Report to Congress

User Fees Assessed and Collected

FY 2021

Report in Response 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)

Executive Summary

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 section 743 (21 U.S.C. 379j-31), giving authority to the Food and Drug Administration (FDA) 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. Section 743(f) of the FD&C Act requires the Department of Health and Human Services to submit a report to Congress each fiscal year in which fees are assessed by FDA, including a description of the fees that were assessed and collected, as well as a summary of both the entities that paid these fees and the types of businesses in which these entities engaged.

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I. 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 section 743 (21 U.S.C. 379j-31), giving authority to the Food and Drug Administration (FDA) to collect fees from (1) the responsible party for each domestic and foreign food facility that is subject to a reinspection, (2) importers that are 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 Department of Health and Human Services (HHS) to submit a report to Congress each fiscal year in which fees are assessed by FDA, including a description of the fees that were assessed and collected, as well as a summary of both the entities that paid these fees and the types of businesses in which these entities engaged. 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 in section 743(f) for HHS to submit a report on the user fees collected by FDA and the entities paying these fees. This is the second annual report submitted in response to this mandate, and the report covers FY 2021.

II. Background

FSMA made changes to the FD&C Act that enable FDA to better protect public health by strengthening its food safety measures. FDA now has several additional 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.

In particular, section 743(a)(1)(A) and (D) of the FD&C Act provides authority to FDA to collect user fees from the responsible party for each domestic food facility that is subject to a reinspection, U.S. agents for each foreign food facility that is subject to a reinspection, and importers who are subject to a reinspection. FDA is authorized to collect fees to cover the costs of the reinspection, which include all expenses, including administrative expenses incurred in connection with (1) arranging, conducting, and evaluating the results of the reinspection and (2) assessing and collecting reinspection fees.

In addition, section 743(a)(1)(B) of the FD&C Act gives FDA the authority to collect user fees from the responsible party for each domestic food facility and from importers who do not comply with a recall order under 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 orders, including technical assistance, follow-up effectiveness checks, and public notifications.

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

FDA is required to establish fees to be collected each fiscal year and publish these requirements in the *Federal Register* not later than 60 days before the start of each year. User fee notices for each fiscal year are available on FDA's "Fees under the FSMA" webpage.[2] The fees are based on an estimate of 100 percent of the costs of conducting reinspections, recalls, and VQIP activities, as described above.

III. User Fees Collected in FY 2021

A. Reinspection Fees

Although FDA did conduct reinspections in FY 2021, FDA has committed to issuing guidance documents for small businesses on the process for requesting a reduction in FSMA reinspection user fees before any fee assessments are issued or before any collections are undertaken. In FY 2021, FDA did not collect any fees for the reinspection of domestic food facilities, foreign food facilities, or importers.

B. Recall Fees

In FY 2021, FDA did not collect any user fees related to a recall order under section 423 or section 412(f) of the FD&C Act.

C. VQIP Fees

In FY 2021, the user fee rate for participation in VQIP was $17,000. This amount was invoiced to and collected from three VQIP importers, totaling $51,000 invoiced and collected. The importers who were approved to participate in VQIP in FY 2021 include a retailer of human and

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

[2] See http://www.fda.gov/food/food-safety-modernization-act-fsma/fees-under-fsma

animal food, a vertically integrated seafood processing and distribution company, and a distributer of consumer products such as olive oil, vegetable oils, and table olives.

This report was prepared by FDA's Office of Food Policy and Response.
For further information please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's home page at https://www.fda.gov/.