SMG 1252.9

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF COMPLIANCE

DIVISION OF INTERNATIONAL COMPLIANCE OPERATIONS

Effective Date: 09/03/2013

1. DIVISION OF INTERNATIONAL COMPLIANCE OPERATIONS (DKKWBG)

A. Develop, coordinate, review, and revise new and amended regulations including Current Good Manufacturing Practices requirements in the Quality System regulation for foreign manufacturers of medical devices.

B. Develop and implement programs to ensure uniform interpretation and application of the Quality System regulation to ensure that medical devices offered for import will be safe and effective and in compliance with the Food, Drug, and Cosmetic Act.

C. Plan, initiate, and coordinate medical device inspections of foreign manufacturers and their products.

D. Enforce the Current Good Manufacturing Practices requirements in the Quality System regulation as they apply to foreign manufacturers of medical devices. Manages and coordinates activities associated with administrative and regulatory actions.

E. Implement, coordinate, and effect actions for medical device manufacturers, distributors, and importers, based on the import and export requirements in the Food, Drug, and Cosmetic Act, in addition to all Agency policies.

F. Issue certificates for requests to export approved medical devices and non-approved medical devices under 801(e) of the Federal Food, Drug, and Cosmetic Act.

G. Jointly leverage international regulatory resources to develop, manage, and oversee a predictable, efficient, effective, innovative, and sustainable international medical device single audit program that allows a single regulatory

audit to satisfy the needs of multiple regulatory jurisdictions; and, instills confidence amongst regulators and stakeholders in program outcomes.

H. Identify the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by foreign manufacturers.

I. Develop, interpret, and issue policy guidance in response to specific requests from the foreign medical device industry, trade associations, other Federal agencies, other countries, State agencies, and the general public.

J. Collaborate with other Center for Devices and Radiological Health (CDRH) Offices, Centers, and Food and Drug Administration (FDA) Offices in developing and implementing Memorandum of Understanding (MOU) and cooperation agreements with foreign governments.

K. Manage a system by which one audit of a quality management system satisfies the needs of multiple regulatory jurisdictions allowing FDA to effectively focus its limited field resources on the most significant public health needs.

L. Accredit and conduct witness audits; head office audits; and critical location audits of internal and third party auditing entities and auditors to ensure effectiveness and compliance with appropriate standards (e.g. ISO 17021, 19011, etc.).

M. Assess the quality of the results of all audits conducted under the single audit program to determine compliance with applicable standards and regulations (e.g. ISO 17021, GD 211, 21 CFR 820, 21 CFR 803, etc.).

N. Establish and maintain a compliance program for the auditing of accredited third party entities describing the audit process and acceptable and unacceptable results; as well as the mechanism by which accreditation will be maintained or revoked.

O. Provide assessment results and feedback necessary to maintain an effective auditing network including periodic meetings of representatives of the auditing entities to discuss the program’s effectiveness; changes in the program; and program improvements.

P. Maintain standardized training program to train and accredit FDA and third party auditing cadres.

Q. Develop the Information Technology (IT) infrastructure necessary to support a system by which one audit of a quality management system satisfies the needs of multiple regulatory jurisdictions.

R. Develop jointly with other regulatory bodies (e.g. Health Canada) the training necessary to train auditors and auditor entities in the single audit process requirements.

2. FOREIGN ENFORCEMENT BRANCH (DKKWBG1)

A. Serve as the Compliance Branch for all international quality system inspections, and oversee international device quality and enforcement of adulteration provisions of the FD&C Act.

B. Act as CDRH's lead on international device quality enforcement strategy, and serve as a liaison between other Office components, Center components, and Office of Regulatory Affairs (ORA).

C. Issue inspection requests and assignments that specify the inspectional emphasis and expertise needed to assure agency effectiveness.

D. Prepare and identify gaps, set regulatory expectations for industry in the area of international quality and develop proactive strategies to reduce risk.

E. Manage the compliance cases for international facilities, including evaluating and monitoring corrective actions.

F. Prepare and monitor responses to Agency and Center inquiries from foreign regulatory authorities.

G. Collaborate with other Office components in implementing MOU and cooperation agreements with foreign governments.

H. Assist in the identification of strategic partnerships with foreign regulatory authorities.

I. Identify, modify, or develop FDA/United States (US) policy regarding medical device compliance activities.

J. Identify and develop mechanisms for intra and inter center communication regarding international medical device compliance issues.

K. Review and identify relevant international standards to develop appropriate intra, inter and extra center engagement mechanisms.

3. IMPORTS BRANCH (DKKWBG2)

A. Establish and implement CDRH import procedures and policies consistent with the direction of the FDA Import Safety Action Plan.

B. Update and revise import alerts/draft import alerts.

C. Review labeling to support compliance actions, develop import bulletins, and import alert recommendation.

D. Provide guidance on import questions/issues from CDRH counterparts, field offices and stakeholders (Congress, media, agencies and the public).

E. Develop import strategies, guidance and policies.

F. Providing training and outreach information to FDA personnel and industry on import policy and regulations.

G. Prepare compassionate use responses and recommendations.

H. Prepares issue or position papers and guidance, identifies relevant data or develops data requirements; preparing status reports.

I. Answer Industry inquiries regarding status of their requests, assistance with submissions and invoices.

J. Respond to Freedom of Information requests.

K. Respond to authentication request from Foreign Ministries of Health.

4. EXPORTS BRANCH (DKKWBG3)

A. Provide guidance on export questions/issues from CDRH counterparts, field offices and stakeholders (Congress, media, agencies and the public).

B. Develop export strategies, guidance and policies.

C. Providing training and outreach information to FDA personnel and industry on export policy and regulations.

D. Prepares issue or position papers and guidance, identifies relevant data or develops data requirements; preparing status reports.

E. Provide technical and regulatory assistance to Centers, Divisions, Districts, and Industry, addressing questions or concerns relating to the exporting of medical devices; Interpret provisions of the FD&C Act and 21 CFR Parts 800 to 1299.

F. Receive, track, review requests for export certificates.

G. Review and research the compliance status, recalls, and registration & listing statuses of each certificate request submitted; issue export certificates to Industry.

H. Answer Industry inquiries regarding status of their requests, assistance with submissions and invoices.

I. Manage the Export Program.

J. Process export permit request [Section 801(e)(2)] for unapproved products that does not meet the requirements under Section 802.

K. Manage and perform quality assurance checks to review and approve/deny requests for export certificates.

L. Respond to Freedom of Information requests.

M. Respond to authentication request from Foreign Ministries of Health.

N. Serve as CDRH representative on the Agency Export Certificate Working Group.

O. Develop and create policies and procedures in the processing of export requests.

5. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Heath on September 3, 2013.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE
DIVISION OF INTERNATIONAL COMPLIANCE OPERATIONS

OFFICE OF THE DIRECTOR

Foreign Enforcement Branch
Imports Branch
Exports Branch

Staff Manual Guide 1252.9
Organizations and Functions
Effective Date: September 3, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Compliance, Division of International Compliance Operations organization chart depicting its organizational structure.

OFFICE OF THE DIRECTOR:

- Foreign Enforcement Branch
- Imports Branch
- Exports Branch