SMG 2830.3

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

AGREEMENTS WITH OTHER GOVERNMENT AGENCIES - ARRANGEMENTS WITH FOREIGN GOVERNMENTS: MOUs, CONFIDENTIALITY COMMITMENTS

SHARING NON-PUBLIC INFORMATION WITH FOREIGN GOVERNMENT OFFICIALS

Effective Date: 10/18/2005
Changed: 03/21/2006

of Current status of Non-Public Information Previously Shared.

1. PURPOSE

This staff manual guide (SMG) establishes Agency-wide policies and procedures for all U.S. Food and Drug Administration (FDA) employees related to sharing non-public information with foreign government officials. This SMG applies to the management of requests for non-public information, the establishment of confidentiality arrangements to enable sharing non-public information, the management of non-public documents, and the maintenance of records related to the sharing of non-public information with foreign government officials, including representatives of international organizations that perform counterpart functions to FDA. For purposes of this SMG, the term “foreign government, foreign government official, and foreign government counterpart agency” includes such international organizations.

All such information exchanges must be pursuant to a written confidentiality arrangement with the foreign government counterpart agency and, as needed, other appropriate written authorized releases, regardless of who initiated the activity.

The Office of International Programs (OIP) in the Office of the Commissioner is the Agency’s lead for all international commitments, arrangements, and agreements. All commitments, arrangements, or agreements regarding disclosure of otherwise non-public information to foreign government officials must be negotiated and cleared by OIP. Only the Commissioner of Food and Drugs or the Deputy Commissioner for International and Special Programs is authorized to sign such commitments, arrangements, or agreements.

2. BACKGROUND

FDA’s public health responsibilities have become increasingly complex as (a) medical product development, authorization, marketing, promotion, and transport and (b) animal and human food-related health issues have become increasingly more global. In many areas of FDA’s product oversight responsibilities, the majority of the products (or at least a portion of the product) have a foreign, rather than a domestic, point of origin. Our international work and the relationships with our counterpart agencies around the world are now an integral part of the routine work of the FDA. The U.S. Congress acknowledged this new reality by enacting Section 903(b)(3) of the Federal Food, drug, and Cosmetic Act. In that section, in which Congress specified the mission of FDA, Congress specifically states that the Administration “shall participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal

arrangements." (Italics added). Congress made clear that international work is not discretionary FDA work, but an integral part of the fundamental FDA statutory mission.

There is great benefit for FDA when agency officials interact with their regulatory counterparts in many areas of the world to enhance public health promotion and protection both in the United States and worldwide. Therefore, FDA has established procedures for entering into information-sharing arrangements with foreign government counterparts that allow FDA to share and receive information not available to the public as part of cooperative law enforcement or cooperative regulatory efforts.

FDA regulations (21 C.F.R. § 20.89) permit, but do not require, FDA officials to share non-public information with a foreign government or international organization that performs counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts. FDA staff may share such information provided they comply with this regulation by following the procedures set out in this staff manual guide.

3. POLICY AND SCOPE

All FDA employees must adhere to the procedures set forth in this SMG.

A. Permissible sharing. Use these procedures for the discretionary sharing with a foreign government or international organization of non-public information otherwise exempt from public disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, or other law.

B. Limitations. Do not use these procedures to:

1. Share information with the public, U.S. federal or state/local governments or courts, or Congress, including Congressional chairpersons, who might also direct GAO inquiries. See 21 C.F.R. §§ 20.83, 20.85, 20.86, 20.88 and 20.87; or

2. Share information with a foreign government or international organization if the information:

    a. Is publicly available;

    b. Is the type of information normally exempt from disclosure to the public under FOIA, but is available to the public to the extent necessary to carry out an administrative or court enforcement action (21 C.F.R. § 20.91);

    c. Relates to a person or product not regulated by FDA; or

d. Has been provided to FDA by a foreign government or international organization and is subject to an FDA commitment to maintain the confidentiality of the information.

4. DEFINITIONS

A. Definitions Concerning the Foreign Government or International Organization

1. **Counterpart functions** (to FDA's functions) include, among others, administrative or regulatory law enforcement, health oversight, product application review, compliance review, standard setting, and public health functions.

2. **International organization** refers to an organization established by law, treaty, or other governmental action and having the responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. International groups that do not meet this definition may not receive information under 21 C.F.R. § 20.89. Examples of international organizations covered by the procedures are the World Health Organization (WHO), Pan American Health Organization (PAHO) and other regional subsidiaries of WHO, and the Food and Agricultural Organization (FAO) of the United Nations. Organizations that have not been incorporated under international or domestic law, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), International Conference on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH), or Global Harmonization Task Force (GHTF) are not international organizations for purposes of these procedures.

3. **Official of a foreign government** refers to a permanent or temporary employee of, or agent contracted by, a foreign government, or its sub-national components (e.g., states). An embassy is considered an agency of the foreign government it represents.

B. Definitions Concerning the Types of Information That Could be Shared

1. **Non-public information** refers to information that is protected from disclosure to the public by United States law, such as the Freedom of Information Act, the Privacy Act, the Trade Secrets Act, the Economic Espionage Act, the National Childhood Vaccine Injury Act, and the Federal Food, Drug, and Cosmetic Act. Examples of non-public

information include confidential commercial information, trade secret information, predecisional FDA communications or documents (such as draft regulations or draft guidance documents), investigative information, enforcement information, and other non-public information, such as personal privacy information.

2. **Confidential commercial information** covers information that is related to a business or trade and is "confidential." The definition of "confidential" depends on the circumstances under which the information was submitted to FDA. In the case of information that FDA requires to be submitted, the information is "confidential" if its disclosure is likely to cause substantial harm to the competitive position of the submitter. In cases in which the submitter provided the information to FDA voluntarily, it is "confidential" if the commercial information is of a type that the submitter would customarily not release to the public. Examples of confidential commercial information might include sales statistics, amount or source of income (e.g., a company's list of customers), profits or losses, expenditures (of any person, firm, partnership, corporation or association), name of suppliers or subcontractors, or brand of equipment. An Establishment Inspection Report (EIR) or a medical officer's review or discussions about a review, including strategies related to the review, may contain confidential commercial information.

3. **Investigation** refers to any systematic observation, inquiry, or examination of a possible violation of any (federal) statutes, rules, regulations, and/or other laws.

4. **Information compiled for law enforcement purposes** includes, but is not limited to, information compiled during or about an investigation for purposes of bringing any potetial or actual enforcement activities. Information compiled for law enforcement purposes may be withheld from disclosure to the public if, among other things, disclosure of the information could reasonably be expected to interfere with enforcement proceedings, disclose the identity of a confidential source, constitute an unwarranted invasion of personal privacy, or would disclose law enforcement procedures and techniques the disclosure of which would risk circumvention of the law. Examples of law enforcement information are information relating to regulatory enforcement action, such as an Establishment Inspection Report (EIR), recall audit check report, or complaint/injury follow up form. Examples also include information received from any person who is the subject of an FDA investigation that relates to that investigation, information relating to possible criminal prosecution, information about techniques and procedures for law enforcement investigations or prosecutions, guidelines for law enforcement investigations or prosecutions, and information about

statements of witnesses or other sources concerning possible violations.

5. **Open investigatory information** is information, compiled for law enforcement purposes, which is protected from disclosure to the public because FDA has not yet decided whether administrative or regulatory action is warranted, or a decision has been made to take such action, but such action has not yet been concluded (see 21 C.F.R. § 20.64(d)).

6. **Personal privacy information** as used in this SMG is information about an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Examples include information that identifies an individual, such as the individual's home address, telephone number, social security number, or other unique identifiers. Prsonnel or medical records, adverse event reports, or law enforcement records are examples of records that may contain personal privacy information exempt from public disclosure. Medical records submitted under the Vaccine Adverse Event Report System and others are prohibited by statute from being further disclosed.

7. **Predecisional information** refers to opinions and recommendations that are part of agency deliberations. It includes, but is not limited to, non-public draft regulations, draft guidance documents, draft regulatory initiatives, draft FDA policy or procedural statements, draft legislation, certain inter-governmental communications, and FDA discussions/deliberations about any of those items. A discussion that includes opinions and recommendations, e.g., a medical officer's opinions or strategy about a review for a pending application, might also involve other types of non-public information, such as confidential commercial information. In that case, also refer to the definition and procedures related to confidential commercial information.

8. **Trade secret information** is any commercially valuable plan, formula, "recipe," process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process; for example, information relating to the manufacturing process. Sec. 301(j) of the Federal Food, Drug, and Cosmetic Act prohibits most disclosures of trade secrets without the sponsor's authorization. Trade secrets are frequently found in EIRs, device Premarket Notifications (510(k)'s), device Pre-market Approval Applications, New Drug Applications, Biologic License Applications, Investigational New Drug Applications, Investigational Device Applications, Investigational New Animal Drug Applications, certain

technical proposals or bids from contractors, medical officer reviews, and other documents.

C. Definitions Concerning FDA Terms

1. **Center/OC-Offices:** Includes all program Centers – the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Medical Devices and Radiological Health, and the Center for Veterinary Medicine; the National Center for Toxicological Research; the Office of Regulatory Affairs; and all Office of the Commissioner Offices.

2. **Lead Center/OC-Office:** The Office of International Programs (OIP) in the Office of the Commissioner is the lead Office for the sharing of non-public information with foreign government officials. OIP, along with the Office of Policy and Planning in the Office of the Commissioner, are responsible for coordinating with the Centers/OC-Offices the information sharing and for complying with 21 C.F.R. § 20.89. Unless otherwise noted, the lead Center/OC-Office is the one that is responsible for regulating the product that is the subject of the information to be shared, or, where there are various products at issue, has custody of the majority of the relevant information at issue.

3. **Center/OC-Office contact person:** Each Center/OC-Office must have a designated Point-of-Contact (POC) for addressing and coordinating issues involving sharing of other-wise non-public information with foreign government officials. When instances that warrant non-public information exchanges arise, the Center/OC-Office contact person will be notified and/or consulted by the OIP Disclosure Coordinator (OIP DC).

4. **OIP Contact Person:** The OIP DC is the primary point of contact for all non-public information disclosure questions. OIP's staff persons assigned as leads on individual international information sharing commitments or agreements are the point of contact on questions related to information sharing under the auspices of a duly constituted international commitment or agreement. Questions regarding disclosure of non-public information may be directed to the OIP lead on an individual international commitment or agreement (e.g., EC-EMEA, Health Canada, Swissmedic, etc.), or the OIP DC. It is the responsibility of the individual OIP lead and OIP DC to coordinate within OIP.

5. **Share:** Refers to the conveying of information in any form (oral, paper, floppy diskette, CD-ROM, microfiche, email, etc.) and in any manner

(e.g., transmitting the information to a location outside FDA, discussing information outside FDA, or permitting a visiting scientist or official to access information on FDA premises). The supporting documents required and the extent to which one may share information under this SMG will vary, depending on the type of information to be shared and the form of sharing. Sharing information applies to instances when a foreign government counterpart requests the information, as well as when FDA wishes to initiate the sharing or to receive information.

6. **Sponsor:** For purposes of this SMG, sponsor collectively refers to the person who submits or owns the otherwise non-public information submitted to FDA, assumes the responsibility for or initiates a scientific investigation of a regulated product or clinical study of a new biologic or drug, or is considered an applicant under FDA regulations.

5. RESPONSIBILITIES AND PROCEDURES

All requests from foreign government regulatory counterparts for non-public information must be made in writing. If you receive an oral request, ask the requesting party to submit its request in writing to the OIP DC. If you receive a written request, refer the request to the OIP DC. An electronic mail message suffices as a written request for this purpose. In public health emergency need situations, in which there is insufficient time to make a formal written request, the Deputy Commissioner (International and Special Programs) may authorize the immediate sharing of non-public information that is the subject of discretionary disclosure, such as investigative or compliance information, to the foreign government counterpart when there is an existing confidentiality arrangement in effect. In this situation, if authorized, the oral request must be followed within 24 hours by a written request from the foreign government counterpart stating the emergency need for the information and confirming the commitment made at the time of the disclosure to keep the information confidential.

Each Center/OC-Office must adhere to the following procedures when sharing non-public information with or receiving non-public information from foreign government officials or an international organization.

A. Sharing Non-Public Information

When a request is received from a foreign government counterpart for information that is, or may be, non-public, the following steps must be taken:

1. Notification and Determination

a. The person receiving the information request notifies the Center/OC-Office POC, who will promptly notify the OIP DC or the OIP lead for a specific international commitment or agreement.

b. OIP will determine if there is an existing confidentiality commitment, arrangement, or agreement with the requesting foreign government counterpart. This should be determined at this point so that FDA knows early that a confidentiality commitment may need to be implemented in the event a decision is made to share the information requested.

c. OIP will determine, in consultation with the Center/OC Office POC as needed, if the requested information is publicly available or is non-public information. If the information is publicly available, it may be shared outside of the procedures in this SMG.

d. If the information requested to be shared is non-public information, OIP, in consultation with the appropriate Center/OC Office POC, will determine if FDA will consent to sharing the requested information. Each involved Office or Center is responsible for promptly obtaining the necessary supervisory consultations within their respective Office or Center. In the event FDA determines that it will deny the request, OIP will so notify the requester, providing the reason(s) for the denial, which must be documented and made a part of the record kept to document the request and response.

e. If the FDA decision is to share the requested information, OIP will determine if an appropriate confidentiality arrangement has previously been signed by the requesting authority that would cover sharing of the requested information. See Attachment A. If one is in place, proceed to the next step. If one is not in place, **the non-public information may not be shared until a confidentiality arrangement is executed by the requester.** In that instance, OIP will work with the appropriate Center/OC-Office to establish the appropriate commitment(s) necessary for the sharing of the non-public information.

f. OIP will coordinate the information sharing process. Under this process, the POC for the Center/OC Office that holds the requested information will consult with the appropriate Center/OC Office staff to collect the information and determine its status (i.e., confidential commercial, predecisional, trade secret, law enforcement, etc.). The Center/OC Office FOIA staff or the OIP FOIA staff will make necessary redactions of any trade secret information and send the documents to the OIP DC. With regard to predecisional information, OIP and OPP are currently delegated authority to share non-public

predecisional information. Non-public predecisional information may only be shared with a FOREIGN government official with the explicit authorization of the Deputy Commissioner (International and Special Programs) or his/her designee.

g. OIP will assure that the appropriate supporting documents are in place. Different categories of information require different supporting documents (see section 7 “Supporting Documents”). **Under no circumstances should non-public information be shared without the appropriate supporting documents signed and in place, except in the public health emergency needs situations noted previously.**

2. Sharing the Information

a. The Deputy Commissioner (International and Special Programs) must either in each individual case or as part of a comprehensive determination authorize the sharing (release) of non-public information with a foreign government official. In the case of non-public pre-decisional information, the Deputy Commissioner will first informally consult with the Associate Commissioner for Policy and Planning.

b. When the Deputy Commissioner (International and Special Programs) has authorized the release of the non-public information, OIP will determine the appropriate foreign government official authorized to receive the information. See Attachment B.

c. OIP will determine how the information is to be shared – orally (in person, via the telephone, or by video-conference) or written (e.g., fax, email, courier delivery, postal delivery). Given that communications under this SMG will often involve time-sensitive and important collaborations and that these communications occur across many cultural boundaries (including different time zones and working schedules), and given that e-mail is in many ways as secure as a phone call, e-mail is an appropriate vehicle for transmitting non-public information to counterpart foreign government agencies, provided the processes in this SMG are followed and the person sending the e-mail has confirmed that the recipient is appropriately committed under a confidentiality arrangement (i.e., that the recipient indeed works for the appropriate counterpart agency and that s/he understands the need to abide by the obligations under the confidentiality arrangement.) As the ability to encrypt e-mail communications with specific foreign government counterparts is implemented, e-mail communications

under this SMG will be subjected to appropriate encryption protocols.

d. If the information is to be shared orally, the conversation should be prefaced by a statement that “the information you are about to receive is pursuant to [identify the appropriate confidentiality commitment and/or agreement]; the information is non-public information and must be treated as such”. This discussion must be documented in a note to the file. In each instance, OIP will coordinate with the appropriate Center/OC Office to determine who will actually provide the information to the appropriate foreign official. The assigned OIP person will usually participate in the oral presentation of information.

e. If the information is to be shared in writing – either through a letter, fax, or electronic mail transmission – the information should be transmitted using the transmittal letter attached to this SMG (Attachment C) or, if by email, by an upper case statement at the beginning of the email that reads: “THE INFORMATION IN THIS EMAIL AND ANY ATTACHMENTS IS BEING PROVIDED TO YOU UNDER THER TERMS OF OUR CONFIDENTIALITY ARRANGEMENTS.” The information to be shared, with the appropriate cover letter, should be sent from the appropriate Center/OC-Office to the OIP DC for further transmittal to the appropriate foreign government official.

f. Where possible, each page must be stamped with a legend that reads as follows: “Official United States Food and Drug Administration Documents Subject to Confidentiality Arrangement. Do Not Disclose without written permission of US FDA or information owner.”

g. If the recipient of non-public documents later requests a determination of whether the documents have lost their non-public status, such confirmation may be conveyed using the model language in Attachment F.

3. Record keeping

a. OIP will maintain a record of all requests for sharing non-public information with a foreign government official and the responses.

b. As mentioned previously in the SMG, if the decision is to deny the request, OIP will make an appropriate record of the request, the reason for the denial, and will keep a copy of the denial letter as part of the record.

c. Once information is shared with the foreign government counterpart, OIP will update the record of the request to reflect what information was shared, by whom, on what date, and by what means.

d. When information is shared, a written confirmation of receipt should be requested and obtained from the foreign government counterpart.

e. OIP will maintain comprehensive records of the non-public information that is shared with the foreign government counterpart.

B. Hosting Foreign Government Officials At FDA, Where Non-Public Information May Be Shared

A confidentiality arrangement must be in place with the foreign government prior to hosting a foreign government official, if the foreign government official has either requested to visit FDA or been invited to visit FDA and during the visit (or placement) the official will either have access to non-public information or where non-public information may be shared with the official(s). In those cases, the following steps must be taken:

1. The foreign government official must complete a Visitor Commitment Form (Attachment D), which must be kept on file in the Center/OC Office hosting the foreign official and a copy of the signed document must be sent to the OIP DC.

2. Records of the information the foreign official has access to during the visit should be maintained in the Center/OC Office and a copy and list of such information must be sent to the OIP DC.

C. Receiving Non-Public Information

FDA also receives non-public information from foreign government counterparts, and the foreign government disclosing or offering to disclose such information may wish to keep it from public disclosure. Incoming information may be a result of a request by FDA for the information or due to a foreign government counterpart that wishes to share the information with FDA.

In either instance, the following steps must be taken:

1. The Center/OC-Offices must establish and maintain a secure file in their Document Control Units to store any non-public information received from foreign government officials.

2. Each file should designate who has authorized access to the files. The Center/OC-Office individuals with access to this information must maintain the confidentiality of the non-public information to the same extent FDA protects the confidentiality of other non-public information it creates or obtains, to the extent permitted by law.

3. A record and list of the information received must be created to include the date of the receipt, by whom, and a general description of the information received. This record should be provided to:

   a. The Center/OC Office POC, and

   b. The OIP DC

4. The file should be retained, retired, or destroyed by the Center/OC Office according to the Records Retention Schedule entry applicable to the use to which the file is put (there is no separate schedule entry for shared documents). The file should have a retirement or disposal date for destruction of file contents. The file should designate if the contents are to be permanently archived. OIP should be notified of the status of the file during these stages.

5. Employees handling non-public information received from foreign government officials should be certified as trained in information security procedures.

6. The OIP DC must be notified IMMEDIATELY if there is ANY request for release of non-public information that has been received from foreign government officials under terms of an executed confidentiality arrangement with FDA. Such information can only be released upon authorization of the Commissioner, Deputy Commissioner (International and Special Programs), or the Assistant Commissioner for International Programs.

D. Non-applicability of Other Disclosure Authorities Vested in the FDA

This SMG does not apply to disclosures by the FDA under the authorities in FDA regulations 21 C.F.R.§ 20.91, and Section 705 (b) of the Federal Food, Drug, and Cosmetic Act. Those provisions permit, under duly authorized procedures, the FDA to use non-public data or information to the extent necessary to support or undertake an administrative or judicial enforcement action (20.91), or to disseminate information regarding foods,

drugs, devices, or cosmetics in situations involving imminent danger to health or gross deception of the consumer (Section 705(b)).

6. CONSULTATIONS

If you have a question, consult, as needed, with the OIP DC. Working together with the OIP DC, further information may be obtained, as needed, from appropriate agency officials.

7. SUPPORTING DOCUMENTS

In order to share non-public information with a foreign government official, appropriate documents must be prepared, signed by the appropriate officials, and be on file in OIP. Examples of these documents are at Section 9 of this SMG – (Attachments). These documents include:

A. Statement of Authority and Confidentiality Commitment (Attachment A): This document is needed in order to share, in any form, confidential commercial (with a sponsor authorization or a public health interest determination - See Attachment E and B respectively) or trade secret information (with a sponsor authorization), or otherwise non-public information that the Agency wishes to share confidentially with foreign government officials.

B. Internal Memorandum Authorizing Disclosure With Optional Public Health Interest Finding (Attachment B): This document is needed for the Deputy Commissioner (International and Special Programs) to authorize the sharing of non-public information with foreign government officials. In addition, this document is needed where the Deputy Commissioner (International and Special Programs) determines that sharing confidential commercial information without sponsor authorization is in the interest of public health.

C. Sponsor Authorization (Attachment E): Written authorization to disclose specific confidential commercial and/or trade secret information must be obtained from the sponsor in each instance. The sole exception for confidential commercial information is where FDA determines that disclosure of confidential information would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product(s) or information concerning an investigation – see C.F.R. § 20.89(c)(1) (ii) (B) and Attachment B. Trade secret information may NOT be shared without sponsor authorization.

D. Visitor's Commitment (Attachment D): This document is needed when foreign government officials visit FDA and will either have access to non-

public information (i.e., during a placement), or non-public information will or may will be shared while visiting FDA.

8. REFERENCES

The following references are relevant to this SMG:

A. 21 C.F.R. § 10.115 (Good guidance practices).

B. 21 C.F.R. § 20.61 (Trade secrets and commercial or financial information which is privileged or confidential).

C. 21 C.F.R. § 20.62 (Inter- or intra-agency memoranda or letters).

D. 21 C.F.R. § 20.63 (Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy).

E. 21 C.F.R. § 20.64 (Records or information compiled for law enforcement purposes).

F. 21 C.F.R. § 20.89 (Communications with foreign government officials), as amended, effective May 22, 2000.

G. 21 C.F.R. § 20.91 (Use of data or information for administrative or court enforcement action).

H. 21 C.F.R. § 20.101 (Administrative enforcement records).

I. Preambles to 21 C.F.R. § 20.89 found at 58 FR 61598 (November 19, 1993), 60 FR 63372 (December 8, 1995)15, 63 FR 40069 (July 27, 1998), and 65 FR 11881 (March 7, 2000).

J. Sec. 301(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(j).

K. A Center/OC Office's procedures, which support or supplement this SMG, on sharing non-public information with a foreign government or international organization.

L. 18 U.S.C. § 1905 (Trade Secrets Act).

M. Staff Manual Guide 1410.24, Disclosure of Official Records and Authorization of Testimony.

N. 21 C.F.R. § 20 Subpart D Exemptions.

9. EFFECTIVE DATE

The effective date of this guide is October 18, 2005.

10. Document History -- SMG 2830.3, Sharing Non-Public Information with Foreign Government Officials

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/18/2005	N/a	Office of International Programs, HF-3	Murray M. Lumpkin, M.D., Deputy Commissioner
Change	03/21/2006	5(A)(2)(a)	Office of International Programs, HF-3	Murray M. Lumpkin, M.D., Deputy Commissioner