4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2700]

Food for Human Consumption; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously exercised our FSMA authority to collect fees for export certificates issued for food for human consumption.

DATES: The fees described in this document for export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, will be effective October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kate Meck, International Affairs Staff, Center for Food Safety and Applied Nutrition (HFS-550), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2307, CFSANExportCertification@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, the "FDA Export Reform and Enhancement Act of 1996" (Pub. L. 104-134, amended by Pub. L. 104-180) amended sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381 and 382). As a result of the 1996 amendments, section 801(e)(4) of the FD&C Act provides that persons exporting a drug, animal drug, or device may request FDA to certify that the product meets the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Upon a showing that the product meets the applicable requirements, the law provides that FDA shall issue export certification within 20 days of the receipt of a request for such certification. The law also authorizes us to charge up to $175 for each certification issued within the 20-day period.

In January 2011, section 801(e)(4) of the FD&C Act was further amended by FSMA (Pub. L. 111-353) to authorize FDA to issue, and charge fees for, export certificates for food. Under section 801(e)(4)(C) of the FD&C Act, an export certification can be made in such form (including a publicly available listing) as FDA determines appropriate.

This notice focuses on the fees to be assessed with respect to export certificates issued by the Center for Food Safety and Applied Nutrition (CFSAN) for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. This notice applies to foods such as produce, grains, processed foods, food additives, color additives, food contact substances, generally regarded as safe ingredients, infant formula, and all other foods not specifically excluded. Dietary supplements, medical foods, and foods for special dietary use are excluded from this notice.

II. Fees To Be Assessed for Export Certificates

CFSAN estimates the annual costs of the export certification program for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, to be approximately $975,000 per year for preparing and issuing export certificates. The costs are due to payroll and operating expenses. Specifically, there are four cost categories for preparing and issuing export certificates in general: (1) direct personnel for research, review, tracking, writing, and assembly; (2) an information technology system used for tracking and processing certificates; (3) billing and collection of fees; and (4) overhead and administrative support. In fiscal year (FY) 2017 CFSAN issued approximately 4,072 export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. Because CFSAN has not been charging fees for issuing these export certificates, the program has been covered by appropriated funds.

As mentioned previously, FDA may charge up to $175 for each certificate. Certificates for some of the foods that are the subject of this notice cost us more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost FDA less than $175 to prepare. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced FDA costs for preparing those certificates.

The following fees will be assessed starting October 1, 2018, for export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use:

Table 1--CFSAN Fees for First, Second, and Subsequent Export Certificates

Type of Certificate	Fee (dollars)
First certificate	175
Second certificate for the same product(s) issued in response to the same request	155
Subsequent certificates for the same product(s) issued in response to the same request	100

The fee for issuing the first export certificate for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, will be at the maximum allowable amount and consistent with the export certification fees assessed since FY 1997 by other FDA Centers that provide export certification for drugs and devices. It is also consistent with the export certification fees assessed by the Center for Veterinary Medicine (CVM) for certificates for animal food, which CVM began assessing in FY 2016 because the FSMA amendments to section 801(e)(4) of the FD&C Act also apply to animal food. The fees for issuing subsequent certificates continue to differ among the Centers, based on varying costs.

Dated: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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