OFFICE OF NEW DRUGS

Management of the PTCC Safety Pharmacology Subcommittee

CONTENTS

PURPOSE

- This MAPP describes the roles and responsibilities of the Pharmacology and Toxicology Coordinating Committee (PTCC) Safety Pharmacology Subcommittee, the structure and function of the subcommittee, the procedures to be used in designating members to serve on the subcommittee, and the responsibilities of those designated to serve on the subcommittee.

BACKGROUND

- Pharmacology committees have been established in the Center for Drug Evaluation and Research (CDER) to develop regulatory guidance for use by sponsors and applicants, to apply current scientific knowledge to emerging technical problems, and to aid in the review process. The Safety Pharmacology Subcommittee was initially formed as an ad hoc committee to ascertain the need for a formal guidance document on the safety pharmacology studies that should be conducted for pharmaceuticals intended for human use. Because this committee serves important functions that support its continuing activities, the PTCC Safety Pharmacology Subcommittee is now being constituted as a permanent subcommittee of the PTCC to provide CDER divisions with consultations and recommendations on safety pharmacology issues and studies. Establishment of this committee will increase the consistency of safety pharmacology requirements among CDER drug product review divisions.

OBJECTIVE

- To serve as a source of advice and assistance to the PTCC and Office of New Drugs (OND) on safety pharmacology issues.

- To review, consult, and provide written recommendations on safety pharmacology issues and studies to CDER divisions.

ORGANIZATION

Oversight

- The PTCC provides oversight for the PTCC Safety Pharmacology Subcommittee.

Membership

- **Chair/Co-Chair**: The Safety Pharmacology Subcommittee Chair, who is a pharmacology/toxicology reviewer, and the Safety Pharmacology Subcommittee Co-Chair, a pharmacology/toxicology team leader, are selected by the subcommittee and approved by the PTCC. Nominations are presented to the PTCC, voted on, and approved within 30 days of the PTCC presentation, unless informed by the PTCC Chair of disapproval or reasons for a delay. Candidates for Chair and Co-Chair are selected for their experience, interest in safety pharmacology, and organizational and managerial skills.

  Each Chair and Co-Chair serve for a 2-year term. Terms may be extended beyond the 2-year period with review and approval by the Safety Pharmacology Subcommittee and PTCC.

- **Members**: The Chair or Co-Chair will invite members to serve on the basis of qualifications, time, ability to actively participate, and interest in safety pharmacology. Qualified representation from the various CDER Offices will form the regular membership of up to 10 persons. Recognized experts, generally from outside CDER, may be asked as ad hoc members to perform a variety of one-time or other duties, such as serving on working groups, providing advice on special projects, or commenting on policy initiatives. Ad hoc members may also come from governmental bodies outside of CDER or the academic community. Ad hoc members are non-voting members.

  New members may be added to the committee as needed. At the end of a 2-year term, regular members will have the option of remaining on the committee or resigning to serve other CDER functions. Membership is reviewed by the PTCC either annually or when substantial changes in membership occur. The membership will be presented to the PTCC by the Chair or Co-Chair and will generally be voted on and approved within 30 days of the PTCC presentation, unless informed by the PTCC Chair of disapprovals or reasons for a delay. A member who fails to attend three consecutive meetings may be removed from the committee membership unless extenuating circumstances, such as illness or a temporary increase in workload, are reported to the committee Chair or Co-Chair.

- **Executive Secretary**: Either the Chair or Co-Chair may act as Executive Secretary, or they may appoint either a full-time or part-time Executive Secretary to the PTCC Safety Pharmacology Subcommittee.

- **Other Participants**: To facilitate productivity of the committees, invitations to guests and the use of smaller ad hoc working groups to address specific issues are encouraged.

RESPONSIBILITIES

The PTCC Safety Pharmacology Subcommittee will:

- Serve as a source of advice and assistance to the PTCC, OND, and CDER on safety pharmacology issues. The committee can also accept consults from other FDA Centers.

- Develop, as needed, policies and procedures related to safety pharmacology issues. PTCC comment and approval will be obtained prior to implementation of any policy, practice, or procedural change. Proposals for development or amendment of policies and procedures will be presented for comment from the PTCC; for issues with Agency-wide implications, comments from other Centers will be sought. The latter may be facilitated by inclusion of ad hoc committee representation.

- Prepare recommendations, as needed, for safety pharmacology study design and the need for studies to address specific issues.

- Recommend CDER staff and/or experts in the field of safety pharmacology to represent CDER in extramural regulatory/scientific activities. Representatives will be approved by the PTCC.

- Create working groups on specific issues mandated by the PTCC and/or CDER. Ad hoc members, consultants, and other non-voting observers from other divisions, Centers, or Federal government organizations may be included in the activities of the Safety Pharmacology Subcommittee to facilitate Center and/or Agency interactions. The Safety Pharmacology Subcommittee Chair or Co-Chair will inform the PTCC of the creation of all working groups and their membership.

The Chair and Co-Chair of the PTCC Safety Pharmacology Subcommittee will:

- Schedule and conduct meetings of the committee as required to fulfill the committee's objectives.

- Prepare an agenda and distribute it to the committee members before each committee meeting.

- Ensure that copies of all records of committee meetings and other deliberations of the committee are recorded and placed in a file maintained by the Executive Secretary for the PTCC Safety Pharmacology Subcommittee.

- With the assistance of the committee members, create and maintain a Task List for the committee, describing major tasks the committee is undertaking, projected milestones and completion dates, the current status of each project, and plans for any future projects.

- Report semi-annually to the PTCC on the activities of the committee. In preparation for each of

these semi-annual meetings, the co-chairs should provide to the PTCC at least a week in advance of the meeting an updated Task List, a summary of achievements since the last report to the PTCC, a projection of activities for the next 6 months, and a list of issues for which PTCC input is needed.

The Executive Secretary will:

- Arrange and organize meetings. Issues to be brought before the PTCC Safety Pharmacology Subcommittee should be directed to the attention of the Executive Secretary, who will consult with the co-chairs of the PTCC Safety Pharmacology Subcommittee in making up the agenda.

- Distribute documents.

- Ensure that files of committee activities are maintained.

- Prepare brief minutes of each meeting and distribute them to the committee members. Minutes will also be filed electronically on the designated shared drive under the subdirectory established for the PTCC Safety Pharmacology Subcommittee.

The Members of the PTCC Safety Pharmacology Subcommittee will:

- Represent their division's or office's views on issues considered by the committee that pertain to their areas of responsibility and expertise.

- Communicate with their division or office management about the deliberations of the committee.

- Regularly attend the meetings and review and evaluate all materials necessary to discuss and vote on program and project prioritization activities. If a member cannot attend a meeting, an alternate may be designated to attend, with the concurrence of the co-chairs. The co-chairs may replace committee members who have missed three consecutive meetings without extenuating circumstances.

- Understand that they may be assigned additional responsibilities by the Chair and Co-Chair, and that they have the right to accept or reject the designated responsibilities.

PROCEDURES

- **Meetings**. Meetings of the PTCC Safety Pharmacology Subcommittee should be held at least quarterly, and as needed. Issues to be brought before the PTCC Safety Pharmacology Subcommittee should be directed to the attention of the Executive Secretary, who will schedule them in consultation with the co-chairs of the PTCC Safety Pharmacology Subcommittee.

- **Voting.** At least six of the voting members of the PTCC Safety Pharmacology Subcommittee must be present for voting on issues to occur. If unanimous agreement is not reached on an issue brought to the committee for a vote, areas of disagreement should be documented in the meeting

minutes.

- **Communications Between the PTCC Safety Pharmacology Subcommittee and Management.** The activities of the PTCC Safety Pharmacology Subcommittee will be communicated to the OPS Office Directors, OND Division Directors, and Pharm-Tox supervisors; and the OND Associate Director for Pharmacology and Toxicology through distribution and electronic filing of the minutes and reports of subcommittee meetings.

EFFECTIVE DATE

This MAPP is effective upon date of publication.