[Docket No. 94D–0123]

International Memoranda of Understanding; New Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a new Compliance Policy Guide (CPG) 7150.19 entitled ''International Memoranda of Understanding.'' The text of the CPG is published in this document. The guide sets forth policy for initiating, developing, and monitoring agreements such as memoranda of understanding (MOU's) between FDA and foreign governments.

ADDRESSES: CPG 7150.19 is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Richard M. Garwood, Office of Regulatory Affairs (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2175.

SUPPLEMENTARY INFORMATION: The FDA International Harmonization Task Force recommended in December 1992 that guidance be developed that describes the agency's objectives, and promotes uniformity, in developing MOU's with foreign government agencies or with international organizations. MOU's enhance FDA's ability to carry out its mission and promote harmonization of laws and regulations, compliance activities, and enforcement actions. Harmonization facilitates the efficient and effective execution of FDA's programs and promotes international trade.

It is the policy of FDA to pursue the development of MOU's that will further the agency's domestic public health mission. MOU's between FDA and an agency of a foreign government or an international organization should be designed to:

(1) Enhance FDA's ability to ensure that regulated products are safe, effective, of good quality, and properly labeled;

(2) Allow FDA to utilize its resources more effectively or efficiently, without compromising its ability to carry out its responsibilities; and

(3) Improve communications between FDA and foreign officials concerning FDA-regulated products.

This policy is detailed in the new CPG 7150.19, entitled ''International Memoranda of Understanding,'' the text of which is provided below. FDA MOU's are negotiated in accordance with the Department of State's Circular 175 procedures.

In order to facilitate future reorganization of the CPG manual system, the entire contents of CPG 7150.19 will be duplicated, assigned a second number, 7156.00, and carried in a second location in the CPG manual system. This fact will be cross-referenced and notated in the CPG manual system.

The text of CPG 7150.19 entitled ''International Memoranda of Understanding'' follows:

Compliance Policy Guide, Food and Drug Administration, International Memoranda of Understanding

SUBJECT:

This guide sets forth policy for initiating, developing, and monitoring agreements such as memoranda of understanding (MOU's) between the Food and Drug Administration (FDA) and foreign governments. The general principles herein may also be applicable to MOU's with international organizations.

BACKGROUND:

The FDA International Harmonization Task Force recommended in December 1992 that guidance be developed that describes the agency's objectives and promotes uniformity in developing MOU's with foreign government agencies. MOU's promote harmonization of laws, regulations, and enforcement activities. Further, MOU's, if negotiated and implemented properly, enhance FDA's ability to carry out its mission. Attachment A to this Compliance Policy Guide (CPG) sets forth the agency's criteria for setting priorities for international MOU's.

The three categories of MOU's described in the following paragraphs are merely examples. These categories are not mutually exclusive, and the concepts may be altered or combined as necessary. Because officials of sovereign nations have different approaches to regulation, FDA needs to maintain flexibility in its discussions with these officials.

Reciprocal Agreements with Countries Having the Same or Similar Systems

MOU's may provide for the mutual assessment of the comparability of specific FDA programs or activities with those of a foreign regulatory authority. These MOU's are similar to mutual recognition agreements (MRA's), referred to in recent trade agreements, and include equivalence agreements. FDA MOU's that provide for the mutual assessment of the comparability of a foreign regulatory system or measure are suitable when it can be determined that FDA's controls and the foreign regulatory authority's controls are comparable and are designed to provide the same level of protection. Under one form of such agreements, mutual acceptance of data and information, such as analytical findings and inspection results, may ordinarily be considered adequate for regulatory decisions. The MOU's now in place for the exchange of results of good manufacturing practices and good laboratory practices inspections are examples. Under another form of such agreements, FDA and another country may agree that their regulatory systems governing certain products are the same or similar and are designed to provide the needed level of protection, enabling each country to consider reducing the rate of inspection or sampling of imports from the other country that would otherwise be necessary.

Certification of Import/Exports

MOU's may establish certification criteria for products regulated by FDA. Historically, these MOU's have concerned products exported to the United States with inherent or consistent quality or safety problems. However, they may also involve products with a good compliance history (see Attachment A of this CPG). They may identify controls to be employed by the exporting country to assure the validity and reliability of certification. Such agreements should be designed with the intent of reducing the FDA rate of inspection or sampling that would otherwise be necessary and with the intent of providing a basis for assurance that the consumer protection objectives of FDA are being met. Certification may be shown by marks on the product, container, or entry documents or by other paper or electronic communication. An MOU based on the controls to be employed and maintained by the exporting country to ensure that articles exported comply with FDA laws and regulations may render such certifying marks, documents, or other communication unnecessary.

Communications

Formalizing communication links facilitates the exchange of technical, scientific, and regulatory information. Technical cooperation leads to better understanding of safety and quality standards for products traded between the United States and other countries and promotes harmonization. Improved communications with foreign officials may improve FDA decisionmaking and reduce resource expenditures for monitoring foreign made products.

POLICY:

It is the policy of FDA to pursue the development of MOU's that will further the agency's public health mission. FDA intends to enter into an MOU only with an agency of a foreign government or an international organization. The MOU should be designed to meet the following goals:

(1) To enhance FDA's ability to ensure that regulated products are safe, effective, of good quality, and properly labeled;

(2) To allow FDA to utilize its resources more effectively or efficiently, without compromising its ability to carry out its responsibilities; and

(3) To improve communications between FDA and foreign officials concerning FDA regulated products.

Further, before accepting the procedures and activities, including enforcement methods, of foreign governments as equivalent to its own, FDA will seek assurance that such activities provide the same level of product quality, safety and efficacy that is provided under the Federal Food, Drug, and Cosmetic Act (the act); the Fair Packaging and Labeling Act; the Public Health Service Act; and any other relevant law of the United States. FDA may find it necessary to confirm by on-site review or other appropriate means that the foreign government agency has the necessary authorities, product standards, capabilities, and infrastructure to successfully achieve the proposed terms of the MOU, and, therefore, that a determination of equivalence can be made. Where appropriate, FDA will publish a proposed equivalence determination for comment.

FDA's criteria for deciding when to initiate consideration of developing MOU's are set forth in Attachment A of this CPG. FDA intends to review and update these criteria periodically.

Affected agency units will review the proposal for a new or revised MOU for consistency with the agency's international policy objectives and priorities before an FDA component begins substantive discussions with foreign officials about the MOU.

FDA auditing may be necessary to assure that the circumstances supporting the basis for an agreement continue to exist, whether or not the foreign government intends to conduct audits. The liaison office identified in the MOU is responsible for preparing a written evaluation. Participating FDA components will be queried by the responsible liaison office as to the overall effectiveness of the agreement, whether provisions should be added or deleted, and whether the MOU should be terminated.

Countersigned agreements are commonly referred to by FDA as ''Memoranda of Understanding.'' However, some foreign governments have requested that such documents be titled as ''Notes Verbale,'' ''Arrangements,'' or ''Mutual Recognition Agreements.'' Regardless of title, such agreements will be filed in chapter 56 of the Compliance Policy Guides Manual, and a notice of availability will be published in the **Federal Register**.

An ''exchange of letters'' should be used in lieu of a formal agreement when the actions contemplated require only a limited resource expenditure and do not rise to the significance of a formal agreement. For example, an exchange of letters could formalize an understanding that each agency will provide the other with documents that are available upon request to any member of the public. Each letter should set out only the actions to be carried out by the agency signing the letter and not mutual considerations. Clearance of exchange of letters will be by the same process as used for MOU's except that, after clearance, the FDA letter may be signed by the appropriate Center or Office Director. Copies of the letters exchanged should be placed in the cooperative agreements portion of the Compliance Policy Guide Manual.

FDA's practice is to enter into MOU's for a period of 5 years. Each existing MOU should be evaluated at least once during the 5 year period of the agreement to determine whether the MOU should be modified, continued, or canceled. As part of the evaluation of an MOU, the agency may conduct independent or joint inspections or analyze imported products to evaluate the effectiveness of the MOU.

DEVELOPMENT GUIDANCE:

Developing an MOU with a foreign government requires coordination between the sponsoring center or office, the Office of Regulatory Affairs (ORA), the International Affairs Staff/Office of Health Affairs (IAS/OHA), and the Office of Policy (OP). Generally, there are three phases in the process as described below:

Stage I—Exploring Feasibility

a. The sponsoring Center or Office makes a preliminary assessment whether the proposed MOU is in line with FDA policy goals. If the sponsoring Center or Office believes that the MOU should be pursued, the Center or Office informs ORA (HFC–10) in writing and explain why it believes that the MOU should be pursued.

b. The initiating agency component provides a general description of the agreement it wishes to develop, e.g., mutual recognition of a quality assurance program, product certification, information exchange, etc.

c. The parties exchange information on laws, standards, and other requirements for subject products, inspection and sampling abilities, and analytical methodology, as appropriate.

d. On-site review of facilities, operations, and controls may be arranged.

e. If the foreign government appears not to be, and in FDA's opinion is not, capable of developing an adequate infrastructure to carry out the intended program, the sponsoring agency component will explain FDA's position in writing and suspend further action until FDA's concerns are adequately addressed. The letter addressing this issue should be reviewed by OP and IAS/OHA.

Stage II—Determining Effectiveness

a. If discussions are to continue, IAS/OHA should be notified so that appropriate notification to the Department of State (DOS) can be made.

b. The parties may consider an informal trial to gain confidence in the planned agreement. A draft MOU may be prepared along with a protocol that may provide a basis for the trial. Together these documents may include:

(1) A complete description of the trial program.

(2) Information regarding roles and capabilities of involved government and private organizations.

(3) Certificate issuance and use procedure, if any.

(4) Audit frequency and measures to be applied.

(5) Description of training or information needs.

c. Whether or not there is a trial, FDA may conduct as appropriate independent or joint inspections with the foreign government, or analyze imported products to evaluate the effectiveness of the program.

Stage III—Finalizing an MOU

a. The MOU should be prepared for clearance after the substance of the MOU has been finalized, including after rulemaking, where appropriate.

b. If appropriate, instructions for auditing the agreement should be issued to field offices by the sponsoring center or office, through ORA.

Attachment A

Food and Drug Administration Criteria for Memoranda of Understanding

In deciding whether to begin discussions that could lead to the development of an MOU, an agency component should consider the factors that are listed below.

Health Benefits (Including Risk Reduction) Associated With Products or Programs

FDA should consider the benefits to public health (particularly for the United States population) when it sets priorities for its international activities.

Products Imported into the United States

FDA should place a higher priority on international activities that are directed toward improving the quality, safety, or efficacy of products offered to consumers in the United States. For example, FDA should give a low priority to investing resources in developing a memorandum of understanding with a foreign country that covers a product where there is little likelihood of significant exports to the United States or significant risk to the public.

History of Compliance Problems

FDA should place a higher priority on international activities directed toward remedying product defects that have been demonstrated to be previous compliance problems or where there is a demonstrated scientific basis for increased surveillance.

Comparative Costs of Alternative Programs

FDA should pursue international programs and activities that provide the greatest benefit in relation to the resources required to administer them. For example, the costs of developing, implementing, and monitoring an agreement should be weighed against the costs of higher sampling levels to obtain the same degree of confidence in rates of compliance in the absence of an agreement.

Regulatory Burden on Industry

FDA should consider the regulatory burden on industry that could be diminished by harmonization efforts. However, these activities need to be compatible with FDA's primary public health mission, the act, and other laws and regulations that FDA enforces.

U.S. Foreign Policy Objectives and Priorities of Other U.S. Government Agencies

FDA should be knowledgeable of U.S. foreign policy objectives and international programs and policies of other U.S. Government agencies and appropriately

balance these interests with those of FDA's primary mission.

The statements made herein are not intended to bind the courts, the public, or FDA, or to create or confer any rights, privileges, immunities, or benefits on or for any private person, but are intended merely for internal FDA guidance.

Dated: June 7, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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Health Resources and Services Administration

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects. To request more information on the proposed project, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

1. Study of Physicians' Educational Preparation for Practice in Managed Care Settings—New—A mail survey will be conducted of primary care physicians and medical directors in managed care organizations to assess their views of the adequacy of their preparation for practice in that setting. The survey of physicians will be limited to those who graduated between 1986 and 1990. The information will be used by the Bureau of Health Professions to formulate recommendations for curriculum changes. Because this is a mail survey, automated collection techniques will not be used. Burden estimates are as follows:

	No. of respondents	No. of responses per respondent	Avg. burden/response (in hours)
Physicians	1800	1	.25
Medical directors	200	1	.25

2. Study of the Dissemination of the Maternal and Child Assistance Programs Model Application Form—New—A telephone survey will be conducted of (1) governor's offices in 59 states and territories, (2) the leadership of state-level maternal and child assistance programs in 59 states and territories, and (3) the leadership of local maternal and child assistance programs in 10 carefully selected jurisdictions across the country. The survey will provide data on the effectiveness of the federal dissemination of the maternal and child assistance programs Model Application Form, and on the use and impact of the Model Application Form or other similar consolidated application forms on maternal and child assistance programs and clients. The data collected will inform Members of Congress, which mandated the development and dissemination of the Model Application Form, and state and federal maternal and child assistance program leaders about the effectiveness of the federal dissemination process, the extent of Model Application Form and other consolidated application form implementation, and their impact on agency operations and program clients. Because this is a targeted telephone survey with limited numbers, automated collection techniques will not be used. Burden estimates are as follows:

	No. of respondents	No. of responses per respondent	Avg. burden/response (in hours)
Governors office	59	1	.5
State level officials	236	1	.5
Local level officials	50	1	.5

3. Evaluation of Special Projects of National Significance: Adolescent Focussed Grantees—Under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Special Projects of National Significance are supported to evaluate and disseminate innovative models of care. In order to fulfill the evaluation requirements of the Act, grantees collect, on an ongoing basis, information on numbers of clients served, characteristics of those clients, services provided, and outcomes of those services. The information will be used to identify models of care with promise for national replication and dissemination. Most data are collected by care providers who complete very brief (one page or less) forms to document each client contact, and some data will be collected directly from volunteering care recipients. Burden estimates follow:

	No. of respondents	No. of responses per respondent	Avg. burden/response (in hours)
Care providers (nurses, case managers, counselors)	232	407	2.4 hours (2.8 minutes per form).
Care recipients	495	1	1 hour.