

## Report in Brief

Date: June 2022

Report No. A-01-19-01500

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

The Food and Drug Administration's (FDA's) oversight responsibility has become increasingly complicated because many drugs used in the United States are manufactured overseas. FDA reported that 74 percent of active pharmaceutical ingredient manufacturers and 54 percent of finished goods manufacturers are located outside the United States. In 2017, FDA began making changes to its foreign inspection program to enhance its ability to protect the public health. Congress has continued to express concerns about FDA's foreign drug inspection process.

Our objective was to determine whether FDA's foreign drug inspection process has improved since programmatic changes were implemented in 2017. Specifically, we determined whether:

- (1) timeframes for the foreign for-cause drug inspection process improved after FDA implemented the 2017 programmatic changes,
- (2) FDA's foreign for-cause drug inspection process followed applicable policies and procedures, and
- (3) lead investigators conducting foreign for-cause drug inspections met FDA's training requirements.

### How OIG Did This Audit

We reviewed all 64 foreign for-cause drug inspections that occurred during the period January 1, 2016, through March 31, 2017, and all 68 foreign for-cause drug inspections that occurred during the period January 1, 2018, through March 31, 2019.

## The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply

### What OIG Found

FDA's timeframes for completing the steps in the foreign for-cause drug inspection process generally improved after it implemented programmatic changes in 2017. However, we found that: (1) FDA did not always follow its policies and procedures for foreign for-cause drug inspections and (2) FDA could not provide documentation to support that all lead investigators completed the required training before they conducted inspections.

According to FDA, it had limited resources and faced unexpected events and complex circumstances. FDA did not ensure that it recorded certain information in the Establishment Inspection Report (EIR), such as whether an inspection was announced. If FDA does not follow its policies and procedures related to timeliness, regulatory deficiencies may not be corrected in an efficient manner. FDA did not ensure that lead investigators completed required training before they conducted inspections because FDA did not have policies and procedures that required investigators' supervisors to verify that lead investigators completed the required training prior to being assigned to an inspection. FDA officials told us that due to multiple location moves, FDA misplaced records indicating that lead investigators completed training requirements. It is a vulnerability to have lead investigators conduct inspections before ensuring that they are qualified.

### What OIG Recommends and FDA Comments

We recommend that FDA identify and implement additional ways to improve the timeliness of its foreign for-cause drug inspection process. We also made other procedural recommendations that are listed in the report.

In written comments on our draft report, FDA concurred with our recommendations. FDA stated that it is working to improve the timeliness of the overall foreign for-cause inspection process. Furthermore, pending approval by Congress, FDA stated that it has committed to goals regarding the timing of foreign facility followup inspections. FDA also stated that it is addressing ways to reduce the time spent writing and reviewing EIRs and that it is conducting a workload analysis for individuals responsible for determining final classification, issuing warning letters, and holding regulatory meetings. FDA stated that it will soon begin implementing a new system to better document and track investigators' qualifications and certification.