DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practices for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practices for Finished Pharmaceuticals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 06, 2015, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practices for Finished Pharmaceuticals'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0139. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13696 Filed 6–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1069]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Blood Establishment Registration and Product Listing, Form FDA 2830'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 09, 2015, the Agency submitted a proposed collection of information entitled, ''Blood Establishment Registration and Product Listing, Form FDA 2830'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0052. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13697 Filed 6–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Draft Guidance for Industry on the Voluntary Qualified Importer Program for Food Importers and Guidelines in Consideration of the Burden of the Voluntary Qualified Importer Program Fee Amounts on Small Business; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry on the Voluntary Qualified Importer Program (VQIP) for importers of human or animal food. The draft guidance describes VQIP, which provides for expedited review and importation of food offered for importation by importers who voluntarily agree to participate in the program. The draft guidance describes the eligibility criteria for, and benefits of, participation in VQIP. The draft guidance also provides information on submitting an application for VQIP participation, obtaining a facility certification for the foreign supplier of a food imported under VQIP, the VQIP user fee, conditions that might result in the revocation of VQIP eligibility, and criteria for reinstatement of eligibility. We are issuing the draft guidance in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Although you may comment on any guidance at any time (21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it completes a final version of the guidance, submit either electronic or written comments on the draft guidance by August 19, 2015. Submit either electronic or written comments on the proposed collection of information by August 4, 2015.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Office of Enforcement and Import Operations (ELEM–3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance, including comments

regarding the proposed collection of information, to *http://www.regulations.gov.* Submit written comments on the draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to this draft guidance: Domenic Veneziano, Office of Enforcement and Import Operations (ELEM–3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301–796–0356.

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) (FSMA) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards.

FSMA also requires FDA to establish a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified under FDA's accredited third-party audit program, as well as other measures that support a high level of confidence in the safety and security of the food they import. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health.

Section 302 of FSMA amended the FD&C Act by adding new section 806, Voluntary Qualified Importer Program (21 U.S.C. 384b). Section 806(a)(1) of the FD&C Act directs FDA to establish this voluntary program for the expedited review and importation of food, and to establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP. Section 806(a)(2) directs FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP.

In accordance with section 806 of the FD&C Act, we are announcing the availability of a draft guidance for industry on VQIP. The draft guidance provides information on all aspects of VQIP participation, including the following:

- Benefits of VQIP participation;
- Eligibility criteria;
- Instructions for obtaining facility certifications for foreign suppliers;
- Instructions for completing a VQIP application;
- VQIP user fees;
- Conditions that might result in revocation of VQIP benefits; and
- Criteria for reinstatement of VQIP benefits.

When this program begins, we encourage food importers with robust supplier verification programs to apply for participation in VQIP. We believe that the benefits of VQIP participation, including expedited entry and reduced sampling by FDA, will be of substantial value to importers. We also anticipate that VQIP will benefit the public health by incentivizing the adoption of robust supplier verification programs and by allowing FDA to focus its resources on food shipments that pose a higher risk to public health and will facilitate risk-based admissibility practices.

We anticipate that VQIP application review will need to be limited in the program's first year of operation due to the demands on Agency resources necessitated by the initial establishment of the program and review of applications. For the purpose of calculating the fee, we have estimated that we would receive 200 notices of intent to participate and be able to review 200 applications in the first year. However, depending on the amount of resources needed in initiating the program, it might be possible that we will be able to review fewer or more than 200 applications in the first year. Applications will be reviewed in the order that they are submitted. We request comment on this potential limitation on participation in the initial year of VQIP.

II. Guidelines in Consideration of the Burden of the VQIP Fee Amounts on Small Business

FSMA directs FDA to collect fees to fund the VQIP program. Under the process established by FSMA, FDA must issue a proposed set of guidelines that consider the burden of the VQIP fee on small businesses and provide for a period of public comment on these guidelines. It is important to note that these guidelines have no binding effect on the Agency or the industry; instead they provide an opportunity for FDA to consider the burden of VQIP fee amounts on small businesses, and for the public to comment. By publishing these guidelines, FDA intends to gather the necessary information to determine if the fee will burden small businesses. After we issue these guidelines and consider the comments, FDA will publish a **Federal Register** notice with information about the actual fee schedule for the program at least 60 days prior to the start of the program in accordance with section 743(b)(1) of the FD&C Act.

More specifically, section 107 of FSMA amended the FD&C Act by adding new section 743, Authority to Collect and Use Fees (21 U.S.C. 379j–31). Section 743(a) of the FD&C Act authorizes FDA to assess and collect fees from each importer participating in VQIP to cover the administrative costs of the program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year. The fee rates must be published in a **Federal Register** notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act).

Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, this notice sets forth a proposed set of guidelines in consideration of the burden of fee amounts on small business. These guidelines provide an opportunity for public comment.

In order for small businesses to comment effectively, FDA has preliminarily estimated a possible fee amount based on an estimate of the number of importers we expect to participate in VQIP (200 in Fiscal Year (FY) 2018) and our estimate of 100 percent of the costs of administering the program, which we anticipate will be $3.4 million in FY 2018. The total estimated administrative costs of the program includes the costs of the application review process for 200 applications, the costs of conducting inspections of importers (both foreign and domestic) accepted into the program, the costs of our final determination of eligibility into the

program, and annual Information Technology (IT) maintenance costs. Using these assumptions, FDA estimates, at this time, that the annual fee would be approximately $16,400, if an equal fee were assessed on each of 200 participants. This number is only a preliminary estimate and intended to provide small businesses with an estimate of what the program might cost so that they can comment on any burden the fee might impose. After considering all comments on these guidelines, we will publish the actual fee in a **Federal Register** notice published in accordance with section 743(b)(1) of the FD&C Act prior to the fiscal year when we begin program benefits.

We estimate a flat $16,400 fee to be paid by all VQIP participants. We have used this model for this estimate in light of the voluntary nature of this program. There is no requirement for an importer to pay a fee unless the importer decides to participate in the program. We do not anticipate that fees charged as part of a voluntary program that provides the benefit of expedited review and importation of foods would present a burden on small businesses because a business will choose to apply only if the anticipated benefit exceeds the fee amount.

Based upon our current estimate of approximately $16,400 for the annual VQIP fee, we are requesting comment on whether and how this fee might be a burden on small business. Please provide as detailed information as possible regarding any potential burden. In addition, we seek comment on the following questions:

- If the fee does create a burden on small business, should FDA consider a reduction in the fee?
- If FDA were to consider a reduction in the fee, how should FDA define a small business for purposes of determining who is eligible for a fee reduction? Should FDA consider annual gross sales or value of the import entry (based on U.S. Customs and Border Protection data)? What other criteria could be used?
- If FDA were to consider a reduction in the fee, should the fee be increased for larger importers to ensure full reimbursement of FDA costs for the program?
- If FDA were to consider a reduction in the fee, how should any reduction be structured? Should the reduction be an established percentage of the full fee for all small businesses? What percentage would be appropriate? Should it vary based on annual gross sales or the value of the import entry?
- Should FDA consider an alternative structure that might indirectly reduce fees for small businesses by charging different fee amounts to different VQIP participants depending on the number of facilities included in the application and/or the number of products included in the application? Would such an approach result in small businesses paying lower fees than larger businesses?

III. Paperwork Reduction Act of 1995

The draft VQIP guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with estimates of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite 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.

Title: Draft Guidance for Industry: FDA's Voluntary Qualified Importer Program.

Description: This draft guidance document describes the FDA policy regarding requests for participation by food importers in the Agency's Voluntary Qualified Importer Program (VQIP). The VQIP provides for expedited review and importation of food offered for importation by importers who voluntarily agree to participate in VQIP. An importer who has voluntarily agreed to participate in VQIP will meet the application and inspection criteria outlined in the guidance document, including a facility certification for the VQIP food offered for import.

Description of respondents: FDA anticipates a need to limit the number of applications for the VQIP program to 200 applicants for FY 2018, which is the first year that VQIP will be operational. Each applicant will be an importer of record (IOR), the manufacturer, owner, or consignee. This limit will enable FDA to conduct a timely and efficient review of the applications to ensure that approved applicants begin receiving the benefits of participation in VQIP by October 2018.

Information collection burden estimate: The burden of this information collection consists of preparation of documents for VQIP application, completion of VQIP application package, annual renewal of VQIP status, and development of written procedures and other documentation of the VQIP Quality Assurance Program (QAP).

Recordkeeping Burden: In summary, the total one-time recordkeeping burden on importers under VQIP is estimated at 32,000 hours (see table 1). The annual recordkeeping burden of complying with the draft VQIP guidance document is estimated at 3,200 hours (see table 2).

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Guidance document provision	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping (in hours)	Total hours
QAP preparation	200	1	200	160	32,000
Total One-Time Recordkeeping Burden					32,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Guidance document provision	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
QAP modification	200	1	200	16	3,200
Total Annual Recordkeeping Burden					3,200

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

The draft guidance describes how VQIP applicants will prepare and document implementation of a QAP. Written policies and procedures related to the QAP are to be organized and submitted with the VQIP application (see Section F of the draft guidance document). The QAP will include information on the applicant's company profile, organization structure, and quality policy statement. The QAP will also include information on the applicant's company food safety system, food defense system, training, documentation of contracts that fulfill any task within the QAP, and procedures for record retention.

The majority of provisions in the QAP Food Safety Policies and Procedures section are similar to proposed requirements for food safety plans in FDA's proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Prevention Controls for Human Food (PC proposed rule) (78 FR 3646, January 16, 2013), or proposed requirements in FDA's proposed rule on Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (IA proposed rule) (78 FR 78014, December 24, 2013). The QAP Food Safety Policies and Procedures section states that the VQIP applicant should provide the following: (1) Analysis of the regulations and requirements that apply to the imported food, the processor, grower, transporter and importer; (2) risk analysis that identifies the safety and security vulnerabilities and the preventive controls that should be instituted to ensure product safety (similar to the hazard analysis requirement in the PC proposed rule (§ 117.130)); (3) mitigation strategies for each safety vulnerability identified during your risk analysis (similar to the corrective actions requirement in the PC proposed rule (§ 117.145) and mitigation strategies in the IA proposed rule (§ 121.135(b)); (4) mechanism for verifying food and firm compliance throughout the supply chain; (5) process for periodic review of food and firm compliance (similar to verification requirements in the PC proposed rule (§ 117.150)); (6) procedures for communicating information; (7) corrective action procedures (similar to corrective actions requirements in the PC proposed rule (§ 117.145)); and (8) training plan.

The QAP Implementation section directs the VQIP applicant to describe its procedures for auditing and updating the QAP, and its procedures for ensuring its VQIP QAP is current and appropriately implemented (similar to the verification implementation and effectiveness requirements in the PC proposed rule (§ 117.150(d)).

Under the PC proposed rule, the food safety plan requirements include written hazard analysis, description of preventive controls, monitoring the implementation of the preventive controls, corrective action procedures, verification procedures, and recall plan. In the PRA analysis for the PC proposed rule, the recordkeeping burden for preparing a food safety plan is estimated at 110 hours (Ref. 1). We use the recordkeeping burden of preparing a food safety plan, 110 hours, as a proxy for the burden to prepare QAP Food Safety Policies and Procedures.

The VQIP food defense security criterion is similar to the Food Defense Plan requirement under proposed § 121.126 in the IA proposed rule. Under the IA proposed rule, the food defense plan must include the written identification of actionable process steps, focused mitigation strategies, procedures for monitoring, corrective action procedures, and verification procedures. In the Preliminary Regulatory Impact Analysis (PRIA) of the IA proposed rule, we estimated that, on average, it would take an operations manager and a legal counsel 20 hours each to prepare a food defense plan (Ref. 2). Therefore, we estimate that, on average, it would take 40 hours for an applicant to prepare the food defense portion of the VQIP QAP.

We expect that it will take a VQIP applicant no longer than 10 hours to provide its company profile, organization structure, quality policy statement, documentation of contracts, and procedures for record retention. On average, the preparation of a QAP by a VQIP applicant is estimated at approximately 160 hours (110 + 40 + 10). In estimation of the one-time recordkeeping burden to prepare a QAP manual, we assume that VQIP importers do not already have a similar manual in place (*e.g.,* food safety plan under the PC proposed rule, food defense plan under the IA proposed rule). The one-time recordkeeping burden for 200 VQIP applicants to prepare QAPs is estimated at 32,000 hours (200 applicants × 160 hours/applicant) (see table 1). To the extent that some importers do have QAP manuals in place, the burden would be overestimated.

A VQIP importer is expected to update its QAP on an on-going basis. We estimate that it would take 10 percent of the effort to prepare the QAP, or 16 hours, to update the QAP each year. Therefore, we estimate the annual recordkeeping burden of modification of the QAP for 200 VQIP importers at 3,200 hours (200 importers × 16 hours/importer) (see table 2).

Reporting Burden: In summary, the total one-time reporting burden of participation in VQIP by 200 importers is estimated at 18,000 hours (see table 3). Total annual recordkeeping burden for VQIP importers is estimated at 4,000 hours (see table 4).

TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Guidance document provision	Number of respondents	Number of responses per respondent	Total one-time responses	Average burden per response (in hours)	Total hours
Initial VQIP application	100	1	100	80	8,000
Initial VQIP application with re-submissions	100	1	100	100	10,000
Total One-Time Reporting Burden					18,000

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance document provision	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Renewal of VQIP application	200	1	200	20	4,000
Total Annual Reporting Burden					4,000

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

The draft guidance document allows for food importers to apply for VQIP. We estimate that up to 200 qualified importers will be accepted in the first year of VQIP. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for the VQIP program. For the purpose of this analysis, we assume that 50 percent of all applications received will require additional information and it would take an additional 20 person-hours by the importer to provide that information. Therefore, we estimate that 100 importers will spend 8,000 hours (80 hours/importer × 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer × 100 importers) to submit their initial VQIP applications for a total one-time reporting burden of 18,000 hours (see table 3).

The draft guidance document states that each VQIP participant will submit to FDA a notice of intent to maintain its participation in VQIP and update information on its original application on an annual basis. We expect that each of the expected 200 importers in VQIP would apply to renew their intent to maintain their participation in VQIP. We expect that annual applications to renew participation in VQIP will take significantly less time to prepare than initial applications. We use 25 percent of the amount of effort to prepare and submit the initial application for acceptance in VQIP. Therefore, it is expected that, on average, each VQIP importer will spend 20 hours every year to complete and submit an application for renewal of its VQIP status. The annual burden of completing the renewal application for VQIP status by 200 importers is estimated at 4,000 hours (200 applications × 20 hours/application) (see table 4). For the purposes of the PRA analysis of the draft guidance document, we have estimated costs assuming that, during the annual application process, affected importers will do their paperwork properly and completely the first time. Because we assume that importers will have learned about supporting documentation they need to submit during the initial application process, we have not estimated an additional burden for less than complete annual applications. If we assumed a less consistent outcome, the annual burden might be slightly higher.

IV. Comments

Interested persons may submit either electronic comments regarding this draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

Persons with access to the Internet may obtain this draft guidance at either *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

VI. References

1. U.S. Food and Drug Administration. Proposed Analysis of Economic Impacts—Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, available under Docket No. FDA–2011–N–0920.
2. U.S. Food and Drug Administration. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (78 FR 78014, December 24, 2013).

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13706 Filed 6–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0126]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Ebola Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations), one of which was amended after initial issuance, for in vitro diagnostic devices for detection of the Ebola virus in response to the Ebola virus outbreak in West Africa. FDA