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

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OIVD Submissions Workshop April 25, 2011

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 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 50,000 Telephone and Email Inquiries in 2010.
- 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

- 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

- 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

- **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**

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
- 1400 Determinations per year (20% from Foreign Firms)

Consumer Assistance

- 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%

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

CDRH Learn

- Newest Online Resource for Industry Education.
- October 2008 CDRH Learn went “LIVE”.
- 31 Available Modules, including:
  - 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)
  - MDR
  - Export Certificates
- 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.

Telephone/Fax/Email

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

- **Toll-Free Number**
  - 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