Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

Joseph Tartal, Technical Branch Chief

OIVD Submissions Workshop 2010

Why DSMICA?

- **Section 10 of the "Medical Device Amendments of 1976" required:** *"an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices"*

- **Section 15 of the SMDA of 1990 established** *an office of international relations to participate in meetings and enter into agreements with foreign countries to facilitate commerce in devices between the U.S. and such countries.*

- **Section 738 of MDUFMA of 2002 established** *a fee reduction for small business; fee waiver and fee reduction regarding premarket approval fees and premarket notification fees.*

Who We Are

- DSMICA is a Division of the Office of Communication, Education and Radiation Programs (OCER)
  - Currently 21 employees:
    - Science Background
    - International Relations specialists
    - Consumer communications specialists
    - Former FDA investigators, ODE reviewers, Industry and Medical Professionals.

What We Do

- We respond to a range of questions and needs that are as broad as the medical device industry, itself!
- We function as the CDRH point person for the implementation of Third Party Programs and assessment of third parties [AP for 510(k) review and AP for Inspection].
- While founded in the law, our function is based on the belief that education fosters voluntary compliance.

Who assist's DSMICA?

- DSMICA responds to over 90% of inquiries without consultation or referral to other Offices.
- Over 60,000 Telephone and Email Inquiries in 2009.
- Primary contacts for consultation or referral are:
  - Office of Compliance (OC)
  - ODE/OIVD Branch Chiefs
  - Office of Surveillance and Biometrics (OSB)
  - Office of International Programs (OIP)

Manufacturers And G to G Assistance Premarket guidance

(34,000 Phone and Email Inquiries)

- Device classification
- Electronic Registration & Listing
- Premarket Notification & Premarket Approval processes
- Compliance with Q.S. (Design Controls)
- User Fees
- Investigational Device Exemptions
- Explanation of laws (FDAAA), regulations & policies.

Manufacturers And G to G Assistance Postmarket guidance

(14,000 Phone and Email Inquiries)

- Compliance with Quality Systems
- Reporting adverse events
- Changes to existing devices
- Detentions of imported devices
- Recalls and other corrective actions
- Exporting medical devices
- Reporting changes in device ownership, company names, etc.

International Assistance

(7,000 Phone and Email Inquiries)

- OIP and FDA Foreign Offices
  - Confidentiality Agreements; Participate in IWG; Training and guidance for FO staffers
- Foreign Regulators
  - Capacity Building; Technical Assistance; HBD; Speaking Requests
- Foreign Manufacturers & Associations
  - Technical Assistance; Speaking Requests

Device Advice: Device Regulation and Guidance

International Information (Medical Devices)

- Important New Changes to Canadian Regulatory Quality Systems Requirements
- Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative
- Contacts

International Information (Devices)

Within FDA, the Center for Devices and Radiological Health (CDRH) develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices; to promote quality in mammographic services; and to control unnecessary human exposure to potentially hazardous radiation and ensure the safe, efficacious use of such radiation. The Center reviews and evaluates medical device premarket approval (PMA) applications, exemption requests for investigational devices (IDEs), and premarket notifications [510(k)s]. CDRH also develops and enforces performance standards for medical devices and radiation-emitting electronic products and GMP regulations.

Under the Safe Medical Devices Act of 1990, CDRH has established an International Staff to coordinate the development of agreements with foreign countries in order to facilitate trade in devices.

CDRH Resources

- Exporting Medical Devices
- Importing Medical Devices
- Third Party Review
- Third-Party Inspection (Devices)
- Summary Technical Document (STED) Pilot Program
- Device Registration and Listing

Small Business Determinations (Domestic and Foreign)

- Applicant that qualifies as a small business is eligible for reduced fees ($100 million or less / $30 million or less - first PMA free)
- Applicant must qualify as a small business at least 60 days before their first submission in a fiscal year
- Small Business status expires at the end of the fiscal year
- 1300 Determinations per year (20% from Foreign Firms)

Consumer Assistance

(5,000 Phone and Email Inquiries)

- FDA the premier "consumer protection agency"

- Direct response to medical device and radiation-emitting product related concerns from the public

- Explanation of the duties, responsibilities and authorities of the Center

Stakeholder Requests

510(k)	22%
Quality System	16%
New Company	12%
Registration/Listing	12 %
Import/Export	9%
Labeling	8%
IDE	7%
PMA	6%
Inspectional	4%
Other (e.g. classification/standards)	4%

Frequently Referenced Web Pages

- **Device Advice:**
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance
- **CDRH Learn:**
  - www.fda.gov/cdrh/cdrhlearn
- **Third Party Review:**
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/
- **Third Party Inspection:**
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection
- **International Homepage:**
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/InternationalInformation/
- **Consumer Homepage:**
  - www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/

Device Advice

- Self-service site for medical device and radiation emitting electronic product information
  - Is my product a medical device?
  - What is the device classification?
  - How to market your device?
  - Postmarket Requirements
  - Import/Export

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

Medical Devices

Device Advice: Device Regulation and Guidance

Search Device Advice

go

Information for regulated industry on determining how to comply with the federal laws and regulations governing medical devices.

Additional Information

- DSMICA Staff Directory

Spotlight

- Follow Us on Twitter

Recalls & Alerts

- List of Device Recalls
- Recalls Database
- Public Health Notifications
- How to Report a Problem (Medical Devices)

Approvals & Clearances

- Recently-Approved Devices
- 510(k) Clearances
- PMA Approvals

Contact Us

1-800-638-2041
301-796-7100
CDRH-Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue

CDRH Learn

- Newest Online Resource for Industry Education.
- October 2008 CDRH Learn went "LIVE".
- 23 Available Modules:
  - Overview of Regulatory Requirements: Medical Devices
  - Quality System Regulation 21 CFR Part 820 Basic Introduction
  - Device Establishment Registration and Listing
  - Overview of the Premarket Notification Process – 510(k)
  - How to Get Your Electronic Product on the U.S. Market
  - Bioresearch Monitoring (BIMO)
- Interagency Agreement (IAG) with U.S. State Department to translate all modules into Chinese (Mandarin) and Spanish.
- Certificate Available for each Topic upon Successful Completion of a Post Test.

Search Favorites

v/Training/CDRHLearn/default.htm

Training & Continuing Education Courses

CDRH Learn

Welcome to CDRH Learn, FDA's Center for Devices and Radiological Health (CDRH) Web page for industry education. CDRH is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products. We are committed to educating industry on the relevant policies and regulations.

CDRH Learn is our latest innovative educational tool. It consists of a series of training modules describing many aspects of medical device and radiological health regulation, covering both premarket and postmarket issues. This tool is intended to provide the medical device and radiological health industry with an information resource that is comprehensive, interactive, and easily accessible.

Disclosure:

The presenters are FDA/CDRH staff and therefore, as employees, have claimed no interests, financial or otherwise, with medical device or radiation-emitting products that may be shown in any of the presentations.

Related Links

- Device Advice: Device Regulation and Guidance
- Suggest Future Topics for CDRH Learn

Contact Us

1-800-638-2041
301-847-8142 Fax
cdrhlearn@fda.hhs.gov
CDRH Learn
CDRH-Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-4303
Silver Spring, MD 20993

Telephone/Fax/Email

- **Most Efficient Way to Reach DSMICA Email: dsmica@fda.hhs.gov**

- **Contact Numbers**
  - Phone: 800-638-2041 or
    301-796-7100
  - Fax: 301-847-8149

- **Medical Device Specialists**
  - Monday - Friday 8:00 a.m. to 5:00 p.m. EST