4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0143]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Supplier Verification Programs (FSVP) for Food Importers

OMB Control Number 0910-0752--Extension

This information collection supports FDA regulations at 21 CFR Part 1, Subpart L--Foreign Supplier Verification Programs for Food Importers, as well as associated guidance. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. The regulations are intended to help ensure that food imported into the United States is produced in compliance with specific processes and procedures, including reasonably appropriate risk-based preventive controls. The regulations establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances that a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions.

To assist respondents with understanding the regulatory requirements, we have developed Agency guidance, which is available at: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.

In the *Federal Register* of October 22, 2018 (83 FR 53271), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section(s)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Exemption for food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with U.S. Customs and Border Protection 1.509, 1.511, 1.512	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Information Collection Activity; 21 CFR Section(s)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
FSVP Recordkeeping, including hazard determination, written procedures, reevaluation; audits; and corrective actions:					
Determine and document hazards; 1.504(a)	11,701	1	11,701	3.5	40,954
Review hazard analysis; 1.504(d)	11,701	7	81,907	0.33 (20 minutes)	27,029
Evaluation of food and foreign supplier; 1.505(a)(2), 1.511(c)(1)	11,701	1	11,701	4	46,804
Approval of suppliers; 1.505(b), 1.512(c)(1)(iii)	8,191	1	8,191	12	928,292

Reevaluation of food and foreign supplier; 1.505(c), 1.512(c)(1)(ii)(A)	11,701	365	4,270,865	0.25 (15 minutes)	1,067,716
Confirm or change requirements of foreign supplier verification activity; 1.505(c), 1.512(c)(1)(ii)(A)	2,340	1	2,340	2	4,680
Review of other entities assessments; 1.505(d), 1.512(c)(1)(iii)	3,510	1	3,510	1.2	4,212
Written procedures for use of approved foreign suppliers; 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i)	11,701	1	11,701	8	93,608
Review of written procedures; 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii)	11,701	1	11,701	1	11,701
Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3)	11,701	1	11,701	2	23,402
Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)-(2) 1.511(c)(5)(i)	11,701	4	46,804	3.25	152,113
Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3) 1.511(c)(5)(iii)	11,701	2	23,402	0.33 (20 minutes)	7,723
Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(4)(ii)(A)	11,701	2	23,402	3	70,206
Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(4)(ii)(B)	11,701	2	23,402	1	23,402
Review records; 1.506(e)(1)(iii), 1.511(c)(4)(ii)(C)	11,701	2	23,402	1.6	37,443

Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(4)(iii)	11,701	6	70,206	0.25 (15 minutes)	17,552
Document hazard controls; 1.507(a)(1)	11,701	3.17	37,092	1.25	46,365
Written assurances; 1.507(a)(2), (a)(3), and (a)(4)	11,701	8.72	102,038	0.50 (30 minutes)	51,019
Disclosures that accompany assurances; 1.507(a)(2), (a)(3), and (a)(4)	102,038	1	102,038	0.50 (30 minutes)	51,019
Document assurances from customers; 1.507(c)	36,522	2.8	102,262	0.25 (15 minutes)	25,566
Document corrective actions; 1.508(a), 1.512(b)(4)	2,340	1	2,340	2	4,680
Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1)	2,340	1	2,340	5	11,700
Subtotal for FSVP Recordkeeping Itemized Above			4,984,046		1,917,186
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511(b)	11,701	2.88	33,699	2.25	75,823
Document very small importer/certain small foreign supplier status; 1.512(b)(1)	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3)	50,450	2.8	141,260	2.25	317,835
Total					2,361,294

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

We are retaining the currently approved burden estimates. The FSVP requirements became effective May 30, 2017, and we continue to evaluate associated burden.

Dated: February 21, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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