Meetings of scientific advisory committees organized by OND to discuss safety issues for specific drugs. In the case of Arava, for example, ODS staff were not allowed to present their analysis of postmarket safety at an advisory committee meeting held to review Arava’s safety risks and benefits. Insufficient communication between ODS and OND hindered the decision-making process. ODS management did not systematically track information about ongoing postmarket safety issues, including the recommendations that ODS staff made for safety actions. GAO also found that FDA faced data constraints that contributed to the difficulty in making postmarket safety decisions. GAO found that there were weaknesses in the different types of data available to FDA, and FDA’s access to data was constrained by both its authority to require certain studies and its limited resources.

During the course of GAO’s work for its March 2006 report, FDA began a variety of initiatives to improve its postmarket drug safety decision-making process, including the establishment of the Drug Safety Oversight Board. FDA also commissioned the Institute of Medicine to examine the drug safety system, including FDA’s oversight of postmarket drug safety. GAO recommended in its March 2006 report that FDA take four steps to improve its decision-making process for postmarket safety. GAO recommended that FDA revise and implement its draft policy on the decision-making process for major postmarket safety actions, improve its process to resolve disagreements over safety decisions, clarify ODS’s role in scientific advisory committees, and systematically track postmarket drug safety issues. FDA has initiatives underway and under consideration that, if implemented, could address three of GAO’s four recommendations. Because none of these initiatives was fully implemented as of March 2007, it was too early to evaluate their effectiveness. In the 2006 report GAO also suggested that Congress consider expanding FDA’s authority to require drug sponsors to conduct postmarket studies, as needed, to collect additional data on drug safety concerns.