PHARMACOLOGY AND TOXICOLOGY

Management of the PTCC Reproductive and Developmental Toxicology Subcommittee

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PURPOSE

- This MAPP describes the roles and responsibilities of the Pharmacology/Toxicology Coordinating Committee Reproductive and Developmental Toxicology Subcommittee (PTCC RDTS), as well as the subcommittee's structure and function, the procedures to be used in designating members to serve on the subcommittee, the responsibilities of the members designated to serve on the subcommittee, and subcommittee procedures.

BACKGROUND

- Pharmacology/toxicology subcommittees have been established in the Center for Drug Evaluation and Research (CDER) to develop regulatory guidance for use by sponsors and applicants, to keep current with scientific knowledge to address emerging technical issues, and to aid in the review process. The PTCC RDTS was established in response to questions from industry regarding adequacy of reproductive and developmental study designs and to requests from review staff for study protocol and outcome consultations. In April 2007, the PTCC RDTS was re-established as a CDER subcommittee under the PTCC charter.

REFERENCES

- MAPP 7400.1R *Management of CDER Pharmacology/Toxicology Coordinating Committee* (http://www.fda.gov/cder/mapp.htm)

OBJECTIVES

- The PTCC RDTS seeks to disseminate the appropriate guidance on reproductive and developmental toxicology submissions to both CDER review staff and the pharmaceutical industry by serving as a resource to the PTCC and to the Center on scientific and regulatory aspects of reproductive and developmental issues.

- The PTCC RDTS seeks to provide guidance, address technical problems, and respond to scientific inquiries from CDER review divisions.

ORGANIZATION

Oversight

- The PTCC provides oversight for the PTCC RDTS.

Membership

- **Chairperson/Co-Chairperson** — The chairperson and a team leader (or supervisor) co-chairperson (hereafter *chair/co-chair*) are selected by the subcommittee, with concurrence of the PTCC, based upon their qualifications, expertise, current workload, and organizational and management skills. Each chair/co-chair should serve for a 2-year term, although the PTCC RDTS and the PTCC may re-evaluate the length of the term and may choose to modify the term in 1-year increments. When a chair/co-chair resigns, the subcommittee members will select a new chair/co-chair with the concurrence of the PTCC.

- **Members** — Voting members of the PTCC RDTS include the chair/co-chair and the appointed members. Members are chosen to serve by the PTCC based upon their qualifications, expertise, and interest in the subject matter; their workload; and their ability to participate in subcommittee activities. Membership on the PTCC RDTS may be rotated periodically and may be reviewed by the PTCC. To facilitate productivity of the subcommittee, smaller ad hoc working groups may be formed to address specific issues. A member who does not participate in meetings or subcommittee initiatives may be asked by the chair to resign from the subcommittee unless the chair is informed of extenuating circumstances.

  - **Core members** are reviewers or team leaders (or supervisors) in pharmacology and toxicology from Office of New Drugs review divisions.

  - **Adjunct members** are persons with complementary expertise from other CDER offices and other centers. Adjunct members may attend meetings regularly and share in PTCC RDTS duties, but are nonvoting members and will not vote on PTCC RDTS recommendations. Adjunct members are invited to serve by the PTCC RDTS chair/co-chair, with the approval of the PTCC.

  - **Ad hoc members** are recognized experts, generally from outside CDER, who may be asked to do a variety of short-term duties, such as serve on working

groups, give advice on special projects, and comment on policy initiatives. Expert consultants (paid or not paid) may serve as ad hoc members, and may represent academia, the pharmaceutical industry, or governmental bodies outside of CDER. Ad hoc members are nonvoting members and are invited to serve by the PTCC RDTS chair/co-chair, with the approval of the PTCC.

- **Executive Secretary** — Either the chair or co-chair may act as Executive Secretary, or may appoint an Executive Secretary to the PTCC RDTS. The Executive Secretary's term will be renewed or the position rotated every 2 years.

RESPONSIBILITIES

The PTCC RDTS will:

- Serve as a source of advice and assistance to the PTCC and CDER on scientific and regulatory issues of reproductive and developmental pharmacology and toxicology.

- At the request of CDER review divisions, provide consultations in the form of tertiary review and scientific recommendations regarding reproductive and developmental pharmacology and toxicology issues and studies.

- Develop policies and procedures relevant to reproductive and developmental pharmacology and toxicology.

  – PTCC comment and concurrence will be obtained before implementation of any policy, practice, or procedural change.

  – Proposals for the development, amendment, or implementation of CDER policies and procedures will be circulated for comment from the PTCC and CDER, and, for issues with Agency-wide implications, from other centers. The latter may be facilitated by inclusion of ad hoc committee representation.

- Develop guidance related to nonclinical reproductive and developmental issues, address emerging technical problems, and respond to scientific inquiries from CDER review divisions.

- As needed, develop specific initiatives to keep review staff abreast of the latest developments in reproductive and developmental toxicology (e.g., classes, laboratory visits, seminar series, and journal articles).

- Create working groups to address specific issues mandated by the PTCC. Adjunct members, other nonvoting observers, and consultants from other divisions, centers, or Federal government organizations may be included in the activities of the PTCC RDTS to facilitate cross-center or inter-agency interactions. The PTCC RDTS (chair/co-chair) shall inform the PTCC of the creation of all working groups and their membership.

- Recommend CDER staff and/or experts in the fields of reproductive and developmental pharmacology and toxicology to represent CDER in extramural regulatory and scientific activities; representatives will be approved by the PTCC, as described in MAPP 7400.1R *Management of CDER Pharmacology/Toxicology Coordinating Committee*.

- Function to facilitate and implement good review practice standards for pharmacology and toxicology review divisions.

The Chair/Co-Chair of the PTCC RDTS will:

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

- Prepare and distribute an agenda to the subcommittee members in advance of each meeting.

- Ensure that records of subcommittee activities, including minutes, task lists, documents for the PTCC semiannual meetings, and consults, are maintained in an electronic form on the Pharmacology and Toxicology Web site.

- Review minutes of each meeting prepared by the Executive Secretary.

- With the assistance of the subcommittee members, create and maintain a task list for the subcommittee describing major tasks the subcommittee is undertaking, projected milestones and completion dates, and the current status of each project.

- Report semiannually to the PTCC on the activities of the subcommittee. In preparation for each of these semiannual meetings, the chair/co-chair 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.

- Prepare written responses to consult requests by consolidating comments from PTCC RDTS members, electronically post responses on the shared file server, and transmit the finalized responses to the requesting review division.

The Co-Chair of the PTCC RDTS will:

- Assist the chair as needed, and communicate information from the PTCC to the PTCC RDTS or vice versa, regularly updating both groups with pertinent information. The co-chair may call and run meetings in the absence of the chair or at the chair's request.

The Executive Secretary will:

- Schedule meetings, in consultation with the chair/co-chair, as required for fulfilling the subcommittee's objectives.

- Prepare brief minutes of each meeting, distribute them for comment electronically by e-mail, and post the final version on a shared file server.

The Members of the PTCC RDTS will:

- Maintain a high level of familiarity with important reproductive and developmental toxicology-related scientific and regulatory literature and guidances.

- Review materials in advance of meetings, and have a general willingness to participate in subcommittee activities.

PROCEDURES

- PTCC RDTS meetings should be scheduled at least monthly, and as needed. Schedules for meetings and the meeting locations will be made available to all members by e-mail.

- Consult requests should be made to the chair/co-chair. Divisions wishing to consult the PTCC RDTS should complete the consult request form available on the Pharmacology and Toxicology Web site and submit it to the PTCC RDTS chair/co-chair. Information required from the division making the request for consult on this form includes:

  – The date on which the consult request was made.

  – The date by which a response to the consult request is needed. In general, the PTCC RDTS will respond to consult requests within 30 days of the date the request was made.

  – A delineation of the specific questions requested for consult.

  – Background information pertinent to the specific questions to be addressed.

  Recommendations made by the PTCC RDTS will be delivered to the person or organization that requested the consult for their disposition and action.

- All PTCC RDTS meetings will be documented by minutes that present issues discussed by the membership. All subcommittee decisions with rationales should be documented. Copies of the minutes will be distributed to PTCC RDTS members. Finalized minutes will reside with the Executive Secretary and be posted on the Pharmacology and Toxicology Web site. The activities of the PTCC RDTS will be communicated by the chair/co-chair to relevant office directors, division directors, pharmacology supervisors and team leaders, and primary pharmacology reviewers through electronic filing of minutes and through PTCC updates.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.