

Report to Congress

**Fiscal Year 2020 Annual Report on User Fees Assessed and
Collected**

Submitted Pursuant to Section 743 of the Federal Food, Drug, and Cosmetic Act,
as Amended by Section 107(f) of the FDA Food Safety Modernization Act
(Public Law 111-353)

U.S. Department of Health and Human Services

U.S. Food and Drug Administration

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Date

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Introduction

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 107 of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add new section 743 (21 U.S.C.379j-31), giving the U.S. Food and Drug Administration (FDA) the authority to collect fees from (1) the responsible party for each domestic and foreign food facility subject to a reinspection, (2) importers subject to a reinspection, (3) domestic facilities or importers who do not comply with a recall order, and (4) importers participating in the voluntary qualified importer program (VQIP).

Section 743(f) of the FD&C Act requires the U.S. Department of Health and Human Services to submit a report to Congress, including a description of the fees assessed and collected and a summary of both the entities paying such fees and the types of business in which such entities engage, each fiscal year in which fees are assessed. Specifically, section 743(f) states:

Annual Report to Congress. – Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

FDA assessed user fees under section 743 of the FD&C Act for the first time in fiscal year (FY) 2020, triggering the requirement to submit a report on the user fees assessed and collected under section 743 of the FD&C Act. The following is the first annual report submitted in response to this mandate. The report covers the reporting requirements relating to the user fees assessed and collected under section 743 of the FD&C Act during FY 2020.

Background

FSMA made changes to the FD&C Act that enable FDA to better protect the public health by strengthening its food safety measures. FDA now has several tools to protect the food supply and to provide better oversight of imported food. These tools include the authority to collect user fees for reinspection activities, recall orders, and participation in VQIP.

Subsections 743(a)(1)(A) and (D) of the FD&C Act provide authority for FDA to collect user fees from the responsible party for domestic facilities, U.S. agents for foreign facilities, and importers that are subject to a reinspection. FDA is authorized to assess and collect the costs of the reinspection, which include all expenses, including administrative expenses incurred in connection with arranging, conducting, and evaluating the results of the reinspection.

In addition, section 743(a)(1)(B) of the FD&C Act gives authority for FDA to collect user fees from the responsible party for each domestic facility and from importers that do not comply with a recall order under either section 423 or section 412(f) of the FD&C Act. FDA is authorized to

collect user fees to cover food recall activities associated with such recall orders, including technical assistance, follow-up effectiveness checks, and public notifications.

And finally, section 743(a)(1)(C) of the FD&C Act gives authority for FDA to collect user fees from each importer participating in VQIP under section 806 of the FD&C Act to cover the administrative cost of the program. VQIP provides an expedited review and import entry of human and animal food into the United States for participating importers.¹

FDA is required to establish fees to be collected each fiscal year and publish them in the *Federal Register* not later than 60 days before the start of each year. User fee notices for the current fiscal year are available on FDA's [website](#).² These fees are based on an estimate of 100 percent of the costs to conduct the reinspection, recall, and VQIP activities described above.

User Fees Assessed and Collected in FY 2020

Reinspection Fees

While FDA did conduct reinspections in FY 2020, FDA has committed to issuing guidance for small businesses on the process for requesting a reduction in FSMA reinspection user fees prior to issuing any fee assessments or undertaking collection. FDA did not collect any fees for the reinspection of domestic facilities, foreign facilities, or importers in FY 2020.

Recall Fees

FDA did not collect any fees related to a recall order under section 423 or section 412(f) of the FD&C Act in FY 2020.

Voluntary Qualified Importer Program (VQIP) Fees

In FY 2020, FDA collected \$16,681 in VQIP user fees. User fees were assessed to one domestic importer approved to participate in VQIP. The fees collected are consistent with the fee rate published in the *Federal Register*.³ The importer approved to participate in VQIP is a retailer of human and animal food. FDA anticipates that participation in the VQIP program will increase over time. For the FY 2020 benefit year, the program had two applicants and one was accepted. For the FY 2021 benefit year, the program received and accepted three applicants.

¹ See generally <https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip>.

² See "Fees under the FSMA," at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fees-under-fsma>.

³ See 84 FR 35680 (July 24, 2019), available at <https://www.federalregister.gov/documents/2019/07/24/2019-15742/food-safety-modernization-act-voluntary-qualified-importer-program-user-fee-rate-for-fiscal-year>.