DRUG SAFETY

Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections

What GAO Found

GAO’s preliminary analysis of Food and Drug Administration (FDA) data shows that from fiscal year 2012 through 2016, the number of foreign drug manufacturing establishment inspections increased. From fiscal year 2016 through 2018, both foreign and domestic inspections decreased—by about 10 percent and 13 percent, respectively. However, the total number of foreign inspections surpassed the number of domestic inspections in 2015, and a growing percentage of FDA’s foreign inspections (43 percent in 2018) were conducted in China and India, where most establishments that ship drugs to the United States were located. FDA officials attributed the decline, in part, to vacancies among investigators available to conduct inspections. GAO previously noted the vital role that inspections play in FDA’s oversight of foreign establishments.

FDA has vacancies among each of the groups of investigators who conduct foreign inspections. FDA had 190 investigators in the United States who conduct the majority of foreign inspections, but an additional 58 positions were vacant. FDA was in the process of filling 26 of these vacancies, with 32 remaining. However, according to FDA officials, it could be 2 to 3 years before new staff are experienced enough to conduct foreign inspections. FDA also faces persistent vacancies among investigators in its foreign offices.

FDA investigators identified persistent challenges conducting foreign inspections, raising questions about the equivalence of foreign to domestic inspections. For example, while domestic inspections are almost always unannounced, FDA’s practice of preannouncing foreign inspections up to 12 weeks in advance may give manufacturers the opportunity to fix problems. Investigators from FDA’s China and India offices do conduct some unannounced inspections, but they are involved in a small percentage of inspections in these countries (27 percent and 10 percent, respectively). Further, FDA continues to rely on translators provided by the foreign establishments being inspected, which investigators said can raise questions about the accuracy of information FDA investigators collect.