FDA NOTE TO CORRESPONDENTS

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FDA: Majority of drug and biological product makers meeting postmarketing requirements and commitments

2nd annual report based on more than 1,500 postmarketing studies, clinical trials

Most makers of approved drug and biological products are meeting their regulatory obligations and meeting targets for postmarketing studies/clinical trials in a timely manner, according to a study released today by the U.S. Food and Drug Administration (FDA).

The study, based on the second annual review of the status of 1,551 postmarketing studies/clinical trials, showed that 40 percent of the postmarketing studies/clinical trials had been closed (either fulfilled or released) by FDA. Of the remaining 60 percent, most were in progress and on schedule or the final report has been submitted for FDA review.

The review, done under a contract with Booz Allen Hamilton, examined the backlog of industry postmarketing studies and clinical trials for FDA-approved drugs and biologics. The backlog was defined as all those postmarketing requirements (PMR) and postmarketing commitments (PMC) open when the Food and Drug Administration Amendments Act (FDAAA) was enacted on Sept. 27, 2007.

Under the FDAAA, the agency must annually report the status of the backlog of PMR and PMC for all approved drug and biological products. In addition, manufacturers of drugs and biologics are required to report to the FDA in a timely manner any serious safety issues that are identified from studies or other sources.

Key findings of the study include:

- During the second annual review, the status of 591 PMR/PMCs changed. Nearly half (46 percent) of the PMR/PMCs were updated to fulfilled status, which reflects a significant effort by FDA staff to complete reviews of the large number of submitted final reports identified during the first annual review. Those remaining were updated as a result of study/trial initiation and completion, final report submission or missed milestone dates;
- Only 17 percent of the backlog of PMRs/PMCs were delayed;

- Just 7 percent of PMRs/PMCs on schedule after the first annual review became delayed during the second review.

For more information:

General Information on Postmarketing Requirements/Postmarketing Commitments

FR Notice 2009

09/04/09 – Final Report on the Postmarketing Requirement/Postmarketing Commitment Backlog Review