Information and Analysis Branch:

The Information Analysis Branch (IAB) manages much of the operational tasks for the division. With its technical and project management staff, IAB manages the entry of all medical device reports (MDRs) as well as coordinates activities involving the Manufacturer and User Facility Device Experience (MAUDE) database containing MDR reports, including electronic submission of MDRs. IAB is also the official generator of counts and statistics necessary for the monitoring of adverse events of product problems or for responding to inquiries from government agencies and the public.

Division of Postmarket Surveillance

FDA/CDRH
OSB/DPS

Food and Drug Administration
Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Division of Postmarket Surveillance
10903 New Hampshire Avenue
Building 66, Room 3113
Silver Spring, MD 20993-0002

FDA/CDRH
OSB/DPS

Division of Postmarket Surveillance

Division Overview:

The Division of Postmarket Surveillance (DPS) is responsible for postmarket surveillance of medical and radiation-emitting devices through identification of potential public health risks based on the reports of medical device-related adverse events and device problems received from reporters worldwide.

DPS develops policy and guidance, performs document reviews, and interprets the Medical Device Reporting regulation. DPS also provides technical (clinical, scientific, and regulatory) expertise to develop, plan and implement initiatives to disperse device and radiological health information to the public and private sectors, and serves as technical experts for other government agencies including Congress, public and private sectors and international organizations.

DPS consists of four branches:

- Product Evaluation Branch I
- Product Evaluation Branch II
- MDR Policy Branch
- Information and Analysis Branch

Product Evaluation Branches I & II

The Product Evaluation Branches I & II (PEB) Analysts are a critical link in the device safety chain. They routinely monitor and address medical device adverse event reports for actual or potential risks to patient safety. These reports describe deaths, serious injuries, malfunctions, and near-misses associated with devices used for patient monitoring, diagnostic testing, telemedicine, for medical, surgical, and therapeutic intervention. The reports frequently describe unexpected device problems and failures that occur throughout the use of devices. The staff work in two Branches and are responsible for the following devices: Cardiovascular, Neurology, Gastroenterology & Renal, Radiology, Obstetrics & Gynecology, Urology & Lithotripsy, General Hospital, Orthopedics & Physical Medicine, Ophthalmic, Anesthesia, Otolaryngology (ear/nose/throat), General Surgery, Dental & Infection Control.

MDR Policy Branch:

The Medical Device Report Policy Branch (MPB) is responsible for the interpretation of the Medical Device Reporting requirements specified in 21 CFR Part 803. MPB is composed of MDR Policy Specialists with backgrounds in nursing, engineering, microbiology, public health, and medical technology. As MDR Policy Specialists they provide assistance to medical device Manufacturers, Importers, and User Facilities to ensure that they are meeting their regulatory obligations under the MDR regulation. MPB also works closely with other parts of the FDA and Center for Devices and Radiological Health (CDRH), including the Office of Compliance and Office of Device Evaluation, regarding device reportability issues.

MPB can be contacted for questions regarding the Medical Device Reporting regulation at MPB@fda.hhs.gov or 301-796-6670.