

## FDAnews Device Daily Bulletin

May 28, 2008 | Vol. 5 No. 104

### Postmarket Is CDRH's Top Priority, Official Says

As the FDA unveils its new postmarket initiative to improve the safety of medical products, a CDRH official says postmarket issues have taken precedence over premarket, taking the first-place slot for the center's priorities.

Devicemakers may see more postmarket surveillance studies under Section 522 of the FDA Amendments Act (FDAAA), which allows the FDA to require postmarket surveillance for certain Class II and Class III devices, according to Don St. Pierre, associate director for policy and operations at CDRH.

"I think it's really underutilized and is going to be utilized a lot more in the future," St. Pierre said, speaking at a Regulatory Affairs Professionals Society update on CDRH activities.

He also predicted an expansion of Section 522 postmarket studies for pediatric products. Under FDAAA, the FDA can order surveillance of these products for more than 36 months.

Fortunately for in vitro diagnostics (IVD) makers, postmarket studies are not as common in the IVD world, he said, adding that the center focuses more on the labeling for these products.

The FDA is increasing its attention on imported medical products, particularly after recent incidents concerning medical products from China. Although the agency is setting up satellite offices in China, "we're not getting PMA submissions that say 'China' and running them up a flagpole because we'd be doing that quite a bit," St. Pierre said.

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