OFFICE OF THE CENTER DIRECTOR

Prioritization of Requests for Training and Visits by Foreign Regulatory Agencies and International Regulatory Organizations

CONTENTS

PURPOSE
BACKGROUND
DEFINITIONS
POLICY
RESPONSIBILITIES
PROCEDURES
EFFECTIVE DATE
ATTACHMENT: Commitment to Protect Privileged Information

PURPOSE

This MAPP describes how CDER prioritizes requests for visits and training by representatives from foreign regulatory agencies and international regulatory organizations.

BACKGROUND

The FDA believes that it is valuable to exchange information with other countries on the policies and procedures that FDA uses to regulate products. To this end, FDA has made presentations to international visitors on a variety of topics including the Agency's organization, procedures and other regulatory processes, research programs, and new initiatives. These visitors return to their countries with a greater understanding of health and regulatory issues and approaches in the United States, the FDA's role as a public health protection agency and what is needed to meet FDA's requirements. In addition, visitors take home new ideas and methods for solving health and/or regulatory issues in their own countries.

Working with the Agency=s Office of International Programs (OIP), Office of International and Constituent Relations, CDER responds frequently to requests for visits and for training by citizens of foreign countries. Fulfilling these requests requires a substantial effort and resource expenditures by the Center. Every effort should be made to consolidate the requests so that they may be dealt with in an efficient manner. In general, regulator training should be kept to a minimum so as not to disrupt the review process and burden the CDER review staff.

DEFINITIONS

Foreign Government Official: Under 21 CFR 20.89 (d)(3), the term *official of a foreign government agency* includes, but is not limited to, an agent employed under contract by a foreign government, and an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility.

Training: *Training* means the provision of specific, focused information concerning CDER's regulatory processes and procedures. Training generally lasts one week or more.

Visit: *A visit* is generally less than one week in duration with the objective of obtaining an overview of CDER's regulatory processes and procedures.

POLICY

The following policy applies to all requests to CDER for training and visits by officials of foreign regulatory agencies and international regulatory organizations.

- All training requests must be cleared by CDER=s International Affairs Coordinating Committee (IACC) in consultation with the FDA=s Office of International Programs. (See MAPP 4160.1 for a description of IACC's organization and responsibilities.) If training is to occur for an extended period of time (i.e., for more than one week), the requestor must qualify as a foreign government official under 21 CFR 20.89 and be eligible to sign all of the appropriate paperwork pertaining to protection of confidential information(e.g., see attachment). In addition, all foreign visitors will be subject to supervision.

  In determining the value of the training and whether CDER should expend its resources, the relevance of CDER=s system to the system of the trainee=s country will be considered. Equally important is whether the requested training has the potential to provide CDER with information that would benefit its regulatory process (i.e., the trainee is from a regulatory authority that has important cooperative programs with FDA and the training would
  provide a better understanding of the collaborative region). Those requesting training should be able

to articulate specific goals to better tailor the training and to conserve CDER resources. Ideally, training should result in a demonstrable improvement in the regulatory, enforcement, or technical infrastructure of the foreign country.

- All visit requests must be cleared by the Center=s Associate Director for International Affairs (ADIA), in consultation with the Agency=s OIP. Requests for visits from regulators in foreign countries are generally granted. However, with increasing frequency, CDER receives visit requests from foreign pharmaceutical firms. Because CDER does not usually grant visit requests for domestic companies, visit requests from foreign companies will generally not be granted unless requested by the company=s foreign government.

  Additionally, a representative from the country's embassy or consulate should accompany visitors of foreign pharmaceutical companies. The granting of any visit request will be based on the availability of adequate CDER resources at the time of the request, and visits may be denied if resources are unavailable.

- IACC will refer requests for training for longer than one month to CDER=s Senior Management Team. The Center Director will have final approval of all such requests for training or visits. In general, regulator training should be kept to a minimum so as not to disrupt the review process and burden the CDER review staff.

RESPONSIBILITIES

- CDER staff must forward all requests for visits or training to the ADIA as soon as possible.

- Working with the Agency=s OIP, the ADIA is responsible for triaging requests and consolidating them, as much as possible, to conserve center resources.

- Center staff must protect confidential, commercial, and trade secrets, and other privileged information from unauthorized disclosure. CDER staff working with international visitors must be familiar with the procedures for identifying and safeguarding confidential commercial and trade secret information. When necessary, they must discuss with international visitors the need to protect confidential commercial information and obtain signatures on necessary paperwork pertaining to protection of confidential information. Visitors must sign the FDA Commitment to Protect Privileged Information document at the beginning of their visit (see Attachment).

PROCEDURES

- Requests for training should be forwarded to the ADIA for discussion at the next scheduled IACC meeting. The ADIA will develop a profile of the request for consideration by the members of the IACC and will determine eligibility for signing the appropriate paperwork pertaining to protection of confidential information.

- Requests for visits should be forwarded to the ADIA for consideration and coordination.

EFFECTIVE DATE

This MAPP is effective on the date of publication.

ATTACHMENT

Department of Health and Human Services
Public Health Service — Food And Drug Administration

Commitment to Protect Privileged Information

Whereas, I _____, am to serve on a special assignment with the United States Food and Drug Administration, hereafter referred to as the Agency, I hereby agree, subject to the penalties of Section 1905, Title 18 U.S.C., Crimes and Criminal Procedures (18 U.S.C. 1905), and Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(J)), cited below, to recognize the trust placed in me by the Commissioner of Food and Drugs to protect all privileged information entrusted to me in the following manner:

1. To store it and all notes pertinent thereto in the secured offices of the Agency.

2. To grant access to it only to known employees of the Agency or to such other persons as may be designated in writing by the Agency.

Further, I agree to:

1. Assist FDA in reviewing the security measures I will

employ in protecting privileged information entrusted to me.

2. Return all privileged information and notes pertinent thereto to the Agency upon completion of my assignment, or upon the Agency's request.

3. Report in writing to the FDA official I am assigned to, all incidents in which unauthorized persons might have gained access to privileged information entrusted to me.

4. Not release, publish, or disclose such privileged information specifically any of the facts involved in this matter, including any trade secret matter.

I understand the provision of 21 U.S.C. 331(j) and 18 U.S.C. 1905 and that I am subject to criminal penalties prescribed by law for any violations thereof.

I hereby swear I do not currently have any financial interest whatsoever in any aspect of the commercial drug manufacturing/distributing industry, nor am I planning to enter into that field within one year after concluding my duties with the United States Food and Drug Administration.

_____ _____

SIGNATURE DATE

_____ _____

WITNESSED DATE

STATUTORY REFERENCES

The general Federal confidentiality statute, section 1905, Title 18 U.S.C. Crimes and Criminal Procedure, 18 U.S.C. 1905, provides that:

> "Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment."

Section 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j), prohibits:

> "The using by any person to his own advantage, or revealing, other than to the Secretary or officers or

> employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 705, or 708 concerning any method or process which as a trade secret is entitled to protection."

Section 708 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 379, states:

> "The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of Title 5, United States Code by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this Act, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe."