4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with our Foreign Supplier Verification Programs (FSVP) for Food Importers.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-N-0143 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

We estimate the burden of the information collection is as follows:

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

21 CFR Section	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(c), 1.511(c), 1.512(b)(2)	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	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	98,292
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
1.507(a)(1)	11,701	3.17	37,092	1.25	46,365
Written assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)	11,701	8.72	102,038	0.50 (30 minutes)	51,019
Disclosures that accompany assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(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) and 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: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.
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