FDA Plans to Upgrade Device Safety Monitoring

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration announced on Nov. 9 that it is taking steps to improve its postmarketing surveillance of medical device safety, including moving ahead on a proposal to require electronic reporting of adverse events.

The agency said it has created an action plan based on a major review that was completed in 2005. That review looked at how the Center for Radiological Devices and Health (CDRH) handles recalls and enforcement actions against manufacturers that are not in compliance with FDA rules.

"Today's report details a number of action items that we believe will transform the postmarketing safety program," said Dr. Daniel Schultz, director of CDRH, during a briefing with reporters.

The FDA will focus on making improvements in four major areas: collaboration among experts within CDRH, data systems, communications with patients and physicians about risks and benefits, and enforcement.

CDRH leaders will encourage more cross-organizational collaboration so that premarket, postmarket, and enforcement efforts are better coordinated, said Dr. Schultz.

Some of the biggest changes will come in data collection and analysis. The agency hopes to integrate its passive adverse events reporting system (Manufacturer and User Facility Device Experience Database, also known as MAUDE) and its active system, the Medical Product Safety Device Network (MedSun), said Dr. Schultz. Currently, 350 hospitals have been trained to report device problems on MedSun.

One goal is to recruit more facilities and find a way to upgrade reporting so it is closer to real-time.

The agency also hopes to require manufacturers and others to electronically report adverse events.

Currently, FDA receives about 200,000 reports to MAUDE each year, and the majority are on paper, which delays entry into the system and analysis for any kind of safety signal, Dr. Schultz said. The FDA has been piloting an electronic reporting program, and is in the process of writing a rule to require electronic reporting, he said.

Once data are being reported and analyzed more quickly, enforcement will be more timely also, he said. It will also let the FDA focus enforcement efforts on the highest-risk products, said Dr. Schultz. "When enforcement is necessary, it needs to be done quickly, accurately, and in a way that's meaningful and corrects problems," he said.

The FDA also aims to improve its communications to health professionals and consumers—whether the communications are notices about unsafe devices or simply background on safety and efficacy of products.

CDRH will redesign its Web site to be more consumer-friendly. It will also take a closer look at how best to give out data—and when—on a potentially faulty device.

CDRH is hoping to accomplish most of its planned "action points" without seeking additional funding, at least in the near term, Dr. Schultz said. ■

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