[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.