SMG 2830.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

AGREEMENTS WITH OTHER GOVERNMENT AGENCIES

ARRANGEMENT WITH FOREIGN GOVERNMENTS: MOUs, CONFIDENTIALITY COMMITTMENTS

FOREIGN MEMORANDUM OF UNDERSTANDING

Transmittal Number 94-25 -- Date: 04/29/1994

1. PURPOSE

This guide establishes areas of responsibility and clearance procedures for the development, formalization,approval and monitoring of Memoranda of Understanding (MOUs) between the Food and Drug Administration (FDA) and foreign government agencies or international organizations.

2. POLICY

It is the policy of the FDA to enter into International MOUs that improve consumer protection; help achieve international harmonization; use collective resources more effectively; eliminate duplication of activities by the participating parties; and provide a mechanism for the cooperative exchange of expertise, assistance, and information to help ensure the safety and quality of covered products. Compliance Policy Guide (CPG), Chapter 56, describes Agency policy for developing and negotiating such agreements with foreign countries and international organizations. FDA considers the development and implementation of MOUs to have high priority. This Staff Manual Guide

and Compliance Policy Guide, Chapter 56, will help assure that the execution of agreements occurs in a timely manner.

3. DEFINITIONS

A. Memorandum of Understanding (MOU), as used herein, means any FDA formal agreement including but not limited to ones on information exchange, mutual recognition agreements, and product certification between FDA and one or more foreign governments or international organizations. An Exchange Of Letters (EOL) follows the same clearance procedures but are not considered a formal MOU.

An MOU may not be used to commit the expenditure of manpower, to transfer funds, or to transfer real or personal property. Agreements calling for these actions are considered Interagency Agreements (see Staff Manual Guide 2810.1).

B. Sponsor, as used herein, means the FDA center or office having predominant responsibility for negotiating the proposed agreement.

C. IAS/OHA means the International Affairs Staff, Office of Health Affairs (HFY-50).

D. OP means the International Policy Staff, Office of the Deputy Commissioner for Policy (HF-23).

E. ORA means the Office of Regulatory Affairs (HFC-1).

F. ORM means the Office of Resource Management, ORA (HFC-10).

G. OGC means the Deputy Chief Counsel for Program Review, Office of the Chief Counsel (GCF-1).

H. OCGM means the Office of Contracts and Grants Management, Office of Management (HFA-500).

4. ADVANCE COORDINATION

Any center or office in FDA may identify the possible need or opportunity for a new MOU or for revision of an existing MOU. Before any sponsor begins substantive discussions about developing an MOU with foreign officials, the sponsor informs ORM its interest in pursuing an MOU, along with an explanation of how the MOU is consistent with the agency's criteria (see Attachment A of CPG, Chapter 56). ORM will then consult with other affected units in ORA, IAS/OHA, and OP to allow these offices to determine whether initiation of the MOU would be consistent with the agency's international

policy. IAS/OHA will also determine whether additional coordination and reporting are required with the U.S. Department of State (DOS), other agencies, or foreign embassies.

5. AREAS OF RESPONSIBILITY

Attachment D sets forth the steps in the processing of MOUs and details the responsibilities of agency components:

a. Sponsor

1. The sponsor conducts preliminary discussions with foreign officials on the need for an MOU and makes a preliminary assessment on whether a proposed MOU is consistent with agency criteria (see Attachment A to CPG, Chapter 56). If the sponsor believes that MOU discussions should be pursued, the sponsor contacts ORM and provides its assessment on the viability of ORM will assure that all necessary intra-agency coordination is accomplished. (Step 1)

2. Any interested agency unit will inform the sponsor of possible concerns with the MOU. After receiving agency clearance to initiate discussions concerning the MOU, the sponsor makes contact with the foreign party to initiate discussions toward development of the MOU. Discussions should establish whether the foreign party has the technical and administrative infrastructure necessary to carry out its proposed responsibilities under the MOU. If the MOU is to be a mutual recognition agreement, the MOU discussions should determine whether the relevant foreign program is equivalent to FDA's counterpart program. A preliminary draft MOU is developed. (Step 6)

3. If there is to be an informal trial of the MOU, the sponsor describes the design, conduct, and evaluation of the informal trial; whether there are other units in FDA from whom concurrence should be obtained before initiating the trial; and how to assess the completed trial's degree of success. (Step 7)

4. The director of the sponsoring unit sends a written request to ORM for clearance of the draft MOU prior to commencing final discussions with the other party. (Step 8)

5. After reviewing comments from ORM, the sponsor makes revisions as needed.

    a. If minor changes were made, the sponsor clears them with the foreign party, prepares two or more copies of the MOU for

signature, drafts a transmittal letter to the State Department, and submits all to ORM for coordination with IAS/OHA. (Step 12)

b. If major changes were made to the document during this review, the sponsor returns the draft MOU to ORM for review and clearance (repeats steps 9, 10, and 11).

6. The sponsor performs an assessment of each MOU at least once in the five year period of the agreement. The sponsor initiates appropriate action for continuation, modification, or cancellation of the MOU based on information obtained through these assessments. If the MOU is to be terminated, the sponsor sends a memorandum to this effect to ORM at least two months prior to the termination date. If the MOU is to be continued or modified, the sponsor sends a memorandum to this effect to ORM, together with a copy of the MOU.

b. Office of Regulatory Affairs

Office of Resource Management (HFC-10) (ORM)

1. ORM informs IAS/OHA, OP, and other ORA units that would be involved in implementing the MOU, to ascertain if there is any objection to the proposed MOU. Also ORM, in conjunction with other agency components, reviews each proposed MOU for consistency with agency priorities. (Step

2. If no problems are identified, ORM informs the sponsor to proceed. (Step 5)

3. ORM clears all MOUs through OP, IAS/OHA, OGC, OCGM, other ORA components and other appropriate Offices and Centers. (Step 9)

4. ORM assembles comments on draft MOU and submits them to the sponsor for final negotiation with the foreign party, or for rewrite and reclearance. (Step 11)

5. ORM sends MOUs and draft transmittal letters to IAS so that Circular 175 clearance through the DOS can be initiated. (Step 13)

6. ORM sends original signed MOU to the OCGM for control number and as the repository copy. (Step 16)

7. ORM distributes signed MOU with control number as follows (Step 18):

   a. sponsor;

b. Regulations Policy and Management Staff (HF-26) for publication in the **Federal Register**;

c. Division of Compliance Policy (HFC-230) for publication in the **Compliance Policy Guide Manual**; and

d. Offices that had reviewed the MOU and all other appropriate units.

8. ORM maintains, updates and distributes, at least quarterly, a listing of MOUs in process and any Exchange of Letters in effect or in process, with status information.

9. ORM notifies sponsors when it is time to evaluate an existing MOU to determine if it should be continued, modified, or canceled.

10. If a MOU is to be terminated, ORM notifies IAS for coordination with the DOS and others, as appropriate, prior to communications with the foreign government.

c. Office of Policy (OP) (HF-23)

1. Before substantive discussions begin on developing an MOU, OP helps determine if an MOU is consistent with the agency's international priorities and agency policy objectives. (Step 3)

2. OP reviews draft/final MOU and submits comments to ORM. OP receives a copy of Circular 175 clearance package prepared by IAS and, if it has comments, submits them to IAS/OHA. (Step 10).

3. OP, through the Regulations Policy and Management Staff (HF-26), publishes the MOU in the Federal Register. (Step 19).

d. Office of Health Affairs

International Affairs Staff (HFY-50)

1. Before substantive discussions begin on developing MOU, IAS/OHA helps determine if an MOU is consistent with the agency's priorities and international affairs activities. (Step 3)

2. IAS/OHA provides notification to the DOS, foreign embassies, or other U.S. government agencies prior to initiating discussions, as necessary. (Step 4).

3. IAS/OHA reviews draft/final MOUs and submits comments to ORM. (Step 10)

4. IAS/OHA coordinates Circular 175 clearance (this refers to a December 13, 1955, DOS Circular which provides guidelines on negotiations and signature of treaties and other international agreements including MOUs. The actual procedures to obtain this clearance are codified in Volume 11 of the DOS Foreign Manual, Chapter 700.) with the DOS through the PHS Office of International Health and the Office of International Affairs, OS, DHHS, before a foreign MOU may be signed. At the time IAS/OHA sends a copy of the Circular 175 clearance package to the PHS Office of International Health, IAS/OHA will send a copy of the package to OP. (Step 14)

5. After receiving approval from the DOS, IAS/OHA forwards the transmittal letter to the other party notifying it that FDA is now ready to conclude the agreement, arranges for signing of MOU either singly or in a joint ceremony, and sends signed original MOU to ORM. (Step 15)

6. IAS/OHA coordinates with the DOS and others, as appropriate, if an MOU is to be terminated.

e. Office of Chief Counsel (GCF-1)

The Deputy Chief Counsel for Program Review or designee reviews the draft MOU for legal sufficiency and returns the draft MOU with concurrence or comments to ORM. If, after such clearance, significant changes are made in an MOU, reclearance with the Deputy Chief Counsel for Program Review is necessary. (Step 10)

f. Office of Management

Office of Contracts and Grants Management (HFA-500)

1. OCGM reviews draft/final MOUs and submits comments to ORM. (Step 10)

2. OCGM assigns a control number to the MOU after signature by all parties and sends copy of MOU to ORM. (Step 17)

3. OCGM serves as the central FDA repository for all original copies of executed MOUs.

4. OCGM maintains a current listing of all executed MOUs.

6. CLEARANCE

All international MOUs shall be reviewed and approved by the appropriate center/offices, ORA, OGC, OCGM, OP, and IAS/OHA prior to final discussions and signature. To facilitate this review process, concurrent clearance is essential. If comments and/or clearances are not received within three weeks, the assumption will be made that the document has concurrence without comments.

A proposed MOU that involves responsibilities of two or more Centers/Offices must have the concurrence of all units involved. The sponsor's documents requesting approval of such MOUs shall indicate that concurrences from other affected Centers/Offices have been obtained.

The format of all MOUs will be in general conformance with the outline in the examples of Attachments A, B and C.

All international MOUs will be signed by the Commissioner or designee.

Staff Manual Guide 2830.1, Attachment A

MEMORANUM OF UNDERSTANDING

BETWEEN THE

(Insert Name of the Participating Party)

AND THE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

I. Purpose: Briefly state the specific purpose of the agreement.

II. Background: Describe why the agreement is needed or the opportunity it provides for international harmonization.

III. Substance of Agreement: Provide a comprehensive description of what is being agreed to and the specific responsibilities of each party.

IV. Name and Address of Participating Parties: Self-explanatory.

V. Liaison Officers:

A. For Participating Party:

Individual's Name:

Title:

Address:

Telephone Number:

B. For the Food and Drug Administration:

Same information as above.

VI. Period of Agreement: This agreement becomes effective upon acceptance by both parties. It may be modified by mutual written consent or terminated by either party upon a thirty-day advance written notice to the other party. The parties agree to evaluate the agreement at least once in a five-year period, at which time either party will have the option of continuing, modifying, or canceling the agreement.

APPROVED AND ACCEPTED FOR THE (Name of Foreign Party)
By

_____
Title

_____
Date

_____

APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION
By

_____
Title

_____
Date

_____

Staff Manual Guide 2830.1, Attachment B

MOU FORMAT-MULTIPLE COMMODITIES MEMORANUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE (Insert Name of the Counterpart Participating Party) (Insert Name of Country) Concerning (Insert Types) Products Exported to the United States of America

I. PURPOSE: A Statement of the purposes of the MOU.

II. DEFINITIONS: Definitions of terms used in the MOU.

III. SUBSTANTIVE OBLIGATIONS: A comprehensive description of what each party agrees to do and the specific responsibilities of each party.

IV. TECHNICAL INFORMATION EXCHANGE: A listing of the types of the sharing of expertise, providing assistance, and exchanging information that will help ensure the quality and safety of the product(s) covered by the MOU.

V. SAMPLE COLLECTION: A listing of references or location of sample schedules that FDA or the foreign government will use when auditing sample product(s) covered by the MOU.

VI. ANALYTICAL METHODOLOGY: A listing of the latest edition of references containing methods FDA will use, or equivalent procedures if agreed to by both parties, to determine the compliance of products(s) covered by the MOU.

VII. PARTICIPATING PARTIES: Name and Address of Participating Parties.

VIII. LIAISON OFFICERS:

A. For Participating Party:

1. In the foreign country: Individual's Name: Title: Address: Telephone Number: FAX Number:

2. At the foreign government's embassy:

   Same as above

B. For the Food and Drug Administration:

   For the sponsoring Center: Same as above

IX. ADMINISTRATIVE PROCEDURES: Brief statements on any ways and means on which the parties have agreed in order to give instruction and guidance for the practical implementation and application of the MOU.

X. PERIOD OF AGREEMENT: This MOU will enter into force upon signature by both parties and will continue for a period of five (5) years. The parties agree to evaluate the MOU sometime during the five-year period. It may be extended or amended by written agreement of the parties. It may be terminated by either party upon 30-days written notice to the other. FOR THE (NAME OF FOREIGN PARTICIPATING FOR THE FOOD AND DRUG ADMINISTRATION PARTY) OF (INSERT NAME OF COUNTRY) OF THE UNITED STATES OF AMERICA.

By _____ By_____

Title _____ Title_____

Date _____ Date_____

ATTACHMENT TO MULTIPLE COMMODITIES MOU.

I. COMMODITY (Insert Name of Commodity)

II. DEFINITIONS Definitions of terms used only in the attachment.

III. SAMPLING SCHEDULE List the number of subs (and the weight of each sub) per lot that should be collected for each type of audit analysis.

IV. ANALYTICAL METHODOLOGY Cite the specific procedures that are to be used to analyze audit samples for each specified attribute. If necessary, include sample preparation guidelines.

V. CRITERIA FOR CERTIFICATION List the criteria, by attribute, that should be used by the participating foreign party and will be used by FDA to determine if the commodity complies with the laws enforced by FDA.

VI. EFFECTIVE DATE The provisions of this attachment to the Memorandum of Understanding will become effective (insert number) days after this attachment has been accepted by the (insert name of participating foreign party) and the Food and Drug Administration as indicated below: FOR THE (NAME OF FOREIGN PARTICIPATING FOR THE FOOD AND DRUG ADMINISTRATION PARTY) OF (INSERT NAME OF COUNTRY).

Name _____ Name_____

Title _____ Title_____

Acceptance Date _____ Acceptance Date_____

Effective Date _____ Effective Date_____

Staff Manual Guide 2830.1, Attachment C

_____
_____
_____

Dear _____:

The U.S. Food and Drug Administration (FDA) is pleased to cooperate with your government in facilitating the rapid exchange of documents and information, including Good Manufacturing Practice (GMP) inspectional information pertaining to medical devices.

Upon request from (**FOREIGN GOVERNMENT**), the Center for _____, FDA will furnish the purged (proprietary information removed) copies of medical device GMP Establishment Inspection Reports (EIRs) of the U.S. manufacturers that export to (**FOREIGN GOVERNMENT**), pursuant to Title 21, Code of Federal Regulations, Section 20.89. This regulation governs FDA's communications with foreign governments under the Freedom of Information Act. A copy is enclosed for your information.

Further, FDA will be receptive to (**FOREIGN GOVERNMENT**) request to observe inspections of medical device manufacturers in the United States, when consent is provided by the manufacturers. This will provide opportunities for the comparison of inspection and reporting techniques.

The FDA will also provide, upon request, Device Experience Network reports, e.g. reports required of manufacturers on device failures/malfunction by the Medical Device Reporting Regulations.

When FDA discovers, during the course of inspection activities, or through other means, particular circumstances whereby a medical device presents an imminent and serious danger to the public, FDA will communicate its findings to the (**FOREIGN GOVERNMENT**) in accordance with Title 21, Code of Federal Regulations, Section 20.89. To help ensure that this information exchange initiative works well and meets our needs, we feel that it is important that, at appropriate intervals, and by mutual concurrence, a discussion or meeting take place to assess the activities outlined in this letter.

The FDA contact for these activities is as follows:

Name:
Title:
Address:
Telephone Number:
FAX Number:

This information exchange initiative should lay the ground work for the development of common administrative practices that could lead to the mutual recognition of inspectional findings of our respective investigators.

FDA will be glad to work with your government in exploring means which will lead to further cooperation, such as a Memorandum of Understanding in the medical device area. We look forward to receiving your response.

Sincerely yours,

_____
_____

Enclosure

_____
_____
_____

U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20785

Dear _____:

This letter reflects the establishment of a mechanism for facilitating the mutual exchange of medical device Good Manufacturing Practice (GMP) inspectional information, between (**FOREIGN GOVERNMENT**) and the U. S. Food and Drug Administration (FDA).

The (**FOREIGN GOVERNMENT**) endorses the mutual exchange of medical device GMP inspectional information between our two nations. In a spirit of co-operation, and on behalf of the (**FOREIGN GOVERNMENT**), I agree herewith as follows:

1. Upon request from the FDA, the (**FOREIGN GOVERNMENT**) will furnish copies of medical device GMP establishment inspection reports of (**FOREIGN GOVERNMENT**) manufacturers that export to USA. The (**FOREIGN GOVERNMENT**) will also provide, upon request, information obtained under (**FOREIGN GOVERNMENT'S**) medical device problem reporting scheme.

2. Information shall be provided to the extent that (**FOREIGN GOVERNMENT**) law permits and on the understanding that it will be treated as confidential for intra-agency use only. Such information will not

extend to financial and commercial matters, research matters, proprietary design matters, technical know how" or personal data other than those relating to the duties of the persons concerned, except where this kind of information is necessary to assess compliance with applicable quality assurance requirements.

3. Joint inspections of medical device manufacturers may be conducted in (**FOREIGN GOVERNMENT**) and the United States, provided the manufacturers so consent. This will allow opportunities for comparing inspection and reporting techniques, for exchanging inspection experience and for developing common administrative practices that would enable the mutual recognition of inspectional findings of our respective auditors and investigators.

4. When the (**FOREIGN GOVERNMENT**) discovers during the course of its inspectional activities, or through other means, particular circumstances which cause a medical device to be of imminent and serious danger to the public, it will immediately communicate its finding to the FDA.

5. At appropriate intervals, and by mutual agreement, the (**FOREIGN GOVERNMENT**) will arrange for meetings between its auditors, technical experts and management and those of the FDA for the purpose of reviewing the progress made through implementation of this information exchange.

6. Liaison officers for the purpose of coordinating these provisions are as follows:

   A. For FDA: Name: Title: Address: Telephone Number: Fax Number:

   B. For Foreign Country: Name: Title: Address: Telephone Number: Fax Number:

I am confident that the implementation of these provisions on a reciprocal basis will provide a sound basis upon which we may plan, program and build, in partnership, better health protection for our two nations.

Yours Sincerely,

_____
_____
_____

Staff Manual Guide 2830.1, Attachment D

STAGES	STEPS	FUNCTIONS	RESPONSIBILITIES*
	10	Comment and concur/nonconcur to ORM.	OP, IAS, GC, OCGM, ORA
	11	Comments to sponsor.	ORM
	12	Coordinate revisions with foreign party & final MOU or reclear to ORM. Prepare draft transmittal letter.	Sponsor
	13	Final document to IAS.	ORM
	14	Clear with State Department through PHS/OIM and HHS/OIA.	IAS
SIGNATURE	15	Make signature arrangement & send transmittal.	IAS, Sponsor
		Signing at ceremony or sequential routing. Signed MOU sent to ORM.	IAS, Sponsor
	16	Signed MOU sent to OCGM.	ORM
IMPLEMENT	17	Assign control number, list, & file original.	OCGM/OH
	18 & 19	Prepare CPG and Notice of Availablility for F.R.	ORM, OP/Regulations Staff
EVALUATE		Decide to continue, revise, or terminate.	Sponsor, ORA, OP, IAS
		Prepare decision letter with input of ORA and IAS. (Decisions to be reviewed by OP.)	Sponsor, ORA to coordinate, OP, IAS

*First office listed has the lead for coordinating the function.

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