PROGRAM DESCRIPTION

OFFICE OF PHARMACEUTICAL QUALITY

Center for Drug Evaluation and Research Biopharmaceutics Council

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PURPOSE

This MAPP describes the organization, membership, and procedures of the Biopharmaceutics Council in the Center for Drug Evaluation and Research (CDER).

BACKGROUND

Biopharmaceutics is a broad-based scientific discipline that studies the effect and interplay of the physicochemical properties of a drug, its dosage form, and the intended route of administration on the rate and extent of the drug's absorption. Currently, CDER has multiple offices and multiple programs addressing various issues related to biopharmaceutics. Coordination is needed to foster collaboration and promote consistent and integrated biopharmaceutics-related activities throughout CDER. The formation of the CDER Biopharmaceutics Council (the Council) will help achieve these objectives.

POLICY

The Council is a multidisciplinary and cross-organizational panel providing senior management support to CDER on the development and application of policies, practices,

and recommendations related to biopharmaceutics in drug review processes, as well as to other CDER programs, as appropriate.[1]

The Council will help ensure that biopharmaceutics-related policies, practices, and recommendations are implemented in a consistent manner throughout CDER. The Council will meet on a regular basis to consider biopharmaceutics-related issues that are complex or precedent-setting and require senior management input. The Council may establish subcommittees and working groups to address biopharmaceutics-related issues, provide direction and feedback to the groups, and ratify group recommendations.

Issues pertaining to biopharmaceutics may be submitted to the Council by any CDER staff member. Although the issue discussed by the Council may have been triggered by a concern for a specific product, the recommendation from the Council may be applied to all similar products as deemed appropriate. Product-specific recommendations will be remanded to the appropriate review division and/or office for consideration.

For the purposes of the Council, biopharmaceutics-related issues generally have implications for product quality (e.g., release testing) and/or clinical effectiveness or safety (e.g., formulation and physicochemical effects on drug absorption). To be considered by the Council, a biopharmaceutics-related issue typically would meet one or more of the following criteria:[2]

- A novel design or approach to address a biopharmaceutics issue
- A precedent-setting biopharmaceutics policy or practice requiring senior management input
- A biopharmaceutics issue on which CDER appears to have taken inconsistent positions
- An existing biopharmaceutics policy position or practice that should be reconsidered in light of scientific or regulatory advances
- A biopharmaceutics issue that may be triggered by a specific product but will be applicable to other products

[1] Development of biopharmaceutics-related policy documents is commonly led by policy-focused organizations, such as the Office of Pharmaceutical Quality/Office of Policy for Pharmaceutical Quality, Office of Generic Drugs/Office of Generic Drug Policy, or Office of Translational Sciences/Office of Clinical Pharmacology/Guidance and Policy Team, within CDER. The activities of this Council will support those policy development efforts.

[2] The Biopharmaceutics Classification System (BCS) Committee at CDER provides expert advice on product BCS classification for incoming innovator and generic drug applications.

- Significant proposed procedure changes that could have an impact on how a biopharmaceutics assessment is performed

- Strategies for implementation of a new biopharmaceutics policy or practice

- Strategies for effective communication of a new or existing biopharmaceutics policy or practice

PROCEDURES

1. Any individual, including the Council members, or organizational unit in CDER (the requestor) may refer a biopharmaceutics-related issue to the Council for evaluation by submitting a proposal to the Executive Secretary. The proposal should be no more than one to two paragraphs and include the following:

    - The biopharmaceutics issue to be resolved
    - The trigger that raised the biopharmaceutics issue

2. The Council Governance Body will review the proposal and select and prioritize issues for consideration with appropriate input from Council members.

3. If the Council Governance Body does not select the proposal for consideration by the date specified by the requestor, the Executive Secretary will provide an explanation for the Council's decision. Reconsideration by the Council of such decisions can be requested.

4. If the Council Governance Body selects a proposal for consideration:

    - The Executive Secretary will inform the requestor (i.e., the individual or organizational unit that submitted the proposal) of the acceptance of the proposal for Council discussion. The Executive Secretary may schedule a pre-meeting with the individual or organizational unit to help with refining the biopharmaceutics issue to be discussed.

    - The requestor will prepare and submit a background document (see Attachment 1), which includes the summarized biopharmaceutics issue, to the Project Manager. The background document should provide all of the necessary information to understand the biopharmaceutics issue to be discussed, and may include questions for the Council to consider and potential recommendations for Council concurrence.

5. A Council meeting will be convened.

    - The Project Manager will schedule the meeting and invite experts from CDER and FDA staff to participate in the discussion at the Council Governance Body's discretion.

    - The requestor will provide a 10-minute overview of the biopharmaceutics issue at the beginning of the meeting.

    - The Council will deliberate and agree on recommendations. Once the Council agrees on a recommendation, all parties attending the Council meeting will be notified of the final recommendation.

    - When the Council reaches an agreement on a recommendation regarding a biopharmaceutics issue at the scheduled meeting:

        – The Council, with the input from the relevant policy-focused organizations within CDER, will recommend an appropriate communication for the policy or recommendation reached and any action items recommended. This could include recommending the development of one or more of the following:

            ▪ Decisional memorandum

            ▪ MAPP (new or revision to current MAPP)

            ▪ General guidance (new, revision to current guidance, or addendum to current guidance)

            ▪ Publication in an appropriate journal[3]

            Until such documents are drafted and distributed, the Council, with the input from the relevant policy-focused organizations within CDER, will recommend the appropriate communication strategy to disseminate recommendations to CDER staff.

        – If the Council believes that a current MAPP, guidance, or other document conveys the policy or recommendation on the biopharmaceutics issue discussed at the meeting adequately, the Council may recommend that training for CDER staff on the biopharmaceutics issue is needed. The Council, in consultation with the relevant policy-focused organizations within CDER, may recommend that the Division of Learning and

[3] Any new policy agreed upon by the Council should not appear for the first time in a journal article.

Organizational Development in the Office of Executive Programs develop and implement such training. If the policy or recommendation included in the current MAPP, guidance, or other document is being misunderstood externally, the Council may work with the relevant policy-focused organizations within CDER to develop and implement a communication strategy to explain the described biopharmaceutics policy or recommendation.

- When the Council does not make a recommendation regarding a biopharmaceutics issue at the scheduled meeting, it may:

  – Establish a subcommittee or a working group to explore the question further and return to the Council with recommendations for Council discussion on how to proceed; and

  – Identify specific questions/concerns for the requestor to research and provide answers, returning to the Council at a future meeting for further discussion.

- If the Council establishes a working group, offices and participants will be identified and included in the action items.

- The Project Manager will archive the biopharmaceutics issues discussed and action items, as appropriate, in an electronic database accessible to all CDER staff.

6. The Council Governance Body may meet with appropriate CDER staff to debrief on the Council meeting and to coordinate action items when needed.

7. Action items that do not have a due date based on statutory or other organizational need will be addressed no later than 1 year after the Council meeting was held.

DEFINITIONS

Biopharmaceutics Policy: A policy that generally concerns biopharmaceutics and has implications for product quality (e.g., release testing) and/or clinical effectiveness or safety (e.g., formulation and physicochemical effects on drug absorption).

Subcommittee: A standing committee established by the Council to address a policy or scientific issue that requires continual assessment or serve as an ongoing function for the Council. The subcommittee typically performs ongoing activities that are more detailed and/or directed to a specific biopharmaceutics issue.

Working Group: A group of individuals assigned to work on a specific project, with a defined deliverable and completion date, that is not being addressed by a standing subcommittee.

ORGANIZATION

Membership

The CDER Biopharmaceutics Council includes the following:

- Council Governance Body:
  - Director, Office of Pharmaceutical Quality (OPQ)/Office of New Drug Products/Division of Biopharmaceutics;
  - Director, Office of Translational Sciences (OTS)/Office of Clinical Pharmacology; and
  - Director, Office of Generic Drugs (OGD)/Office of Bioequivalence or Office of Research and Standards
- Executive Secretary: Selected on a rotating basis from each of the Council Governance Body's offices and serves for a 2-year term.
- Project Manager: Selected on a rotating basis from each Council member's offices and serves for a 2-year term.
- Members:
  - Director (or his/her designee), OGD/Office of Generic Drug Policy/Division of Policy Development
  - Director (or his/her designee), OGD/Office of Bioequivalence or Office of Research and Standards
  - Director (or his/her designee), OPQ/Office of Lifecycle Drug Products
  - Director (or his/her designee), OPQ/Office of New Drug Products
  - Director (or his/her designee), OPQ/Office of Testing and Research
  - Director (or his/her designee), OPQ/Office of Policy for Pharmaceutical Quality

  - Director (or his/her designee), OTS/Office of Study Integrity and Surveillance

- Other participants: Representative(s) sent by any Council member to participate on his or her behalf when the member is unavailable for the Council meeting.

- Other invitees: The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and any other relevant office within FDA will be invited by the Council to send a representative to attend those meetings of known interest at the discretion of the Council Governance Body.

Subcommittees

- Chair: The Council Governance Body in consultation with the Council members will select a chair for each subcommittee.

- Members: The Council members will nominate representatives with expertise from their organizational units to participate in the subcommittee.

- Duration of service: Subcommittees may have an extended life span. Subcommittees will be disbanded when they have successfully completed their goal or their purpose no longer meets the goals of the Council.

Working Groups

- Chair: The Council Governance Body in consultation with the Council members will select a chair for each working group.

- Members: The Council members will nominate representatives with expertise from their organizational units to participate in the working group. The working group chair may select additional members taking into account the members' expertise and interest in the topic. In general, working group membership should not exceed 10 members plus the chair.

- Duration of service: Working groups should have a limited life span. The working groups will adjourn when they have successfully completed their goal or additional work is not required as determined by the Council.

EFFECTIVE DATE

This MAPP is effective on May 16, 2019.

ATTACHMENT 1

CDER Biopharmaceutics Council
Background Document Template

Purpose –

[The CDER Biopharmaceutics Council background document is a *stand-alone* document describing a biopharmaceutics policy issue(s) that requires a recommendation from the CDER Biopharmaceutics Council. It should convey the biopharmaceutics issue to be resolved, the trigger that raised the biopharmaceutics issue, and the date by which a response is needed. The document should follow the CDER Style Guide, be no more than three to five pages, and provide all the necessary information to understand the biopharmaceutics issue to be discussed.]

Introduction –

[Provide an overview of the biopharmaceutics issue to be resolved.]

Background –

[Describe scientific, biopharmaceutics, and regulatory areas that address the biopharmaceutics issue to be resolved. If applicable, include any areas and issues that have been raised; the regulation and/or guidance that has an impact on the biopharmaceutics issue; any considerations and advice already provided in discussions with the sponsor or applicant; and any other important aspect, such as previous advice given to other sponsors, applicants, or staff or relevant precedent-setting decisions, that would affect the recommendation to be provided. The information should include ideas, including any differing opinions, on how the biopharmaceutics issue should be addressed.]

Questions to be Considered by the Council –

[List the questions that the Council should consider in response to the biopharmaceutics issue to be resolved. The questions should be general, applying to all drugs and/or biological products or a group of drugs and/or biological products. Questions should not be product-specific.

If possible, please include options with the preferred outcome highlighted.]

Presentation –

[Provide all presentation materials to be used by the individual or an identified lead from an organizational unit seeking Council evaluation. The presentation will be

limited to no more than 10 minutes and may only reference materials provided in the background document. A PowerPoint presentation is not required.]

Attachments –

[Attach any additional background material, such as reviews, guidance, or regulations. Attachments are not required, but such attachments are supplementary to the background document.]