OFFICE OF THE CENTER DIRECTOR

International Activities Coordinating Committee (IACC)

CONTENTS

PURPOSE

This MAPP outlines the organization and responsibilities of the International Activities Coordinating Committee (IACC).

BACKGROUND

IACC was established to lead the Center's participation in international initiatives and to provide a forum for coordination and discussion of new international initiatives. The IACC, in coordination with the Office of Commissioner, also initiates requests for training and visits to the Center by citizens of foreign counties.

An important focus of CDER=s international activities is the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. CDER also participates in discussions of scientific and technical matters with regulatory counterparts throughout the world, working with the Deputy Commissioner and the staff of the Office of International and Constituent Relations (OICR) and its Office of International Programs (OIP). CDER participates in formal yearly meetings that occur under the direction of OIP, which includes a trilateral meeting (Canada, United States, and Mexico); a tripartite meeting (Canada, United States, and the United Kingdom); and a bilateral meeting (European Commission and United States). CDER also participates in many activities sponsored by the

World Health Organization (WHO), including the biannual International Conference of Drug Regulatory Authorities (ICDRA). These activities conform to the mandate of the Food and Drug Administration Modernization Act of 1997 to "participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal agreements." 21 U.S.C. ' 903(b)(3).

DEFINITION OF INTERNATIONAL ACTIVITIES

International activities include the following.

1. Standard setting (international standards, harmonization, regulations and legislation)
2. Regulatory and compliance surveillance (import monitoring, foreign inspections, agreements, other import activities)
3. Scientific collaboration (scientific meetings, research collaboration)
4. Technical assistance, training, and education (expertise, materials)
5. Hosting foreign visitors
6. Monitoring trade and export issues relating to health and safety
7. Cooperating with other governments (bilateral and multilateral, joint reviews, U.S. government initiatives)
8. Cooperating with international organizations (WHO)
9. Communicating with other U.S. federal agencies on international issues
10. Providing support to intra- and inter-agency liaisons on international matters.

POLICY

- All international initiatives that may affect Center resources will be brought to IACC for review, discussion, and endorsement prior to implementation. Subject to approval by the Center Director and in consultation with appropriate Office of Commissioner staff, IACC will develop policies on new international initiatives. If IACC endorses a new initiative, a request for approval will be made

to the Center Director. The Center Director will have final approval of any such request.

- All new international initiatives developed in other Centers' coordinating committees or other Commissioner-level committees that involve an extension of CDER policy to the international arena will be brought to IACC for consideration, especially if there is an intent to harmonize the policy or provide information about it to the international community.

- IACC will review requests for training and visits to the Center by citizens of foreign countries (see MAPP 4160.2). IACC may refer certain requests to CDER=s Senior Management Team (SMT). The Center Director will have final approval of all such requests for training or visits

ORGANIZATION

The Center Director is Chair of the IACC. The Executive Secretary of IACC is the Center=s ADIA. Their respective offices nominate IACC members. Representation will come from the Office of Medical Policy, Office of Review Management, the Office of Pharmaceutical Science, the Office of Compliance, the Director of the Regulatory Policy Staff, the Office of Training and Communications, and the Office of Information Technology. CDER staff participating in international activities will be included in meetings when appropriate. Staff from the Office of the Commissioner and representatives of other Centers will be invited to attend when needed.

RESPONSIBILITIES

- IACC is responsible for reviewing all new international initiatives that may affect CDER resources. In consultation with the Office of the Commissioner, IACC will determine whether to endorse any new initiative. If IACC endorses any new initiative, a request for approval will be made to the Center Director. The Center Director will have final approval of any such request.

- IACC may request information on ongoing international activities when necessary, but will not become involved in the day-to-day management of such activities.

- IACC will participate in the collection of information about a new initiative on an international activity, create a forum for discussion of the initiative, work to build a consensus position on the initiative, and present the endorsed consensus with additional views and opinions to the Center Director for a final decision. Subcommittees and working groups will be formed when necessary.

- The CDER ADIA will coordinate the Center's response to incoming documents concerning IACC activities. In this capacity, the ADIA will coordinate CDER and IACC's response to all internal FDA and external requests regarding new international initiatives. These requests will be transmitted

first to CDER Executive Operations Staff (EOS) at HFD-006. After logging a request, CDER=s EOS will forward the document to the ADIA for distribution to the appropriate CDER staff. Responses will return through the CDER ADIA to the CDER EOS after being cleared by the Deputy Center Director.

- All inquiries concerning the tracking of a document should be directed to the EOS. Requests for documents and other requests relating to this function will pertain specifically to new international initiatives (see Definitions) and will not include general information requests from overseas or clearance of documents relating to ongoing international activities.

- Additionally, IACC provides a forum for:

    1. Discussing international issues within CDER and developing policy on new international initiatives

    2. Coordinating new international initiatives on activities within CDER and between CDER and other FDA staff

    3. Disseminating information about international regulatory activities to all CDER staff

    4. Supporting CDER=s representation to and coordination of all new international initiatives outside the Center, including the International Working Group meetings sponsored by the OIP/OICR and the international activities of other Centers and management units within the FDA

- The Executive Secretary of IACC is responsible for:
    1. Arranging and organizing meetings of the IACC

    2. Distributing documents

    3. Maintaining the files of the committee and files on other international activities

    4. Preparing minutes of meetings

    5. Ensuring accuracy of IACC documents

- Subcommittees and/or working groups of IACC may be formed and are responsible for:

    1. Implementing new international initiatives

    2. Serving as a source of advice and assistance to IACC on assigned topics

3. Developing policies and procedures when needed

PROCEDURES

- IACC meetings will be held monthly when feasible. Emergency meetings will be called to discuss pressing initiatives.

- Agenda items should be e-mailed to the Executive Secretary of IACC a week before the next scheduled meeting. Issues to be brought before IACC should be directed to the attention of the Executive Secretary who will attempt to schedule them in the upcoming meeting.

EFFECTIVE DATE

This MAPP is effective on the date of publication.