As part of the Food and Drug Administration’s (FDA) oversight of the safety and effectiveness of medical devices marketed in the United States, it inspects domestic and foreign establishments where these devices are manufactured. To help FDA address shortcomings in its inspection program, the Medical Device User Fee and Modernization Act of 2002 required FDA to accredit third parties to inspect certain establishments. In response, FDA has implemented two such voluntary programs. GAO previously reported on the status of one of these programs, citing concerns regarding its implementation and factors that may influence manufacturers’ participation. (Medical Devices: Status of FDA’s Program for Inspections by Accredited Organizations, GAO-07-157, January 2007.)

This statement (1) assesses FDA’s management of inspections of establishments—particularly those in foreign countries—manufacturing devices for the U.S. market, and (2) provides the status of FDA’s programs for third-party inspections of medical device manufacturing establishments. GAO interviewed FDA officials; reviewed pertinent statutes, regulations, guidance, and reports; and analyzed information from FDA databases. GAO also updated its previous work on FDA’s programs for inspections by accredited third parties.

Few inspections of medical device manufacturing establishments have been conducted through FDA’s two accredited third-party inspection programs—the Accredited Persons Inspection Program and the Pilot Multi-purpose Audit Program (PMAP). From March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA’s Accredited Persons Inspection Program. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries’ requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise might not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 made several changes to program eligibility requirements that could result in increased participation by manufacturers. PMAP was established on September 7, 2006, and as of January 11, 2008, two inspections had been conducted by an accredited organization through this program, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities.