

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF INTERNATIONAL PROGRAMS

Effective Date: 07/08/2011

1. OFFICE OF INTERNATIONAL PROGRAMS (DLLA).

- A. Leads the formation of global alliances and global information sharing among regulators, in order to improve product quality and safety
- B. Serves as the Agency leader and focal point for all international matters
- C. Serves as the primary agency liaison with other U.S. Government components (involved in international issues), international multinational organizations and foreign governments (including Washington, DC embassies) for policy formulation and execution impacting FDA and FDA regulated products
- D. Provides leadership to agency program areas for international activities
- E. Serves as the focal point for the agency and the final clearing authority for policies and procedures pertaining to international travel
- F. Serves as the agency focal point for international programs and interactions (including meetings at FDA or abroad) with foreign counterpart regulatory agencies, international organizations, foreign embassies, all foreign officials, and with HHS and all other USG components when international issues are involved
- G. Directs, manages, and leads agency strategic planning, priority-setting and resource allocation processes for FDA international programs
- H. Serves as the agency focal point and final clearing authority for trade issues involving e.g., North American Free Trade Agreement (NAFTA), World Trade Organization (WTO), Free Trade Area of the Americas (FTAA), Asia Pacific Economic Cooperation (APEC), and United States Trade Representative (USTR)
- I. Serves as the agency focal point and final clearing authority for formal arrangements with foreign governments e.g., memoranda of understanding (MOU), mutual recognition agreements (MRAs), exchange of letters,

partnerships, equivalence issues, country assessments, and confidentiality commitments

- J. Serves as the agency focal point and is the agency final clearing authority on policies and procedures for sharing public and non-public information with international counterpart agencies, and, in conjunction with the Office of Regulatory Affairs, import/export policy issues
- K. Manages the agency's foreign offices, including FDA staff deployed in foreign locations and all related budgeting, strategic planning, priority setting and resource allocation

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services, effective July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/23/2007	N/a	OC/OO/ OM/OMP	Secretary of the Department of Health and Human Services
Revision	01/13/2009	N/a	OC/OO/ OM/OMP	Commissioner of the Food and Drug Administration
Revision	08/07/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Secretary of the Department of Health and Human Services
Revision	07/08/2011	renumbered from SMG 1115.1	OO/OM	Secretary of Health and Human Services

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The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of International Programs organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF INTERNATIONAL PROGRAMS