SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food And Drug Administration - Interactions With Major International Organizations

GOAL: To assure appropriate U.S. Food and Drug Administration's (FDA or Agency) communication and interactions with major international organizations, including, but not limited to, the World Health Organization (WHO), the Pan American Health Organization (PAHO), and the Food and Agriculture Organization (FAO). More specific SOP's for certain other organizations (e.g., OECD, Codex Alimentarius) may be written to supplement the policies established in this document.

OBJECTIVE: Establish an agency-wide process for how FDA communicates with, participates in, and responds to requests from major international organizations or about major international organizations' matters, to assure information shared best represents the Agency and the Department of Health and Human Services (DHHS or the Department) and is consistent with the Agency's mission, the Department's international agenda, and the overall U.S. government objectives.

FDA and DHHS play a critical role in providing technical support and assistance to many major international organizations. It is imperative that the manner in which the Agency interacts with these major organizations or about these major organizations' matters assures that all information shared or provided represents an Agency/Department position, and that the Agency/Department's senior leadership is afforded the opportunity to consider all requests from these major organizations and matters pertaining to these major organizations.

DEFINITION: In this document, "office" refers generically only to FDA organizational components that are not located within one of the Centers, such as the Office of Regulatory Affairs, the Office of Policy and Planning, or the Office of Science, among others. It does not refer to organizational components designated as "offices" that are located within one of the Centers.

BACKGROUND: FDA receives many types of requests from these major organizations, including:

A. Review or preparation of documents

B. Speakers at organization sponsored workshops, conferences, or events

C. Technical Assistance from an FDA expert designated as a Temporary Advisor or Expert Consultant

D. FDA experts detailed to the organization for a specific period of time on a specific issue

Requests from these organizations may come into FDA from many channels, including:

A. Directly - through the Office of International Programs (OIP)

B. Directly - through informal contacts around the Agency

C. Directly - through Centers designated as "Collaborating Centers" CDRH: CC for Standardization of Protection Against Non-Ionizing Radiation CDRH: CC for Training and General Tasks in Radiation Medicine (listed as "pending redesignation") CFSAN: CC for Food Contamination Monitoring (listed as "pending re-designation") CBER: CC for Biological Standardization (listed as "pending re-designation") JIFSAN is a CC for Risk Assessment in Food Safety

D. Indirectly, by posting general requests on their web site

E. The Department

F. Other US Government entities

RESPONSIBILITIES:

OIP is the Agency's primary coordinator and clearinghouse for all communications with these international organizations - with one exception noted below.

It is OIP's responsibility to work with the appropriate Center or Office to obtain input/clearance, if needed; interface, as appropriate with the Department; and provide the response back to the international organization. In general, responses should only be transmitted from Centers or Offices directly to the international organization in exceptional circumstances or when a specific transmittal procedure for a specific document or set of documents has been agreed in advance by OIP and the appropriate Center or Office.

In general, DHHS' Office of Global Health Affairs (OGHA) is the Department lead on all WHO matters. It will be OIP's responsibility to assure appropriate coordination with OGHA on all WHO issues and other issues with major international organizations, as appropriate and desired by OGHA.

Exception:

"WHO Collaborating Centers" - Interactions with WHO that are specific to these designated relationships will be the Collaborating Center's responsibility to manage, in terms of the scope of collaborative work to be accomplished.

Requests for expert consultants, technical experts, or temporary advisors must still be vetted through the Office of the Commissioner (OC) as indicated

below, even if the consultancy is within the scope of the work defined through the collaborative work.

It will be the responsibility of the Collaborating Center to keep OIP apprised of ongoing activities through these relationships.

POLICIES:

1. All agreements that designate FDA components as "WHO Collaborating Centers" must be submitted through OIP for approval by the Commissioner (or his/her designee).

2. For all types of incoming requests: *(The timelines are contingent on the turnaround time requested by the international organization or the Department. These timelines assume a two-week response time.)*

   a. Regardless of the channel through which a request covered by this SOP arrives at any FDA component, all incoming requests from major international organizations or about major international organizations' matters must be routed to the appropriate Center/Office's international point of contact and OIP's staff point of contact within ***24 hours*** of receipt. This includes both informal exploratory inquiries and formal invitations or requests. The Center/Office will prepare the proposed Center/Office response to a given request and provide the proposed response - cleared through the Center/Office Director -- to OIP for clearance through Office of the Commissioner (OC) and the Department, as appropriate. OIP will make available to all Center/Office international points of contact and on the FDA intranet a list of who the appropriate OIP points of contact are for these purposes.

   b. In general, the Center/Office will have two ***working days*** to provide a proposed response to OIP.

   c. In general, once OIP receives a proposed response from a Centers/Office, OIP will have five ***working days*** to obtain appropriate OC and DHHS review and/or clearances, finalize the response, communicate back to the Center/Office, and provide the response to WHO/FAO, through appropriate channels.

3. Review or Preparation of Documents

   a. Upon receipt by OIP of a document for review or a request for preparation of a document from a major international organization, OIP will assure that the document is immediately distributed electronically to the appropriate Center(s)/Office(s). It will be the responsibility of the Center(s)/Office(s) to assure the document is

distributed within their Center/Office for review by their appropriate Center/Office staff.

b. Each Center/Office will provide OIP, within the time frames requested when the document/request is sent to the Center(s)/Office(s), one set of comments/proposed document that has been cleared by the Center/Office and represents the views of the Center/Office.

c. OIP will review the comments/documents submitted by each participating Center/Office, consolidate the comments, attempt to resolve any conflicting comments, prepare the final response, obtain appropriate OC and DHHS clearances, and transmit the comments/document to the major international organization via appropriate channels.

d. OIP will maintain files of the incoming document/request for document and FDA's final response.

e. Only responses that have gone through this process and received the clearances outlined in this SOP are considered to represent an official expression of FDA opinion or policy on the matter.

f. No FDA employee may submit responses to such requests without going through this process and obtaining the clearances outlined in this SOP, unless: (a) the response is requested directly of that person by the international organization specifically in his/her personal capacity, (b) the response specifically and clearly states that it is submitted in the submitter's personal capacity and does not represent FDA policy or opinion, (c) the submitter uses no non-public information, to which he/she may have access as an FDA employee, as a basis or background for their private capacity submission, and (d) the submitter has on file an approved outside activity form for performing such activity outside government time.

4. Speakers at International Organization Sponsored Workshops, Conferences, or Events; Technical Assistance from an FDA expert designated as a Temporary Advisor or Expert Consultant; or Requests for FDA experts to be detailed to an international organization for a specific period of time on a specific issue

a. After receiving such requests, OIP will consult with the Principal Associate Commissioner, the Deputy Commissioner, and/or the Commissioner of Food and Drugs to first ascertain if the invitation/request is one that the Agency might want to accept. In addition, OIP will ascertain from the requester specific details on proposed financial support, if any, and expected time commitments required of the FDA representative(s) if the invitation were to be accepted.

b. Once a decision has been made to seek further input on the invitation, OlP will send the invitation to the appropriate Center(s)/Office(s) for consideration of possible appropriate nominee(s) to be the FDA representative(s).

c. The Center(s)/Office(s) will provide OIP with their recommended nomination(s). OIP will obtain final choice clearance from OC and DHHS (as appropriate) and notify the requesting organization of the Agency's decision.

d. In the case of individuals serving as a Temporary Advisor, Expert Consultant, or providing Technical Assistance: Although the Agency has approved an individual's designation as a temporary advisor or designated expert through the general process outlined above, all future interactions with a major intentional organization regarding his/her participation in that capacity must be approved by her/his Center/Office leadership and cleared through OC via OIP.

e. Only representatives that have gone through this process and received the clearances outlined in this SOP are considered to be official FDA representatives for these purposes.

f. DHHS and FDA ethical/financial policies govern FDA official participation in such activities.

g. No FDA employee may participate as an official FDA representative in response to such requests without going through the process and obtaining the clearances outlined in this SOP. An FDA employee may participate in such activities as a private citizen if. (a) the participation is requested directly of that person by the international organization specifically in his/her personal capacity, (b) the participant, specifically and clearly states that s/he is participating in his/her personal capacity and that the participant is does not represent FDA and is not necessarily expressing FDA policy or opinion, (c) the participant uses no non-public information, to which s/he may have access as an FDA employee, as a basis or background for his/her private capacity participation, (d) the participant is using no government funds or government time to participate, and (e) the participant has on file an approved outside activity form for performing such activity outside government time.

J Concur Nonconcur

Murray M. Lumpkin, M.D. Principal Associate Commissioner

5-15-03
Date

Concur Non-concur

Mark B. McClellan, M.D., Ph.D. Commissioner
Food and Drugs

Date

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