Small Manufacturers Assistance

OIVD Submissions Workshop
April 17, 2012

Elias Mallis
Director
Division of Small Manufacturers, International, and Consumer Assistance
U.S. Food and Drug Administration

Three Ways to Contact Us

1. **Email: dsmica@fda.hhs.gov**

2. **Phone: (800) 638-2041 or (301) 796-7100**
   - **Press “1” for consumer questions**
   - **Press “2” for industry questions**

3. **Fax: (301) 847-8149**

CDRH and DSMICA

- **1976 - Medical Device Amendments**
  - Center for Devices and Radiological Health was formed
  - Law mandated "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices"

- **1990 – Safe Medical Devices Act**
  - 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.

- **2002 – Medical Device User Fee and Modernization Act**
  - established a fee reduction for small business; fee waiver and fee reduction regarding premarket approval fees and premarket notification fees.

Who is DSMICA

- division in CDRH's Office of Communication, Education and Radiation Programs (OCER)
- staff of 21 professionals
- **diverse backgrounds:**
  - medicine - engineering
  - radiology - general science
  - quality systems
- **diverse experiences**
  - FDA premarket review - FDA field investigational
  - clinical practice - industry (including IVD)

Our Mission

- Provide timely and comprehensive education, regulatory guidance, and support to our diverse stakeholders.
- Our stakeholders come from the worldwide industry (large and small), consumer and government communities of medical devices.
- Our belief: **Education fosters voluntary compliance and self-reliance.**

What We Do

- answer inquiries from industry and consumer stakeholders [phone, email, fax]
- address all aspects of medical devices and radiation programs
- develop educational training for our stakeholders [workshops, video modules, written guidance]
- manage small business determination (SBD)

Our Major Program Areas

- industry assistance (premarket)
- industry assistance (postmarket)
- consumer assistance
- small business determination (SBD)
- international program
- CDRH external stakeholder notifications
- industry education/training programs

Industry Assistance premarket

- device classification
- electronic registration and listing
- premarket applications (510(k)s, pre-IDEs, IDEs, PMAs)
- quality systems (design controls)
- user fees
- FDA laws, regulations, guidances, and policies

Industry Assistance postmarket

- quality systems (manufacturing)
- reporting of adverse events
- changes to existing devices
- recalls and other corrective actions
- import issues (detention of devices)
- export issues
- transfer of device ownership
- changes to company names, etc.

Common IVD Topics

- laboratory-developed tests (LDTs)
- analyte-specific reagents (ASRs)
- IVD reagents and instrumentation
- CLIA and CLIA determinations
- IVD labeling (21 CFR 809.10)
- use of symbols
- research use only vs. investigational use
- requirement vs. exemption of IDE application

Consumer Assistance

- the premier “consumer protection agency”
- provide direct (phone, email) assistance to consumer stakeholders
- stakeholders are typically patients, family members, and healthcare providers / professionals
- address wide range of questions on medical devices and radiation-emitting products
- explain FDA and CDRH’s role and responsibilities

Consumer Assistance

- activity often an early signal of a potential issue with a medical device
  - questions related to failure or improper operation of a medical device
  - complaint about pain or injury as a result of use
- communications sometimes triggered by FDA, media news release, or TV news story
- current hot topics with medical devices:
  - surgical meshes
  - breast implants

Annual Workload – FY 2011

- **industry assistance**
  - telephone: 23,500 annual [450/week]
  - email: 13,000 [250/week]
  - fax: 660
- **consumer assistance**
  - telephone: 3100
  - email: 2200
  - fax: 121
- **Total Annual: 42,500 [820/week]**

Stakeholder Requests

- 510(k) 22%
- quality system 16%
- new company 12%
- registration and listing 12 %
- import/export 9%
- labeling 8%
- IDE 7%
- PMA 6%
- inspectional 4%
- other (e.g. classification/standards) 4%

Small Business Determinations (SBDs)

- program provides reduced user fee for applicants determined to be a "small business"
- "small business" = gross receipts or sales ≤ **100M**
- annual guidance "FY 2012 Medical Device User Fee Small Business Qualification and Certification"
- if approved, eligible through end of current fiscal year; require new application each fiscal year
- FDA reviews SB request within 60 days
- # of requests in 2011: **1461**
  - ↑ trending upward (reflection of innovation, small business development)

International Program - a collaborative educational effort

- **Office of International Programs (OIP) and FDA Foreign Offices**
  - develop confidentiality agreements
  - participate in international working group
  - develop training and guidance for Foreign Office staff

- **Foreign Regulators**
  - capacity building; technical assistance
  - country-specific collaborations
    - Japan: "Harmonization By Doing" (HBD) Pilot
    - Health Canada

- **Foreign Manufacturers and Associations**
  - technical assistance

Center External Stakeholder Notifications

- **aka "Email Blasts"**
- **sent to targeted distributions lists:**
  - manufacturers
  - consumer groups
  - foreign regulators
  - government agencies
  - professional organizations
  - device/product-specific groups
- **topics typically communicated:**
  - safety communications
  - new guidances, policies
  - public meetings
  - CDRH Initiatives
- **Posted on FDA/CDRH Website:**
  http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm289335.htm

Industry Education and Training Programs

- **Device Advice** [written]
- **CDRH Learn** [video-based]

Device Advice

- **Web-based educational program**
  - comprehensive regulatory assistance on medical device and radiation programs
- **Where to Find This Resource:**

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

Device Advice – general topics

- **Overview of Medical Device Regulation**
  - Is Your Product Regulated?
  - Medical Device Classification
  - Does the Product Emit Radiation?
  - Is the Product a Medical Device?
  - Device – Not a Device
  - Device Classification Panels
  - Class I/II Exemptions
  - Product Code Classification Database
  - Reclassification

- **How to Market Your Device**
  - IDEs, premarket submissions (510(k), PMA, HDE, third party), medical device registration and listing

Device Advice – general topics

- **Postmarket Requirements**
  - quality systems regulation
  - recalls, corrections and removals
  - post-approval studies
  - 522 postmarket surveillance
  - reporting adverse events
  - medical device tracking
  - third-party inspections
- **Compliance Activities**
- **Human Factors**
- **Guidance Documents, Standards**
- **Reprocessing of Medical Devices**
  - single use; reusable

Device Advice - topics

- **Importing and Exporting Devices**
- **International Information**
  - collaborative consultation and review of premarket applications pilot program
  - important new changes to Canadian regulatory quality system regulation
  - Japan-US HBD pilot program initiative
- **Unique Device Identification**

Device Advice – IVD topics

- **IVD regulatory assistance**
- **Clinical Laboratory Improvement Amendments (CLIA)**
- **Overview of IVD Regulation**

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

CDRH Learn

www.fda.gov/Training/CDRHLearn

- **online resource for industry education**
- **video-based presentation with slides**
- **over 40 training modules**
  - projected to develop 10-20 new modules in 2012
- **some modules available in Chinese (Mandarin) and Spanish**
- **some tests have “post-tests” with certificates of successful completion**

CDRH Learn

www.fda.gov/Training/CDRHLearn

- **address range of topics:**

- regulatory overview
- 510(k) and IDE programs
- registration and listing
- medical device recalls and MDRs
- radiation-emitting products
- home-use
- guidances and SOPs
- bioresearch monitoring
- quality system regulation
- export certificates
- software

Telephone/Fax/Email

- **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**

Thank You!

Elias Mallis

email: elias.mallis@fda.hhs.gov
phone: (301) 796-6216