U.S. Department of Health and Human Services
Food and Drug Administration
9200 Corporate Boulevard, HFZ-1
Rockville, Maryland 20850
1-888-INFO-FDA

www.fda.gov/CDRH

Center for Devices and Radiological Health (CDRH)

Promoting and Protecting the Public Health

U.S. Department of Health and Human Services
Food and Drug Administration
9200 Corporate Boulevard, HFZ-1
Rockville, Maryland 20850
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Center for Devices and Radiological Health Organizational Structure

Director
Daniel G. Schultz, M.D.

Deputy Director
Linda S. Kahan, Esq.

Senior Associate Director
Lillian J. Gill

Ombudsman
Les Weinstein, Esq.

Director, Medical Device Fellowship Program
Susan Homire, D.V.M.

Assistant Director for Education & Communication
Mark H. Barnett

Director, Executive Services
Lily Ng

Phone: 301-827-7975
Fax: 301-594-1320

Office of Compliance
Timothy A. Ulatowski
Director
Phone: 301-594-4692
Fax: 301-594-4610

Office of Science and Engineering Laboratories
Larry Kessler, Sc.D.
Director
Phone: 301-827-4777
Fax: 301-827-4787

Office of Device Evaluation
Donna-Bea Tillman, Ph.D.
Director
Phone: 301-594-2022
Fax: 301-594-2510

Office of Surveillance and Biometrics
Susan Gardner, Ph.D.
Director
Phone: 301-594-2812
Fax: 301-594-2965

Office of Communication, Education and Radiation Programs
Lynne Rice
Director
Phone: 301-443-2845
Fax: 301-443-8810

Office of Management Operations
Ruth McKee
Director
Phone: 301-827-7663
Fax: 301-827-0119

Office of In Vitro Diagnostic Device Evaluation and Safety
Steven I. Gutman, M.D.
Director
Phone: 301-594-3084
Fax: 301-827-4595

For additional information, call:
1-888-INFO-FDA
or visit our website at: www.fda.gov/cdrh

Center for Devices and Radiological Health (CDRH)

The Center for Devices and Radiological Health (CDRH), part of the U.S. Food and Drug Administration (FDA), helps ensure that medical devices are safe and effective as authorized by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, helps reduce unnecessary exposure to radiation from medical, occupational, and consumer products as authorized by the Radiation Control for Health and Safety Act of 1968, and assures the quality of mammography as authorized by the Mammography Quality Standards Act of 1992.

Office of the Center Director (OCD)

Office of Communication, Education, and Radiation Programs (OCER)

Office of Compliance (OC)

Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Office of Management Operations (OMO)

Office of Science and Engineering Laboratories (OSEL)

Office of Surveillance and Biometrics (OSB)

Office of the Center Director (OCD)

OCD manages the Center's programs by providing scientific, policy and managerial leadership and direction to the seven offices comprising the Center. OCD provides advice and consultation on policy matters about medical device and radiological health issues to the Commissioner and other FDA officials, Congress, the Department of Health and Human Services, the Public Health Service, other government agencies, the scientific and academic communities, and representatives of regulated industry. It communicates agency initiatives and guidance to consumers and industry in support of the public health. Other activities supported by OCD are the CDRH Ombudsman who investigates outside complaints and resolves disputes, and the Medical Device Fellowship Program.

Office of Communication, Education and Radiation Programs (OCER)

OCER supports CDRH and FDA in assuring the safety and effectiveness of medical devices, radiation-emitting electronic products, and mammography.

OCER serves, collaborates and communicates with the public, the health care community, industry, domestic and foreign governments and agencies to improve health outcomes.

OCER specializes in: providing outreach and education to manufacturers, health care professionals, consumers and caregivers, domestic and foreign governments, and CDRH staff; regulating mammography facilities; developing regulations and guidance for medical devices, radiation-emitting products, and mammography; communicating risks; producing teleconferences, videos, and other television production services; coordinating international activities

training for CDRH staff members; and maintains laboratory collaborations and relationships with scientific researchers in academia and other Federal laboratories. OSEL also coordinates and oversees CDRH's activities that support the development of national and international standards.

OSEL's major laboratory activities fall in the areas of:

(1) Biology
(2) Physics
(3) Chemistry and Materials Science
(4) Electrical and Software Engineering
(5) Solid and Fluid Mechanics
(6) Imaging and Applied Mathematics

Office of Surveillance and Biometrics (OSB)

OSB is responsible for ensuring the continued safety and effectiveness of medical devices after they have reached the market-place. To accomplish this task, OSB conducts statistical analyses, performs targeted epidemiological studies, and directs a nation-wide surveillance system designed to monitor the performance of marketed medical devices. The process begins with statistical analyses of clinical studies that provide the empirical basis for expected device performance. Thereafter, OSB monitors adverse event reports looking for, and responding to, device problems. When problems are uncovered, OSB assembles teams of experts from across the Center to analyze the problem and develop solutions. Most often the solution involves notifying the user community about the problem and suggesting remedies. These notifications are developed and distributed by OSB staff and are sent to the recipient most likely to put the information into action, be it a user group, a hospital risk manager, or individual clinician.

Office of Management Operations (OMO)

OMO advises the Center Director on all management and budget issues. It plans, develops, and implements cost effective Center management policies and programs concerning financial and human resource management, contracts and grants management, ethics and program integrity, committee and conference management, occupational health and safety, and facilities. OMO develops and implements the Center's long-range, strategic, operational plans and budget; manages the Center's time reporting process; evaluates the effectiveness of Center programs; and works in partnership with the Office of the CIO to develop administrative, scientific and technical information system plans and priorities to support the Center. The Freedom of Information Staff responds to public requests for information under the Freedom of Information Act (FOIA).

Office of Science and Engineering Laboratories (OSEL)

OSEL is the laboratory research arm of CDRH, a unique institutional resource covering all major dimensions of medical device science and technology. OSEL scientists provide the Center with a source of independent data that is fundamental to the fulfillment of CDRH's regulatory responsibilities. OSEL routinely contributes to the Center's premarket and postmarket regulatory decision making, and to other CDRH public health support activities.

Specifically, OSEL performs product testing; develops reliable standardized test methods for CDRH and industry use; performs anticipatory scientific investigations on emerging technologies; contributes laboratory data to national and international standards used in CDRH decision making; provides scientific and technical

including global harmonization and mutual recognition agreements; promoting the application of human factors principles to reduce use error; increasing the effectiveness of patient labeling; reducing unnecessary radiation exposure and improving image quality; administering the CDRH radiation safety program; and implementing third party programs.

Office of Compliance (OC)

OC has a primary role in assuring that marketed Medical Devices and Radiological Health Products are safe and effective. OC addresses risk to consumers by evaluating inspectional/investigational data, providing guidance and advice to regulated industry, developing educational and enforcement strategies, and managing CDRH's activities on recalls and legal actions. OC is responsible for advising the Center Director and other FDA officials on legal, administrative, and regulatory programs and policies.

OC develops and monitors, in cooperation with other FDA components, national and foreign medical device and radiological health product inspectional programs. These programs are designed to reduce consumer risk by assuring regulated industry's compliance with the Federal Food, Drug, and Cosmetic Act, other applicable statutes, and with federal regulations such as the quality system and good laboratory practice regulations. OC reviews manufacturing submissions for high risk devices and coordinates manufacturing and biomedical research site inspections. The bio-research monitoring program assesses data integrity and industry's compliance with human subject protection regulations.

OC develops and conducts training programs for FDA field and state personnel. It educates industry via symposia, conferences, and the CDRH web site. OC works with the Office of Regulatory Affair's headquarters and field staff to identify and document potential violations of FDA law and regulations, and to monitor any corrective action to ensure consumers are not exposed to harmful medical devices and radiological products.

Office of Device Evaluation (ODE)

ODE is the office responsible for the evaluation of premarket submissions from the medical device industry. The office plans, coordinates, and renders Agency decisions regarding the approval, denial, and withdrawal of approval for companies to market medical devices in the United States. ODE also authorizes the conduct of clinical trials of unapproved medical devices under the Investigational Device Exemptions (IDE) program. The data gathered in these clinical studies is frequently used to support market authorizations.

ODE primarily evaluates four types of premarket submissions: premarket notification submissions (or 510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), and humanitarian device exemption applications (HDEs). Most devices are cleared for marketing through the 510(k) process with the PMA requirements applying only to high risk class III devices. ODE also coordinates Center classification activities; reviews and initiates petitions for reclassification of devices; interacts with and provides support to the advisory panels which make recommendations on FDA actions regarding select devices; and participates in the Center's postmarket surveillance and enforcement activities, including the continuing review and medical evaluation of device labeling and clinical experience.

Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

OIVD combines the functions of all the offices within CDRH into one organizational unit for cradle-to-grave regulation of in vitro diagnostic devices (IVDs). It carries out this mission by combining the pre-market review responsibilities of ODE, the enforcement responsibilities of OC, and the post-market surveillance responsibilities of OSB. To support these regulatory responsibilities, OIVD maintains strong ties to OSEL for technical assistance, OCER for communication and outreach assistance, and OMO for program management assistance.

OIVD consists of a multidisciplinary group of scientists and other professionals who are collectively dedicated to promoting and protecting public health through clear and consistent regulation of IVDs by applying good scientific principles throughout the Total Product Life Cycle of the device. OIVD has a dual charge to foster the rapid transfer of good new IVDs into the medical market while preventing marketing of unsafe or ineffective devices. The Office strives to ensure the work is transparent in order to allow all stakeholders to obtain the knowledge required to make informed decisions about the development, production, and use of IVDs. In addition, OIVD administers the Clinical Laboratory Improvement Amendments (CLIA) '88 complexity program for the Centers for Medicare and Medicaid Services (CMS) by categorizing commercially marketed in vitro diagnostic tests by level of complexity.