CPG Sec. 100.950 International Partnership Agreements for Compliance Activities

Sec. 100.950 - International Partnership Agreements for Compliance Activities - Agreements among the USFDA, Foreign Government Agencies, and Foreign or Domestic Trade Associations and/or Other Organizations

INTRODUCTION:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new CPG and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and is available electronically to the public. This guidance document represents the agency's current thinking on establishing its partnership agreements with foreign government agencies and foreign or domestic trade associations and/or other organizations concerning compliance activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

BACKGROUND:

The purpose of this CPG is to set forth guidance for establishing an International Partnership Agreement for Compliance Activities among the United States Food and Drug Administration (FDA) and a foreign government agency(s) and, where necessary and appropriate, additional partners including representatives of international organizations, trade associations, and/or other non-government organizations, institutions, or establishments. An International Partnership Agreement for Compliance Activities is intended to be an agreement of specified duration to accomplish specific import program objectives among the FDA and the partners' organization(s). FDA import program objectives for such agreements should be to increase the compliance rate of certain imported commodities where traditional FDA enforcement approaches have proven insufficient to correct public health problems. The parties will agree to solve problems of mutual concern. The components of the foreign government which have the authority and the ability to regulate the production and/or exportation of the commodity that is the subject of the agreement are necessary partners in the agreement.

An International Partnership Agreement for Compliance Activities is very similar to a Foreign Memorandum of Understanding (MOU) which is covered under Staff Manual Guide (SMG) 2830.1 and CPG 100.900. That is, like an MOU, an International Partnership Agreement for Compliance Activities is an international agreement among FDA and foreign government agencies or international organizations. However, an International Partnership Agreement for Compliance Activities differs from a traditional Foreign MOU because it provides for the inclusion as additional partners, where necessary and appropriate, of non-governmental entities such as consumer groups, trade associations, and academic institutions. Individual regulated entities, however, are not included as partners in this type of agreement. For example, an International Partnership Agreement for Compliance Activities might be appropriate where FDA intends to work with a foreign government, an international organization, and a foreign university to investigate alternative approaches to address a microbiological contaminant in a particular food commodity imported into the U.S. from the foreign government. Because non-governmental entities may be included as partners to International Partnership Agreements for Compliance Activities, these agreements raise unique regulatory, ethical, and fiscal concerns that will be scrutinized very carefully by FDA when it considers such an agreement. For this reason, legal and ethical advice should be sought early on in the process to prevent problems from arising including a perception by the public of favoritism or unfairness as to a particular non-government entity. The coordination of FDA's efforts, resources, and expertise with non-FDA partners having other expertise and resources is expected to result in: An increase of consumer protection; the elimination of duplication of compliance activities; increased levels of industry compliance; the expansion of training opportunities; the promotion of evidence sharing; and improved information sharing and dissemination.

The International Partnership Agreement for Compliance Activities specifies the partners' goals, identifies the measurable outcomes desired, and designates primary responsibility for each aspect of the program or activity.

DEFINITIONS:

Compliance: Conformance to the laws, regulations, policies, and programs enforced by FDA and the foreign government authorities.

Foreign Memorandum of Understanding (MOU): A formal, written document which is executed and implemented in accordance with existing guidance (see SMG 2830.1 and CPG Section 100.900). Foreign MOUs are arrangements with agencies of foreign governments or international organizations. They have not incorporated industry, trade associations, or other non-government organizations, or academia involvement. The distinguishing feature of an International Partnership Agreement for Compliance Activities, as opposed to a Foreign MOU, is its ability to include such involvement.

Transparency: The principle that each partner will: publish and make available its laws, regulations and policies to other partners and other interested parties and individuals, whenever possible and appropriate; maintain a process permitting comment from other partners regarding established and developing requirements; allow adequate time for partners to become acquainted with and to adapt systems to comply with requirements; and identify appropriate contact points responsible for answering reasonable questions from other partners.

OBJECTIVES OF AN INTERNATIONAL PARTNERSHIP AGREEMENT FOR COMPLIANCE ACTIVITIES:

The objectives of an International Partnership Agreement for Compliance Activities are to:

1. Establish an agreed upon course of action for accomplishing specific compliance goals entered into by FDA and the partner(s) in which all partners involved agree to share responsibility in an effort to protect public health and to increase regulatory efficiency;
2. Eliminate duplication of compliance activities thereby utilizing resources more effectively;
3. Raise levels of expertise in conducting regulatory, surveillance, technical assistance, and educational efforts; and
4. Improve communication so that information is exchanged and disseminated among partners in an accurate and efficient manner.

CRITERIA FOR ESTABLISHING AN INTERNATIONAL PARTNERSHIP FOR COMPLIANCE ACTIVITIES:

It is appropriate to enter into an International Partnership for Compliance Activities when:

1. Achieving the goals of the partnership will likely result in enhanced consumer protection with respect to the commodity subject to the agreement where traditional FDA enforcement approaches have proven insufficient to correct public health problems;
2. The foreign government that is the partner provides FDA written evidence (statutes, regulations, etc.) of its authority to carry out the partnership;
3. The government partners have effective systems for monitoring and ensuring compliance by the affected industry;
4. All partners agree to adhere to the principle of transparency with regard to the program or activity that is the subject of the partnership agreement.

PROCESS FOR ESTABLISHING AN INTERNATIONAL PARTNERSHIP AGREEMENT FOR COMPLIANCE ACTIVITIES:

In addition to following the procedures for entering into Foreign MOUs established in SMG 2830.1 and CPG 100.900, the following procedures are to be followed.

Preliminary discussions of the partnership activities are to be carried out between the initiating FDA Office, the appropriate Center if not the initiator, the Office of International Programs, International Agreements Staff, and other appropriate headquarters and affected field personnel. The initiating component of the FDA will consider the information presented at the preliminary meeting(s). If the initiating component of FDA believes that an International Partnership Agreement for Compliance Purposes is the appropriate mechanism to pursue, it will contact the appropriate FDA offices to establish a working team. The Office of Chief Counsel should be consulted at an early enough stage to permit thorough review of the complicated ethical and legal questions involved in partnering with public and private foreign entities.

The team members will be responsible for the drafting and clearing of the agreement from their respective Center/offices.

ELEMENTS OF AN INTERNATIONAL PARTNERSHIP AGREEMENT FOR COMPLIANCE ACTIVITIES:

The Agreement includes:

1. Statement of agreement to establish the partnership;
2. Clear identification of the partnership purpose and goal(s) including - specific time frames - targeted outcomes;
3. Identification of resources to be supplied by each partner to carry out partnership objectives;
4. Detailed description of tasks to be performed and outputs to be achieved by each partner;
5. Mechanism for sharing information amongst partners;
6. If the partners intend to share non-public information, confidentiality provisions consistent with applicable laws, regulations, and guidance, including 21 CFR Part 20.
7. Mechanisms for assessing the partnership performance in meeting the established goals:
    - Interim (time frames)
    - Final (time frames);
8. Conclusion and recommendations:
    - Joint review of activities and accomplishments)
    - Provision for a final report including discussion of results of partnership along with recommendations for follow/up if warranted;
9. Identification of contact persons for each partner;
10. Provision for modifying the terms of the agreement;
11. Provision for terminating the agreement: Five (5) years from the time the partnership is signed by all partners or when the goals of the partnership including joint review and report are

completed; or for any other reason upon 30 days notice to the other partners; and

12. Signatures of responsible partners.

COORDINATION WITH OTHER U.S. AGENCIES:

At an early stage in the discussions, contact should be made with the Office of International Programs, International Agreements Staff to permit them to inform or involve other U.S. Agencies that would be impacted by the partnership. In some cases, concurrence from other U.S. Agencies may be necessary or desirable.

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