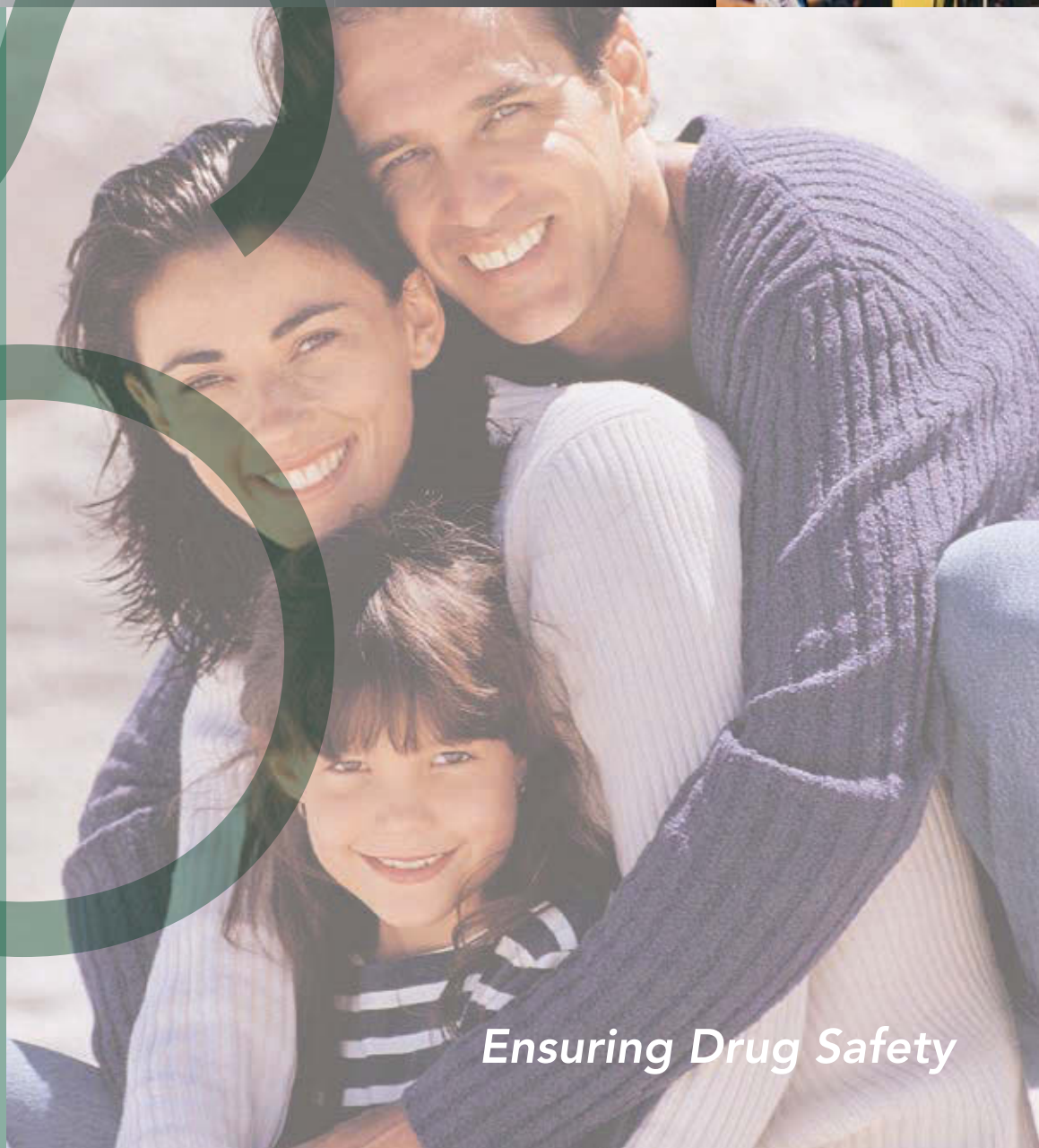
Office of Surveillance and Epidemiology



Ensuring Drug Safety

mission

Drug safety begins with extensive research and testing. Drug safety doesn't end with FDA approval. Once a drug becomes widely used in the general population, side effects and adverse events occur that aren't evident in premarket testing.

The Office of Surveillance and Epidemiology (OSE) continues drug safety by evaluating the safety of FDA approved drugs using a variety of tools. We maintain a system of post-marketing surveillance and risk assessment programs to identify adverse events that may not have appeared during the pre-approval drug development process. We learn about adverse events through required reporting by companies and through voluntary reports submitted to FDA's MedWatch program, which together, total more than 250,000 reports per year. The OSE staff use this information to identify drug safety concerns and recommend regulatory actions to improve product safety and protect public health. Activities include:

- updating drug labeling
- providing additional information to the public
- implementing or revising a drug risk management program
- on rare occasions, reevaluating approval or marketing decisions

OSE works with drug companies to reduce medication errors related to confusing labels, labeling, drug packaging, and drug names that look alike or sound alike.

Division of Pharmacovigilance I & II (DPVI & DPVII)

DPV I & DPV II staff include safety evaluators whose primary role is to detect and assess safety signals for all marketed drug products. They work closely with medical reviewers in the Office of New Drugs (OND) so that potential safety signals are assessed in the context of existing preclinical, clinical, and pharmacologic knowledge of the drugs in question.

Division of Epidemiology (DEPI)

Our epidemiologists review epidemiologic study protocols that are increasingly required of manufacturers as post marketing requirements. They evaluate various post marketing surveillance tools that may be incorporated into risk management strategies, such as patient registries and/or restricted drug distribution systems. They estimate the public health impact of safety signals by evaluating computerized databases and the published literature.

Division of Medication Error Prevention and Analysis (DMEPA)

DMEPA primarily provides premarketing reviews of all proprietary names, labels and labeling in CDER in order to reduce the medication error potential of a proposed product. DMEPA also provides post-marketing review and analysis of all medication errors CDER receives.

Division of Risk Management (DRISK)

DRISK reviews and recommends risk communications, risk management programs under risk evaluation and mitigation strategy (REMS) including REMS elements, for example Medication Guides, communication plans, and elements to assure safe use (ETASU), and evaluates the effectiveness of (REMS). This Division oversees Medication Guides, Patient Package Inserts, and pharmacy, physician, and patient information surveys. DRISK participates in international regulatory liaison activities with the European Medicines Agency including videoconferencing for drug and biologic post-marketing safety issues.

Programs and Activities

- Patient Labeling and Risk Communication
- Medication Guides
- Risk Evaluation and Mitigation Strategy
- Drug Safety and Risk Management (DSaRM) Advisory Committee gained full committee status on June 1, 2002
- Meeting programs, member, and charter information for the DSaRM Advisory Committee.
- MedWatch, the FDA Safety Information and Adverse Event Reporting Program, provides safety information for all FDA regulated medical products (drugs, biologics, medical devices, and dietary supplements) to both healthcare professionals and the general public.
- MedWatch Partners work with FDA to help keep their members informed about medical product safety information.

OSE

Food and Drug Administration

Center for Drug Evaluation and Research

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http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm106491.htm