding, as needed, to questions from the pharmaceutical industry. However, all requests to document biopharmaceutic policy, regardless of origin, should come through the BCC before a technical committee initiates work.

- **Chairs of Technical Committees and Workgroups are responsible for:**

    1. Obtaining input on policy documents from the biopharmaceutic division directors and team leaders before the documents are forwarded for BCC review. Although concurrence from all biopharmaceutic division directors and team leaders is not required, a clearance form that reflects their comments or concurrence should be prepared and forwarded to the BCC with the document.

    2. Obtaining input from outside OPS, if needed, and possibly organizations outside CDER for issues with far-reaching implications. The BCC will determine whether or not the proposed policies and procedures should go outside CDER for review but the responsibility for clearance belongs to the technical committee originating the document.

    3. Scheduling and conducting meetings of the committee, as required, to fulfill the committee's objectives. To implement this responsibility, the chair shall prepare an agenda and distribute it to the committee members in advance of each committee meeting. The co-chair shall call and run meetings in the absence of the chair.

    4. Preparing brief minutes of each technical committee or workgroup meeting and distributing them to the BCC chair, members, division directors, office directors, and team leaders of OCPB and OGD, or notifying these individuals of their

existence via e-mail. Minutes shall be filed on the X: drive under **x:\coorcomm\bcc\year\month\day** under the subdirectory established for each of the committees under BCC.

5. Ensuring that copies of all records of committee meetings and other deliberations of the committee are placed in a file for that specific committee.

6. Reporting periodically to the BCC on the activities of the committee. In each report, the chair should provide to the BCC a summary of achievements since the last report to the BCC, a projection of activities for the next six months, and a list of issues in which BCC input is needed.

- **Members of Committees and Workgroups are responsible for:**

1. Representing their division's/office's views on issues considered by the committees that pertain to their areas of responsibility.

2. Communicating with their division/office management about the deliberations of the committees.

3. Regularly attending the meetings of the committees for which they are the designated representatives. If a member cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the chair.

PROCEDURES

- **Communications with Biopharmaceutic Office Directors, Division Directors, Team Leaders, and Reviewers.**

1. The activities of the BCC will be communicated to the office directors, division directors, team leaders, and reviewers through distribution and electronic filing of the minutes of the BCC committee and workgroup meetings, and through the issuance of guidances.

2. The regular meeting for biopharmaceutic division directors in OCPB and OGD (known as the 4DDs meeting or 4DDs) will serve as the mechanism for facilitating communications between the BCC and the supervisory and reviewing biopharmaceutical staff wishing to bring issues to the attention of the BCC. Issues and

problem situations will be raised first at the 4DDs regular meetings for discussion and resolution where possible. Decisions from this meeting will be brought to BCC for final endorsement, and major policy issues will be brought for resolution.

3. Other mechanisms for CDER biopharmaceutical scientists to raise issues to the BCC are: (a) bring to the attention of their own team leader; (b) bring to the attention of the technical committee chair; (c) bring to the attention of the appropriate representative on BCC; (d) bring to the attention of the Executive Secretary of the BCC. Such issues will then be referred to the proper mechanism for resolution, either the 4DDs meeting, or to the BCC if appropriate.

- **Creation of New Technical Committees or Workgroups**.

1. Suggestions for the creation of committees, including *ad hoc* workgroups that may report to the BCC directly or to a technical committee, should be made in writing to the BCC. Each suggestion should be accompanied by a statement of the proposed objectives of the committee, the names of persons who might serve on the committee as members and as chair and vice-chair, the expected frequency of meetings, the committee's expected life (e.g., 3 months, on-going) the term of its members and the expected method of replacement. See Attachment A for suggested format.

2. The BCC will determine whether the committee should be established and will notify OCPB and OGD biopharmaceutic reviewers and other affected CDER staff of the creation of a new biopharmaceutic committee. A list of current committee members will be maintained by the committee chair(s) and the BCC Executive Secretary.

3. Changes in the objectives of a committee should be submitted to the BCC for concurrence.

- **Disbandment of Technical Committees or Workgroups**. BCC shall disband a committee when:

1. It reaches the end of its scheduled lifetime.

2. It has fulfilled its objectives.

3. The BCC determines the committee is not fulfilling a necessary function in the Center.

At least once per year, the BCC shall review the list of committees to determine whether any of the committees on the list should be disbanded or the membership or chair changed.

If, after discussions with the chair of the committee, it appears that a committee no longer performs a useful function, the BCC shall issue a notice that the committee has been disbanded. A copy of this notice will be filed in the appropriate subdirectory on the X drive with the title "FINAL."

EFFECTIVE DATE

This MAPP is effective on the date of publication.

Attachment A - Form for Creation of a BCC Committee or Workgroup

RECOMMENDATION FOR THE CREATION OF A CDER BIOPHARMACEUTIC COMMITTEE OR WORKGROUP

1. **Name of Committee:**

2. **Objectives:**

3. **Composition:**

   Chairperson:

   Co-Chair:

   Membership:

4. **Meeting Frequency:**

5. **Completion Date:**

   Concur:_____ Non-Concur:_____

   _____ _____
   Chair, BCC Date