U.S. Food and Drug Administration's (USFDA's) Center for Devices and Radiological Health

14th AHWP Meeting

November 5, 2009
Hong Kong

William (Bill) Sutton
Deputy Director, DSMICA, CDRH

U.S. FDA's Mission

- Protect public health
- Promote public health
- Collaborate with other countries
- Collaborate with scientific experts, academia, industry and consumers

Legislative Mandates

1968	Radiation Control for Health & Safety Act (RCHSA)
1976	Medical Device Amendment of 1976
1988	Clinical Laboratory Improvement Amendments (CLIA)
1990	Safe Medical Devices Act (SMDA)
1992	Mammography Quality Standards Act (MQSA)
1992	Medical Device Amendments
1997	Food & Drug Administration Modernization Act (FDAMA)
2002	Medical Device User Fee and Modernization Act (MDUFMA)
2005	Medical Device User Fee Stabilization Act (MDUFSA)
2007	Food and Drug Administration Amendments Act of 2007 (FDAAA)

U.S. FDA Organization

Office of the Commissioner
Margaret A. Hamburg, M.D.

Office of Regulatory Affairs

Center for Biologics Evaluation and Research

Center for Drug Evaluation and Research

Center for Devices and Radiological Health

Center for Food Safety And Applied Nutrition

Center for Veterinary Medicine

National Center for Toxicological Research

CDRH's Organizational Chart

Office of the Center Director
Jeffrey Shuren, M.D., JD, Director (Acting)
Lillian Gill, D.P.A., Senior Associate Director
Vacant, Associate Director for Regulations and Policy
Jonathan Sackner-Bernstein, M.D., Associate Director for Postmarket Operations
Ruth McKee, Associate Director for Management

CDRH Ombudsman
Les Weinstein, J.D.

Office of Compliance
Timothy A. Ulatowski

Office of Communication, Education, & Radiation Programs
Lynne L. Rice

Office of Device Evaluation
Donna-Bea Tillman, Ph.D.

Office of In Vitro Diagnostic Device Evaluation & Safety
Alberto Gutierrez, PhD

Office of Management Operations
Frank Benedetti

Office of Science & Engineering Laboratories
Steve Pollack, PhD

Office of Surveillance & Biometrics
Susan N. Gardner, Ph.D.

We've Moved…

- **CDRH has "*completed*" the move to the FDA White Oak Campus located at:**

  10903 New Hampshire Avenue

  Silver Spring, Maryland 20993 U.S.A.

- **CDRH began the move on May 15, 2009 and ended in August 2009.**

- **http://www.fda.gov/AboutFDA/CentersOffices/CDRH/ucm142391.htm**

CDRH Building WO-66

Who We Are…

- **CDRH is a team of over 1,200 dedicated, highly skilled, and internationally respected public health employees**
  - **Biologists**
  - **Chemists**
  - **Physicists**
  - **Engineers**
  - **Statisticians**
  - **Epidemiologists**
  - **Physicians**
  - **Microbiologists**
  - **Nurses**
  - **Pharmacologists**
  - **Veterinarians**
  - **Toxicologists**
  - **Specialists in Public Health Education and Communication**

CDRH Mission

Get safe and effective medical devices to market as quickly as possible...

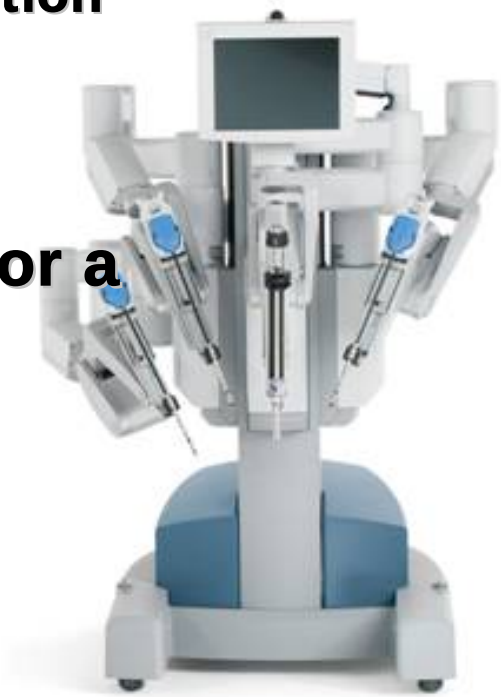
... while ensuring that medical devices currently on the market remain safe and effective.

Help the public get science-based accurate information about medical devices and radiological products needed to improve health.

A medical device is…

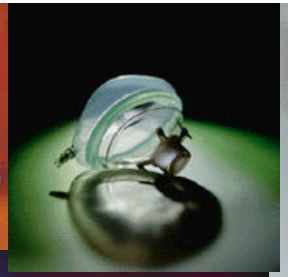
The Section 201(h) of the Food, Drug and Cosmetic Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

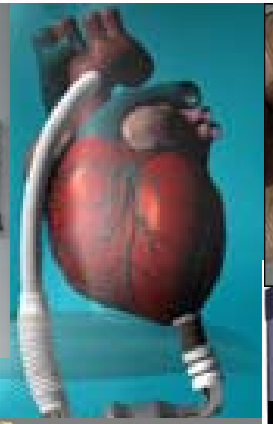
- **As simple as a tongue depressor or a thermometer**
- **As complex as robotic surgery devices**



The products we regulate…

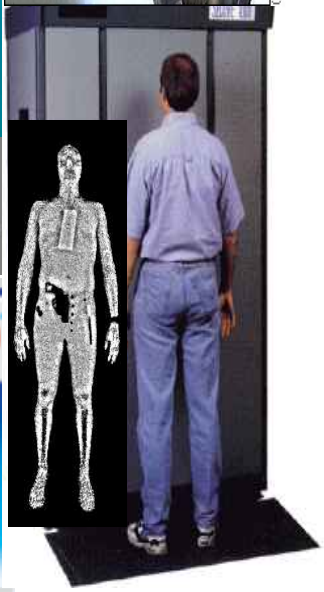


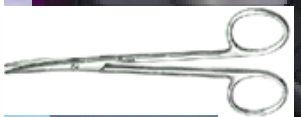















Risk-Based Paradigm

The law gives us the flexibility to calibrate our regulatory touch to the level of potential risk posed by new products

Device Classification

Medical Device Classes:

Class I

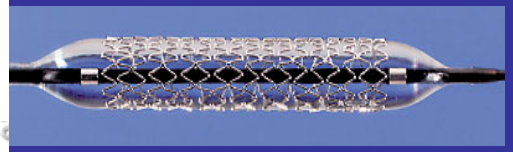
General Controls

Most exempt from premarket submission

Class II

Special Controls

Premarket Notification [510(k)]



Class III

Premarket Approval

Require Premarket Application [PMA]

Additional Classification:

“De Novo”

Device "types" that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood

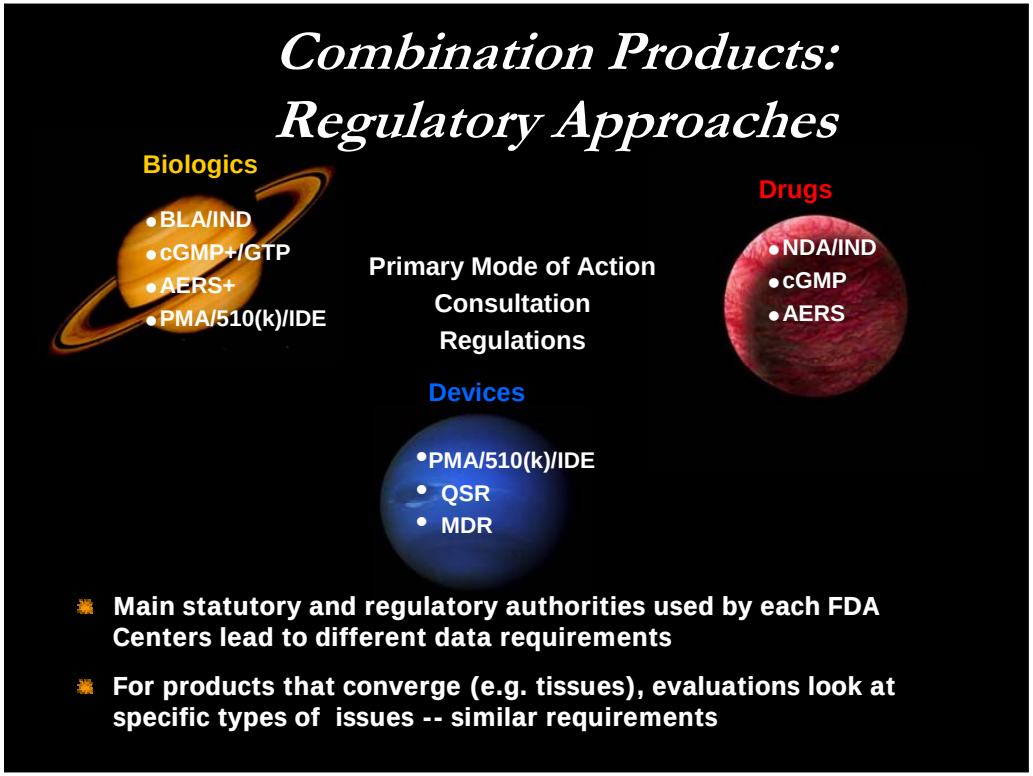
Humanitarian Device Exemption (HDE)

Devices for orphan diseases

Intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the United States

Combination Products

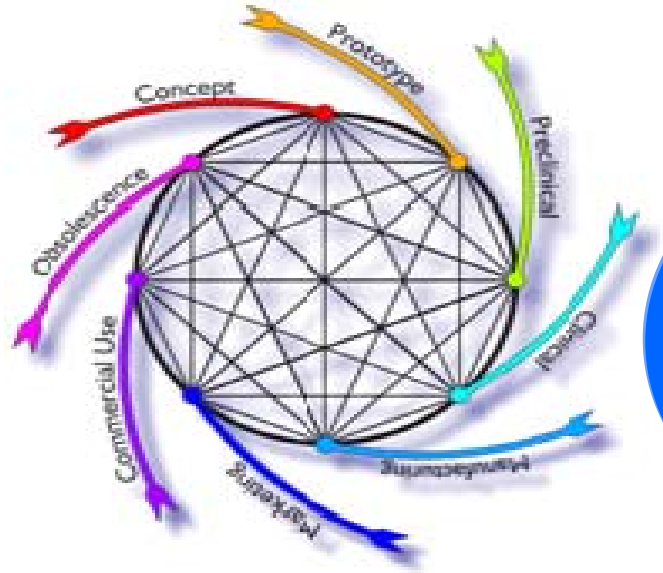
- **Combinations of different types of medical products:**
  - Drug-device
  - Biologic-device
  - Drug-device-biologic
  - Drug-biologic
- **They can be:**
  - Physically or chemically combined
  - Co-packaged in a kit
  - Separate, cross-labeled products



http://www.fda.gov/oc/combination/

Our Total Product Life Cycle Vision

Efficient, Effective, and Predictable Product Development



Ensuring the Safety of Marketed Medical Devices

Enabling Technology and Innovation

Standards Development

- **Standards Participation**
  - 38 Development Organizations
  - 238 Liaison Reps: 220 National Committees and 128 International Committees
  - 538 Standards Activities: 365 National and 173 Other Activities
- **Over 600 Recognized Standards of which 332 are International Standards**
- **http://www.fda.gov/cdrh/stdsprog.html**

Guidance Development

Over 1,100 CDRH Guidance Documents Available

Recently published guidance topics:

- IVD Device Studies:FAQs
- ASRs: FAQs
- Handling Post-Approval Studies Imposed by PMA Order
- In Vitro Diagnostic Multivariate Index Assays
- Writing Dear Doctor Letters for Recalls of ICDs
- Bundling
- Antimicrobial Agents Statistical Guidance on Studies Evaluating Diagnostic Tests
- PMA Supplement Decision-Making Process
- Antimicrobial Susceptibility Test (AST) Systems
- Advisory Committee
- Interactive Review
- DES

Ensuring the Safety of Marketed Medical Devices

Postmarket Surveillance and Response

Postmarket Surveillance Tools

- **Passive Tools**
  - MDR – mandatory reports
  - MEDWATCH – voluntary reports
  - ASR – alternate summary reports
  - Vigilance – international reports
- **Enhanced Tools**
  - MedSun and LabSun – user facility network
- **Active Tools**
  - Epidemiology studies
  - Postmarket surveillance studies
  - Condition of Approval studies

Quality System (QS) Regulations 21 CFR Part 820

- Assure device safety and effectiveness through design and manufacturing controls
- To allow tailoring the controls based on the type of device manufactured
- Are part of premarket review (PMA) for Class III devices
- Are a key element of assuring postmarket safety for all devices
- Similar to ISO 13485
- Standard for which U.S. FDA audits device establishments.

CDRH's Workload

Submissions Received in FY2009

Submissions Received	FY 2009
Original PMAs	30
PMA Supplements (all types)	1553
Pre-IDEs	937
Original IDEs	244
IDE Supplements	4331
510(k)s	4115
Original HDE	4
HDE Supplements	40
513(g)s	116
Total	**11,370**

CDRH International Programs
Scope of Work

- **International Regulatory Activities**
  - Surveillance, Inspections and Enforcement
- **International Harmonization**
  - GHTF, International Consensus Standards, HBD
- **Cooperation with Foreign Government**
  - Beyond Our Borders, PMAP, Training & Technical Assistance
- **Trade Related Activities**
  - Technical Assistance to U.S. Trade Agencies and Certificates of Export (CFG)

Global solutions are needed for a global market!

Communicating risk/benefit information

- **Patient Safety News** www.fda.gov/psn
- **Public Health Notifications** www.fda.gov/cdrh/safety.html
- **One Pagers - New Device Approvals**

  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list+1
- **Listservs - Breast Implants** www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm#meddev
- **Publications and presentations -For Consumers** www.fda.gov/ForConsumers/default.htm

CDRH Learn

www.fda.gov/Training/CDRHLearn/

- **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.**

CDRHLearn

- CDRH Learn Course List (English)
- CDRH Learn Course List (Chinese)
- CDRH Learn Technical Requirements

CDRH Learn Course List (Chinese)

Listed below are the courses CDRH currently offers in Mandarin Chinese. Additional online courses are being developed and will be posted upon completion.

Quality System Regulation 21 CFR Part 820 Basic Introduction

- Online Video Presentation
- Transcript

Page Last Updated: 09/21/2009

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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

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

- **Toll-Free Number**
  - **Phone: +1-301-796-7100**
  - **Fax: +1-301-847-8149**

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

Thank you!

www.fda.gov/CDRH