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FDA's Voluntary Qualified Importer Program

Guidance for Industry

Draft Guidance

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Although you can submit comments on any guidance at any time (see 21 CFR 10.115(g) (2)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 75 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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Food and Drug Administration
Office of Foods and Veterinary Medicine
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

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FDA's Voluntary Qualified Importer Program Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance listed on the title page.

I. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) (FSMA) enables the Food and Drug Administration (FDA or the Agency) 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 Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications regulations (FDA's third-party accreditation regulations), when finalized, (proposed 21 CFR part 1, subpart M)¹, 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.

¹ The final third-party accreditation regulations are expected to publish in early November 2015. The proposed third-party accreditation regulations were published in the *Federal Register* on July 29, 2013 (78 FR 45781). The VQIP program will go into effect after FDA's third-party accreditation program is operational.

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This guidance document describes FDA’s policy regarding requests for participation in FDA’s Voluntary Qualified Importer Program (VQIP) by importers of food for humans or animals. This document provides guidance on:

- The benefits VQIP importers can expect to receive;
- The eligibility criteria for VQIP participation;
- Instructions for completing a VQIP application;
- Conditions that may result in revocation of participation in VQIP; and
- Criteria for VQIP reinstatement following revocation.

This guidance document is presented in question and answer format. This guidance document may be modified (in accordance with FDA’s good guidance practices regulations (21 CFR 10.115)) as VQIP is implemented and evaluated. FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required. This guidance represents FDA’s current thinking regarding what will be considered for participation in VQIP and how the VQIP program will expedite imports. However, we will consider alternative approaches and, as further discussed in this document, we retain our full authority with regard to import sampling and entry decisions.

The pronouns “I,” “me,” “you,” and “your” are used in this guidance to refer to the importer who may want to participate in VQIP. “Agency” and the pronouns “we” and “our” are used to refer to FDA. The term “food” has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(f)), except that, for the purposes of VQIP, food does not include food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) or pesticides as defined in 7 U.S.C. 136(u).

II. Background

FSMA amended the FD&C Act by adding new section 806, Voluntary Qualified Importer Program (VQIP) (21 U.S.C. 384b). Section 806(a)(1) requires FDA to establish the following:

- A program for the expedited review and importation of food offered for importation by importers who voluntarily agree to participate in VQIP, and
- A process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in VQIP.

Section 806(a)(2) of the FD&C Act requires FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP. Section 806(d) states that in reviewing and making determinations on VQIP

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applications, FDA must consider the risk of the food to be imported based on factors such as the compliance history of the foreign supplier and the food safety practices of the importer.

In accordance with section 806(a)(2) of the FD&C Act, FDA is issuing this guidance to provide information on the process for expedited review and importation of food under VQIP, the issuance of facility certifications required to accompany food imported under VQIP, the submission and review of VQIP applications (taking into account the factors set forth in section 806(d)), and other matters related to participation in, and compliance with, VQIP.

III. Questions and Answers

A. Voluntary Qualified Importer Program Benefits

A.1 What are the benefits of VQIP participation?

Importers participating in VQIP will receive the following benefits:

- FDA will expedite entry into the United States for all foods included in an approved VQIP application (VQIP foods). FDA will set screening in its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening system to recognize shipments of food which are the subject of an approved VQIP application to expedite the entry of such food. The system is designed to recognize the information and immediately release the shipment, unless examination and sampling are necessary for public health reasons. (See Question A.5.)
- FDA will limit examination and/or sampling of VQIP food entries to “for cause” situations (i.e., when the food is or may be associated with a risk to the public health), to obtain statistically necessary risk-based microbiological samples, and to audit VQIP. (See Question A.5.)
- In the examination and/or sampling circumstances identified in the previous bullet, FDA will examine an entry and collect samples at the VQIP food destination or other location preferred by the VQIP importer. If exportation is warranted, FDA will assist in fulfilling an importer’s request to U.S. Customs and Border Protection (CBP) to export from the port preferred by the importer.
- FDA will expedite its laboratory analysis of “for cause” or audit samples of VQIP entries, to the extent possible in accordance with public health priorities.
- FDA will maintain a VQIP Importers Help Desk dedicated to responding to questions and resolving issues raised by VQIP importers about VQIP food and this guidance document.
- FDA will post a publicly available list of approved VQIP importers on FDA’s VQIP Web page at [insert link to FDA VQIP Web page]. VQIP importers may choose not to be listed on the VQIP importers list.

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The Agency may suspend any or all of these benefits as necessary to protect public health or in the case of an unforeseen emergency.

A.2 When will I receive the VQIP benefits?

VQIP benefits will begin October 1 following your acceptance into the program and will last through September 30 of the following year (VQIP year), except as noted in Question H.4. (See Section E and Section G for VQIP application information.)

A.3 What information should be submitted at entry to identify a VQIP food?

In addition to the entry data elements you normally transmit during the import process, you should provide the VQIP Affirmation of Compliance (AofC) code and your VQIP application number to identify the entry as a VQIP food. (See Appendix 1, 3. VQIP Application – Subsequent Year.) For each VQIP food entry, you should ensure the import entry information matches the information in your VQIP application for the food.

A.4 Will FDA expedite entry of a VQIP food that is part of a mixed entry (i.e., the entry includes VQIP food and food that is not covered by my VQIP)?

FDA will expedite only the line entry associated with the VQIP food. A non-participating food will be subject to normal FDA line entry review procedures, including routine examination and sampling, when applicable. For this reason, you should ensure that VQIP foods can be easily segregated from non-VQIP foods and moved into commerce. Although FDA will attempt, to the extent possible, to expedite the entry of the VQIP food, entry delays may occur for a VQIP food that cannot be readily separated from a non-VQIP food to allow for FDA examination or sampling of the non-VQIP food.

A.5 Under what circumstances will FDA examine or sample a VQIP food?

A VQIP food may be subject to “for cause” examination when we determine the food is or may be associated with a risk to public health. For example, during an investigation of an outbreak or illness associated with the type of food or with a foreign supplier covered by your approved VQIP application, FDA may examine and sample the VQIP food, even if there is no specific information implicating the VQIP food in the outbreak or illness. VQIP food may, at times, also be subject to microbiological sampling related to specific risk-based surveillance assignments. However, surveillance sampling of a VQIP food will be a low priority and FDA may exclude VQIP food from such sampling altogether if we can obtain adequate statistically-based, non-biased, non-VQIP food samples. If surveillance sampling of a VQIP food is necessary, FDA will collect a domestic-import sample (i.e., collect the sample after the food has been released from import status and entered into domestic commerce). Thus, surveillance sample collection will not delay entry of the VQIP food. FDA may also conduct sporadic audit examinations, which may include some sampling, to verify your compliance with VQIP. FDA laboratories will schedule sample analyses to ensure that a VQIP food sample receives priority over non-

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VQIP food samples collected during the investigation, to the extent possible in accordance with public health priorities.

A.6 Will FDA work with CBP to facilitate resolution of entry-related matters for VQIP foods under CBP's control?

FDA will work with CBP to provide expedited entry for VQIP foods. If you encounter an entry delay by CBP and you believe FDA can help to facilitate a resolution with CBP, you may contact the FDA VQIP Importer Help Desk for assistance. (See Question A.1.)

B. Importer

B.1 Who can participate in VQIP?

You must be a food importer to participate in VQIP. For the purposes of VQIP, importer is defined as the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States (section 806(g) of the FD&C Act). A VQIP importer can be located outside the United States. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record, provided that the importer can meet all the criteria for participation described in this guidance.

B.2 Must I be the importer of record to be a VQIP importer?

CBP defines the importer of record for a food as the person or firm responsible for making entry and payment of import duties, fees, and taxes for the food. Under 19 U.S.C. 1484(a)(2)(B), the importer of record can be the owner or purchaser of the food or, when designated by the owner, purchaser, or consignee, a broker licensed by CBP. As a VQIP importer you may also be, but are not required to be, the CBP importer of record.

B.3 Is the VQIP importer the same as an importer under other FDA regulations applicable to importers of food?

The VQIP importer may be, but is not necessarily, the same as an importer as defined in the Foreign Supplier Verification Program (FSVP) regulations² or the juice and seafood hazard analysis and critical control point (HACCP) regulations. For the purposes of this guidance, the FSVP or HACCP importer means the importer who, for a specific food, is subject to the importer requirements in FDA's FSVP regulations, when finalized, (proposed 21 CFR part 1, subpart L) or the requirements applicable to importers in the

² The proposed FSVP regulations and supplemental proposed FSVP regulations were published in the *Federal Register* on July 29, 2013 (78 FR 3646) and September 29, 2014 (79 FR 58573), respectively. The final FSVP regulations are expected to publish in early November 2015. The requirements of FDA's FSVP regulations apply on the applicable compliance date specified in the final regulation.

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juice or seafood HACCP regulations (21 CFR 120.14 and 123.12, respectively). Under both the proposed FSVP and the HACCP importer regulations, the importer is the owner or consignee at the time of entry into the United States or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States (proposed 21 CFR 1.500 (FSVP)); 21 CFR 120.3(h) (juice HACCP); and 21 CFR 123.3(g) (seafood HACCP)). An FSVP or HACCP importer must be located in the United States. When the FSVP or HACCP importer for a food is a U.S. agent or representative for the foreign owner or consignee, the U.S. agent or representative is responsible for meeting the FSVP or HACCP requirements with respect to that food.

However, as stated in Question B.1, a VQIP importer does not have to be located in the United States. If you are a VQIP importer that is located in the United States, you may also be the FSVP or HACCP importer. If you are a VQIP importer who is also the FSVP or HACCP importer for the food, you should meet the requirements of the applicable FSVP regulations, when finalized, or HACCP regulations. Otherwise, you should ensure that the applicable requirements are met by the FSVP or HACCP importer. (See Question C.1, number 6.)

C. Eligibility

C.1 What are the eligibility criteria for participation in VQIP?

To be eligible to participate in VQIP, you should meet all of the following criteria, some of which are discussed in more detail in questions cross-referenced in a particular criterion:

1. You have at least a 3-year history of importing food into the United States. Your import history is based on importation of all foods, including food that may not be covered under VQIP.
2. You have a Data Universal Numbering System (DUNS) number. (See Questions E.3 and E.4.)
3. You use paperless filers/brokers who received a passing rating during their last FDA Filer Evaluation. (See Question E.10.) The filer/broker is the person responsible for (1) submitting entry and entry summary data on the food into the Automated Commercial System (ACS) or Automated Commercial Environment (ACE) and submitting import documents into the International Trade Auxiliary Communication System (ITACS) or through CBP's Document Imaging System (DIS).
4. No food you import, including a food you do not intend to include under VQIP, is subject to an import alert or Class 1 recall.
5. Neither you nor the non-applicant entities associated with a VQIP food are subject to an ongoing FDA administrative or judicial action (e.g., Import Alert, injunction, and debarment), or have a history of significant noncompliances relating to food safety (e.g., an "Official Action Indicated" (OAI) FDA inspection classification with no documentation of appropriate corrective actions; one or more voluntary Class 1 recalls relating to food safety). "Non-applicant entities"

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- are those entities associated with a VQIP food that conduct activities throughout the supply chain necessary for ensuring that the eligibility requirements of VQIP are met. Non-applicant entities associated with a VQIP food include, but are not limited to, the FSVP or HACCP importer of the food (if other than you), the foreign supplier of the food, and the filer/broker.
6. If you are the FSVP or HACCP importer for a VQIP food, you are in compliance with the supplier verification and other importer responsibilities under the applicable FSVP, juice HACCP, or seafood HACCP regulations. If you are not the FSVP or HACCP importer for a VQIP food, you identify the FSVP or HACCP importer for the food and ensure that the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations.
 7. You have a current facility certification for each foreign supplier of food you intend to import under VQIP. (See Question D.1.)
 8. You develop and implement a VQIP Quality Assurance Program (QAP). Documentation of your QAP must be submitted with your VQIP application. (See Section F.)
 9. Within the past 3 years, you have not been the subject of any CBP penalties, forfeitures, or sanctions that are related to the safety and security of any FDA-regulated product that you imported or offered for import. (See <http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap47-sec1001.pdf> for information about the types of fines and penalties levied by CBP.)
 10. You pay the annual VQIP user fee before October 1 of the year in which you intend to participate. (See Question J.3.)

C.2 May I obtain the food I import under VQIP from any foreign supplier?

Yes. You may obtain the food you import under VQIP from any foreign supplier, provided the foreign supplier has a current food facility certification issued by a third-party auditor/certification body accredited under section 808 of the FD&C Act and in accordance with FDA's third-party accreditation regulations, when finalized. For the purposes of VQIP, the foreign supplier will be the same as in the FSVP regulations, when finalized.

C.3 Why should I have at least 3 years of experience importing food into the United States to participate in VQIP?

FDA believes 3 years of food import history is the minimum needed to adequately evaluate your application for participation in VQIP. FDA will review the history for all food you imported into the United States during the past 3 years, not just the food you wish to import under VQIP. If you have imported food for more than 3 years, we may extend our review to additional years as necessary to adequately evaluate your compliance history. For example, if you have infrequently imported foods for 5 years, we may review your entire 5-year import history. Also, for example, if we find violations relating to the food, foreign supplier, or importer during the past 3 years, we may review

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more than 3 years of your import history to evaluate your follow-up actions for achieving compliance.

C.4 Should I be a participant in CBP's Customs-Trade Partnership Against Terrorism (C-TPAT) program to be eligible to participate in VQIP?

Participation in C-TPAT is not directly linked to participation in VQIP. However, FDA encourages you to participate in C-TPAT to ensure the food you import under VQIP also receives entry benefits provided by CBP under C-TPAT. (See Question F.2, V. Food Defense Policies and Procedures.)

D. Foreign Supplier Facility Certification

D.1 What certification for a foreign supplier do I need to have?

Under section 806(d) of the FD&C Act, you must have a facility certification issued consistent with section 808 of the FD&C Act regarding accreditation of third-party auditors for each foreign supplier's facility from which you want to import a food under VQIP. The foreign supplier's facility must have a facility certification, which would be issued following a regulatory audit conducted by a third-party auditor/certification body accredited under FDA's third-party accreditation regulations (accredited auditor/certification body), when finalized. Either you or the foreign supplier may request the regulatory audit required for facility certification.

D.2 What is a facility certification?

A facility certification is an attestation, issued by an auditor/certification body which has been accredited in accordance with FDA's third-party accreditation regulations, after conducting a regulatory audit and any other activities necessary to establish that a facility meets the applicable requirements of the FD&C Act. All food manufactured or processed at the facility or grown on a farm for which a facility certification is issued are within the scope of the facility certification.

D.3 What is a regulatory audit?

A regulatory audit, for purposes of VQIP, is an audit of a foreign supplier's facility by an accredited third-party auditor/certification body, in accordance with FDA's third-party accreditation regulations. The results of the audit are used to determine whether a foreign supplier is eligible for a facility certification, as described in Question D.2.

D.4 Can I import a raw agricultural commodity under VQIP?

Yes, you can import a raw agricultural commodity under VQIP. You must have a current facility certification for the farm. (See Question D.1.) You should include in your VQIP

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application the certification number assigned by the accredited third-party auditor/certification body who issued the facility certification.

D.5 Must I include a copy of the foreign supplier's facility certification in my VQIP application?

No. However you must provide the certification number assigned by the accredited auditor/certification body who issued the facility certification. FDA will use the certification number you provide in your application to verify there is a current foreign supplier facility certification.

D.6 How often must a foreign supplier's facility from which I import food under VQIP be re-certified?

Under section 808(d) of the FD&C Act, to maintain eligibility for importation under VQIP, the foreign supplier of a VQIP food must obtain re-certification annually. Further, under FDA's proposed third-party accreditation regulations, an accredited auditor/certification body may issue a certification for a term of up to 1 year, but the accredited auditor/certification body would have the discretion to issue the certification for a shorter term (proposed 21 CFR 1.652(b)(1)). Although FDA anticipates that most foreign supplier facility certifications will have a term of 1 year, an accredited auditor/certification body may find it appropriate in some circumstances to issue the certification for a shorter term (e.g., based on seasonal productions). This may require the facility to be re-audited and re-certified more frequently (e.g., when there are multiple seasonal productions during a year).

D.7 What should I do if a foreign supplier's facility certification expires during the VQIP fiscal year?

You are responsible for ensuring that all foreign supplier facility certifications provided in your VQIP application are current and, therefore, you should ensure that you update your application with a current certification before the expiration. You should coordinate with your foreign supplier to ensure a third-party regulatory audit is conducted and a current facility certification is issued before the expiration of the certification you provided in your VQIP application. You should update your VQIP application with the current certification number. FDA will initiate revocation of your participation in VQIP if you import under VQIP a food that is not covered by a current facility certification. (See Question K.1.) If you determine you will no longer import a food under VQIP after the certification for the facility producing the food expires, you should remove the food from your VQIP application when the certification expires.

E. VQIP Application

E.1 How do I submit an application to participate in VQIP?

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To submit an application to participate in VQIP, you will:

- a. Establish an online account on the FDA Industry Systems Web site at www.access.fda.gov. The information in your online account will auto-populate into your VQIP application. You can update or change information in your online account at any time.
- b. Between January 1 at 12:00 a.m. EST and May 31 at 11:59 p.m. EST, submit, online, a Notice of Intent to Participate in VQIP and your application to participate in VQIP during the next fiscal year, beginning October 1 (section 806(c) of the FD&C Act).

Additional information on completing and submitting a VQIP application is provided in Section G and Appendix 1.

E.2 What information will I need to complete my VQIP application?

The VQIP application is divided into Sections A-G as follows:

- Section A. Applicant and Firm Information
- Section B. Foreign Supplier Verification Program (FSVP) Responsible Contact
- Section C. VQIP Quality Assurance Program
- Section D. Filer/Broker Information
- Section E. Foreign Supplier Facility and Products
- Section F. Comments
- Section G. Review Application

To complete your application, you will need information to accurately fill in the fields in each section of the online VQIP application. You will also need to attach your QAP and a product label for each food for which you are applying for VQIP participation.

E.3 What is a DUNS number?

The DUNS number is a unique nine-digit identification number provided by the company Dun & Bradstreet (D&B). Upon request, D&B will assign a DUNS number for each physical location of a business.

E.4 How may I obtain a DUNS number?

You may obtain a DUNS number by contacting D&B at 866-705-5711 or via e-mail to govt@dnb.com. All entities doing business with the U.S. government can receive a DUNS number free of charge and, under normal circumstances, within a few business days when using the D&B Web site.

E.5 How is a DUNS number used in my VQIP application?

For VQIP, FDA will use the DUNS number as the unique identifier for your specific location and for each non-applicant entity listed in your VQIP application (e.g., foreign suppliers, filers/brokers, and FSVP and HACCP importers). You will provide your

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DUNS number in your application. In addition, you will enter the address or DUNS number for each non-applicant entity listed in your VQIP application. If you enter the address, the system will auto-populate the DUNS number, if available. If you enter the non-applicant entities' DUNS numbers, the system will auto-populate the address fields.

E.6 How long will my draft application be maintained in the VQIP application system?

FDA will maintain your draft application in the online VQIP application system for 2 years after the last date that you saved the draft. After you complete and submit your application, a draft will no longer be available.

E.7 Will I be informed of FDA changes to the status of my VQIP application?

Yes. FDA will send an email to the contact person provided in your VQIP application when the status of your application changes. Also, you may check the status of your application on your VQIP Application home page. The status will be indicated as one of the following, as applicable:

- Draft, Not Submitted
- Submitted
- Approved
- Disapproved
- Notice of Intent to Revoke
- Notice of Revocation
- Revoked

E.8 Do I need to resubmit my VQIP QAP each year that I apply for VQIP?

No. You do not need to resubmit your VQIP QAP each year that you submit a VQIP application if there are no changes to the QAP last submitted to the Agency. However, you should ensure that your QAP is current and promptly submit updates to your VQIP QAP food safety and food defense policies and procedures as you make changes throughout the VQIP year. As part of the application process, you will confirm that your QAP is current.

E.9 How can I obtain information for determining my filer/broker's compliance status with FDA?

The FDA Filer Evaluation Program monitors the accuracy of entry data transmitted electronically to FDA by filers/brokers. The best way to determine the status is to build a relationship with the filer/broker. They can provide you with the latest FDA evaluation results. You may also obtain information about a filer/broker's compliance status from FDA Filer Evaluation Outcomes at <http://www.fda.gov/ForIndustry/ImportProgram/ucm282834.htm>.

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E.10 Can I use a filer/broker whose compliance status is not on the FDA Filer Evaluation Outcomes list?

No. A filer/broker who is not listed on FDA Filer Evaluation Outcomes list has not been evaluated by FDA. If your filer/broker has not been evaluated by FDA when you apply for your application, you or the filer/broker may request FDA to conduct a filer evaluation. The results of the evaluation will be included in the list of FDA Filer Evaluation Outcomes after FDA completes the evaluation. If the filer/broker received a passing rating for its FDA Filer Evaluation, you may use the filer/broker for VQIP entries.

F. VQIP Quality Assurance Program

F.1 What is a VQIP Quality Assurance Program (QAP)?

Your VQIP QAP is a compilation of the written policies and procedures you will use to ensure adequate control over the safety and security of the foods you import. Your QAP is part of your VQIP application. (See Question E.8).

F.2 What should be included in my VQIP QAP?

Your VQIP QAP should include the following components, as applicable:

I. Table of Contents

Provide a Table of Contents that lists the information included in your VQIP QAP.

II. Corporate Quality Policy Statement

Provide the corporate quality policy statement relating to food safety and security throughout the supply chain. Explain how the quality policy is communicated to all employees throughout the organization and to non-applicant entities involved in implementing your VQIP QAP. Describe how you will ensure that employees and non-applicant entities receive and understand the corporate quality policy statement.

III. Organizational Structure and Functional Responsibilities

Provide an organizational chart or written explanation of the management structure of your organization. Include the management structure for your VQIP QAP. Provide a written explanation of the functional responsibilities for individuals within your organization involved in developing, implementing, and maintaining your VQIP QAP, including the name and title of the individual who has responsibility for administering your VQIP QAP.

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Identify the functional responsibilities of the non-applicant entities needed to implement your VQIP QAP and how those responsibilities are communicated from your organization to those entities (e.g., contracts). For example, identify your foreign supplier's responsibility relating to conducting a recall of a non-compliant imported food distributed in the United States.

IV. Food Safety Policies and Procedures

Establish policies and procedures you will implement to ensure food safety from source to entry (e.g., temperature and storage controls). Include policies and procedures documents in your VQIP QAP, as follows:

- If the food is subject to the FSVP or HACCP importer regulations and you are the FSVP or HACCP importer, provide a statement affirming you have established procedures to ensure compliance with applicable FSVP or HACCP regulations.
- If the food is subject to the FSVP or HACCP importer regulations and you are not the FSVP or HACCP importer, include procedures for ensuring the FSVP or HACCP importer is in compliance with the applicable FSVP or HACCP regulations.
- Provide written procedures for maintaining current foreign supplier certifications required under section 806(d) of the FD&C Act and any applicable food certifications required under section 801(q) of the FD&C Act.
- Provide written procedures for communicating information to FDA and others (e.g., non-applicant entities, consumers) relating to food and foreign supplier non-compliances that pose a risk to public health. Identify the scope of communications that will be limited to within the organization, and the criteria for, as appropriate, communicating non-compliances to your foreign supplier and other regulatory authorities (e.g., U.S. Federal, State, and local authorities and foreign authorities).
- Provide written procedures for corrective actions to address food and foreign supplier non-compliances that pose a risk to public health. Include procedures to trace and track non-compliant food, to prevent further distribution of the food, and to initiate recall if necessary. Also include procedures for working with a non-compliant foreign supplier to correct the problem, criteria for discontinuing use of a foreign supplier, and procedures to identify alternate suppliers for a food.

V. Food Defense Policies and Procedures

Provide a written description of your food defense system. You should provide your procedures for ensuring your foreign supplier's food defense system is in compliance with FDA's Focused Mitigation Strategies to Protect Food Against Intentional Adulteration regulations (intentional adulteration regulations), when finalized (proposed

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21 CFR part 121).³ In addition, you should provide your procedures for controlling the safety and security of each VQIP food throughout the transportation supply chain. If your food defense system includes participation in CBP's C-TPAT (Level 2 or Level 3) and you acknowledge your participation in C-TPAT in your application, you do not need to provide additional information regarding your transportation food defense procedures.

VI. Experience and Training

Identify the experience and training requirements for employees responsible for implementing the VQIP QAP. Include:

- Requirements relating to knowledge of the FD&C Act and implementing regulations that apply to the foods and the foreign suppliers of foods you import under VQIP (e.g., current good manufacturing practices (CGMPs), FSVP, preventive controls, juice HACCP, seafood HACCP, low-acid canned food, intentional contamination, sanitary transport, and food labeling), and
- The qualifications, knowledge, skills, and training required for each employee who has responsibilities relating to developing, implementing, and maintaining the QAP.

VII. QAP Implementation

Provide your procedures for ensuring your VQIP QAP is current and appropriately implemented, including procedures for auditing and updating the QAP and for providing updates to the QAP in your VQIP application.

VIII. Records

Provide your written procedures for establishing and maintaining records relating to the structure, processes, procedures, and implementation of your VQIP QAP. Your procedures should specify that all written records relating to establishing and maintaining your QAP are to be legible, in English, and made available to FDA upon request.

- The QAP structure, processes, and procedures documents:
 - Should be signed and dated by the individual who has overall responsibility for the QAP.
 - Should indicate their effective date.
 - Should be maintained for as long as they are in effect.
- The records you establish and maintain to implement your QAP:
 - Should be signed and dated by the responsible individual, as indicated in your QAP.

³ The proposed intentional adulteration regulations were published in the *Federal Register* on December 24, 2013 (78 FR 78013). The requirements of FDA's intentional adulteration regulations apply on the compliance date for the published final regulations.

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- Should be maintained for at least 2 years after they are created.

IX. Definitions

Define terms used in your VQIP QAP, as necessary to facilitate understanding and implementation of the QAP.

X. References

Provide references to information or sources used to develop and implement your QAP, as appropriate.

G. Application Period and VQIP Fiscal Year

G.1 When do I submit my VQIP application?

You can submit your VQIP application between January 1 at 12:00 a.m. Eastern Standard Time (EST) and May 31 at 11:59 p.m. EST.

G.2 Do I need to submit a new VQIP application each year?

Yes. You must submit an application for each fiscal year you want to participate in VQIP. However, the online VQIP application system is designed to allow you to use data from the previous year's application to populate your new application. Prior to beginning the process of submitting a new application for a subsequent year, if you intend to cut-and-paste from your current application, you should ensure that your current application is up-to-date (i.e., you have submitted all mandatory amendments that apply to your current application). When you create your new application for a subsequent year, you can add new foods and the required information relating to the new foods. (See Appendix 1.)

G.3 Will FDA send VQIP participants a reminder to submit an application for the next VQIP year?

Yes. During December of each year, FDA will send participating VQIP importers an email reminder to submit a Notice of Intent and a new application if they intend to participate in VQIP during the next fiscal year. The email will state the timeframe for the submissions. FDA will send the email reminder to the contact person identified in the participant's application.

G.4 Will my VQIP application be kept confidential by FDA?

We will protect confidential information in your VQIP application from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20. Your application will be shared with other

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government agencies, such as CBP. This will allow CBP to recognize VQIP applicants and the products they offer for entry into the U.S. This will be done in accordance with applicable statutes and regulations.

H. FDA VQIP Application Review

H.1 How will FDA review my VQIP application?

FDA will review your application for completeness and data accuracy and will evaluate your eligibility for VQIP. FDA will review your compliance history and the compliance history of all foods and foreign suppliers listed in your VQIP application and all non-applicant entities associated with the import transaction within the supply chain for each food, including your filers/brokers. FDA will also review your QAP to evaluate whether you are adequately controlling factors relating to the safety and security of the food you intend to import under your VQIP. If you are a C-TPAT participant, FDA may use CBP audit reports to determine whether CBP has identified food defense concerns relating to your import entries and ensure that you have implemented the transportation food defense policies and procedures in your QAP. If you are not in good standing with C-TPAT, we will consider whether factors relating to your C-TPAT participation status affect your eligibility for VQIP. In addition, FDA will review the labels of all your VQIP foods to determine compliance with FDA's food labeling regulations.

H.2 Will FDA inform me of the reasons for disapproval if my application is not approved?

Yes. During FDA review of your application, if we identify deficiencies which you may be able to readily correct during the application period, we will permit you to correct the deficiencies. However, if corrections are not made or FDA otherwise determines that you are not eligible to participate in VQIP, we will disapprove your application and inform you of the reasons for the disapproval.

H.3 What are some reasons for FDA disapproval of my VQIP application?

Some reasons for FDA disapproval of your application include:

- Your application is incomplete;
- Your QAP is inadequate (e.g., your policies and procedures do not ensure that food safety requirements are met);
- You do not meet one or more of the VQIP eligibility requirements (see Question C.1) and you do not provide an adequate alternative or justification;
- You provide inaccurate data or information; or
- You make false or fraudulent statements in your application.

H.4 Will FDA conduct an inspection before I receive VQIP benefits?

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FDA ordinarily will conduct a VQIP inspection after your application is approved and prior to October 1 of the first year that you participate in VQIP. However, if FDA does not complete the VQIP inspection prior to October 1, when the VQIP year begins, receipt of VQIP benefits will not be delayed pending that inspection, unless FDA's inspection is significantly delayed or prevented because of actions or omissions by the VQIP importer or by restrictions in travel that prevent FDA inspection of a foreign VQIP importer (e.g., Department of State restrictions, safety concerns).

H.5 What is the purpose of the VQIP inspection?

FDA will conduct a VQIP inspection to verify that you meet the VQIP eligibility requirements and have fully implemented the food safety and food defense systems established in your QAP. FDA will notify you in writing regarding results of the inspection.

H.6 What additional information may FDA ask me to submit during Agency review of my VQIP application?

FDA may ask you to submit additional documentation to support your application. For example, if you are the FSVP or HACCP importer, FDA may request a copy of the risk evaluation required under FSVP for a food listed on your VQIP application or the results of any laboratory tests used to comply with FSVP or HACCP regulations for a food listed on your VQIP application. If you are not the FSVP or HACCP importer, FDA may request you to obtain the information from that importer.

H.7 How will FDA contact me if the Agency needs additional information to support my VQIP application?

If FDA needs additional information about your application, we will send an email to the contact person listed in your application.

H.8 How often will FDA evaluate me for VQIP eligibility?

The first year that you submit a VQIP application, FDA will review all aspects of your application and conduct an inspection to verify your eligibility and to ensure you are implementing the food safety and food defense systems stated in your QAP. Thereafter, we will reevaluate your eligibility at least once every 3 years that you participate in VQIP (section 806(e) of the FD&C Act). An event such as an outbreak or recall linked to a food included in your VQIP application (or a similar food), a new hazard associated with a VQIP food, or intelligence data related to violations associated with one or more entities (e.g., foreign supplier, filer/broker) listed on your VQIP application may prompt FDA to reevaluate your eligibility, including conducting an inspection, more frequently than once every 3 years. In addition, FDA will review and evaluate changes to your application as needed, including changes you make when you submit a new application.

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I. VQIP Application Amendments

I.1 What amendments to my VQIP application should I make after the application is approved to ensure that I maintain eligibility to participate in VQIP?

To maintain your eligibility in VQIP (see Question C.1), you should promptly amend your VQIP application to provide information or documentation when you take the following actions:

- Remove a food listed on your VQIP application that is subject to an ongoing FDA administrative or judicial action (e.g., Import Alert, seizure);
- Remove a foreign supplier listed on your VQIP application who is the subject of an ongoing FDA administrative or judicial action (e.g., Import Alert, injunction, suspension of registration);
- Remove an FSVP or HACCP importer of a food who is the subject of an ongoing FDA administrative or judicial action (e.g., Import Alert, debarment);
- Remove a filer/broker who does not meet the VQIP filer/broker requirements;
- Provide updates to your QAP food safety or food defense policies or procedures (see Question F.2 regarding Food Safety Policies and Procedures and Food Defense Policies and Procedures);
- Remove a food label that is no longer applicable to a food and add a new food label;
- Provide a current facility certification issued by an accredited auditor/certification body; and/or
- Provide information or documentation requested by FDA to correct deficiencies.

I.2 What amendments am I permitted to make to my VQIP application for business purposes during the VQIP year?

As necessary for your business purposes, you can amend your VQIP application to add or remove a filer/broker, to add or remove a label for a food already in your VQIP program, or to remove a food, the foreign supplier of a food, or the FSVP or HACCP importer for a food. You also may replace the foreign supplier or FSVP or HACCP importer for a food that is already listed in your VQIP application.

I.3 What changes to my VQIP application are not permitted during the VQIP year?

During the VQIP year, you will not be able to amend your application to add an additional food. A new food to be covered by VQIP can be added only when you submit your VQIP application for the subsequent VQIP year.

I.4 What are the consequences if I do not submit to FDA changes I make to the food safety and food defense policies and procedures in my VQIP QAP?

If FDA determines you made changes to your QAP food safety or food defense policies and procedures without promptly revising the QAP in your application, depending on the

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nature of the changes, FDA may initiate revocation of your participation in VQIP. (See Question K.1.)

J. VQIP User Fees

J.1 Must I pay a user fee to participate in VQIP?

Yes. Section 743 of the FD&C Act (21 U.S.C. 379j-31) requires that each importer participating in VQIP pay a fee to cover FDA's costs of administering the program. FDA will charge the VQIP user fee on an annual basis for each VQIP year that you are approved to participate in VQIP. You must pay the user fee by October 1, the start of the VQIP year.

J.2 What will happen if I do not pay the VQIP user fee before October 1?

If you do not pay the user fee before October 1, you are not eligible to participate in VQIP. For the first year your VQIP application is approved, if you do not pay the user fee before October 1, your VQIP benefits will not begin on October 1. If you subsequently pay the user fee, FDA will begin your benefits after we receive the payment. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP. (See Question K.1.)

J.3 If I withdraw from VQIP or FDA revokes my participation in VQIP, will I receive a refund for the VQIP user fee?

No. The VQIP user fee will not be refunded for any reason.

J.4 Where can I locate VQIP user fee rates for current and past fiscal years?

On or before August 1 each year, FDA will publish a *Federal Register* notice announcing the VQIP user fee schedule for the next VQIP year. Current and past VQIP year user fee rates can also be found at [insert link to FDA web page on user fees].

K. Revocation of VQIP Participation

K.1 Can FDA revoke my participation in VQIP?

Yes. FDA may:

- Revoke your participation in VQIP based on evidence that you do not meet one or more of the VQIP eligibility requirements (see Question C.1), or
- Immediately revoke your participation in VQIP based on evidence that you participated in smuggling or other fraudulent activities (see Question K.3).

Revocation of your participation in VQIP will apply to all foods you import under VQIP.

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K.2 How will FDA notify me of a potential revocation of my participation in VQIP?

If FDA has credible evidence that you do not meet one or more of the VQIP eligibility requirements, FDA will send a Notice of Intent to Revoke your participation in VQIP by email to the contact person identified in your VQIP application. The Notice of Intent to Revoke will explain the basis for the proposed revocation. The Notice of Intent to Revoke will indicate that, within 30 days of the date of the Notice of Intent to Revoke, you must make corrections and provide FDA with evidence of the corrections. Benefits will continue for those 30 days unless FDA believes there is a risk to public health. If all corrections cannot be made within 30 days, you can submit a corrective action plan that includes detailed steps and a timeline for correction. If you do not respond or you do not submit an adequate corrective action plan within 30 days, FDA will revoke your participation in VQIP. FDA will send a Notice of Revocation by email to the contact person identified in your VQIP application. Revocation of benefits will be effective on the date on which FDA sends the Notice of Revocation email. You may seek reinstatement after revocation in these circumstances. (See Section L.)

If FDA obtains credible evidence that you participated in smuggling or other fraudulent activities, FDA will immediately revoke your participation in VQIP. Examples of activities that may lead to immediate revocation include declaring an entry as a VQIP food when it is not or otherwise attempting to smuggle a product into the United States. In such cases, FDA will send a Notice of Immediate Revocation to the contact person listed in your application. The Notice of Immediate Revocation will identify FDA's reason for immediately revoking your participation in VQIP. If you believe revocation was in error, you may contact FDA upon receipt of the notice. Your VQIP participation and, thus, VQIP benefits will stop for all of your VQIP foods on the day that FDA sends the Notice of Immediate Revocation. FDA will not reinstate your participation in VQIP for the remainder of the VQIP year. FDA will not approve your VQIP applications for subsequent years, unless you provide sufficient evidence of affirmative steps to ensure that fraudulent activity does not occur again. Additionally, revocation of VQIP participation does not prevent the Agency from taking other enforcement actions, if warranted.

K.3 How might FDA learn of deviations that impact my participation in VQIP?

FDA may obtain information relating to a potential deviation from the criteria for your VQIP participation through FDA activities (e.g., an FSVP inspection of a VQIP participant) or from other sources. FDA will review information obtained to determine whether a deviation exists and, if so, whether the nature and scope of the deviation warrants the revocation of your VQIP eligibility. Sources from which FDA may obtain information relating to potential deviations include:

- You or other VQIP participants
- FSVP and HACCP importers
- Filers/brokers

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- Recall data and reportable food registry data
- FDA inspection reports and laboratory analytical results
- Third-party auditors
- Foreign suppliers
- Other regulatory government agencies (e.g., CBP, U.S. Department of Agriculture, States, foreign regulatory authorities)

K.4 If I encounter a problem with a VQIP food or a foreign supplier, what action should I take to avoid revocation?

Your participation in VQIP is based on your ability to maintain a high level of control over the safety and security of your supply chain for the foods you import under VQIP. You are responsible for promptly reporting to FDA all deviations that may impact your eligibility to participate in VQIP and your plans for correcting the deviations. Your VQIP QAP should include procedures for taking prompt corrective actions, for updating your procedures as necessary to prevent future occurrences of the problem, and for notifying FDA. (See F. VQIP Quality Assurance Program.)

K.5 If my VQIP participation is revoked, will I lose benefits provided by other Federal importer programs in which I participate?

Decisions relating to a loss of benefits or revocation from other Federal importer programs, such as CBP's C-TPAT program, will be made by the agency that oversees the program. However, in the interest of FDA's continued collaboration with our Federal partners, FDA will share VQIP revocation information with other Federal agencies, when appropriate, in accordance with applicable statutes and regulations.

L. Reinstatement of VQIP Participation

L.1 How can I obtain reinstatement of my participation in VQIP or VQIP benefits after a revocation?

When revocation is based upon evidence that you do not meet one or more of the VQIP eligibility requirements, you may request FDA to reinstate your VQIP participation and VQIP benefits at any time after you have corrected the deviations associated with your revocation. Your request should include documentation of actions you have taken to correct or resolve all of the deviations. The following are examples of information you might submit to support your request for reinstatement:

- If you have been subjected to CBP penalties, forfeitures, or sanctions within the past 3 years, you may need to provide documentation that you have made all necessary corrections and have settled the matter with CBP.
- If you used a filer/broker who was not in good standing with FDA, you may need to:
 - Document that the filer/broker received additional training to ensure improvements in the information submitted to FDA on your behalf,

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- Use a new filer/broker that is in good standing with FDA, or
- Revise your QAP to establish procedures to ensure that you use only filers/brokers that are in good standing with FDA.
- If you used a foreign supplier who did not have a valid facility certification, you may need to remove the foreign supplier and foods received from the foreign supplier from your VQIP application and revise your QAP as necessary to ensure that you maintain current certifications for your foreign suppliers.
- If your revocation is based on a food safety deviation by the foreign supplier, and documentation alone (e.g., revised SOPs, revised HACCP plans, batch records) is not sufficient to show that the foreign supplier has adequately corrected the food safety deviation, you may need to obtain a new third-party facility certification of the foreign supplier.
- If your QAP is deficient or outdated, you may need to document appropriate revisions to address the deficiencies and update your VQIP application with applicable revisions to your QAP.

FDA will review your request for reinstatement as soon as possible after it is received. Prior to approving your reinstatement, FDA will verify whether you have implemented the appropriate corrective actions. FDA may verify your corrective actions by conducting an inspection or by reviewing your documentation of the corrective actions, whichever is appropriate. If your VQIP benefits are not reinstated during the fiscal year in which they are revoked, you may apply for VQIP for the next fiscal year by submitting a new application during the application period. Your application should include documentation of action taken to correct or resolve the basis for your ineligibility that caused the revocation.

FDA will not reinstate your participation in VQIP if your participation was immediately revoked based on evidence of smuggling or other fraudulent activity. (See Question J.3.)

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Appendix 1

Voluntary Qualified Importer Program

VQIP Application

To participate in VQIP, you will need electronic access to FDA's Industry Systems Web site <http://www.access.fda.gov>. Under the "Voluntary Qualified Importer Program" section, you will need to set up a "User Account." During the VQIP application period (i.e., January 1 - May 31 prior to the October 1 beginning of the VQIP fiscal year), you will log on to the "Voluntary Qualified Importer Program" to:

- Submit a Notice of Intent to Participate in VQIP
- Submit a VQIP application

You should gather the information you will need prior to beginning each process. All information submitted will need to be in English.

Note that you do not have to complete the application in one sitting. You may use the "Save to Draft" button to save a partially completed application. You should also "Save to Draft" often as you enter information in the application.

1. VQIP User Account

When you set up your VQIP User Account, you will create a User ID and Password. You will use your User ID and Password for future log in to your VQIP User Account and to the "Voluntary Qualified Importer Program." The information you provide in your VQIP User Account will be used to auto-populate similar fields in your VQIP application. You will need to provide the following information to establish your VQIP User Account:

- Contact information
 - Name
 - Phone number
 - Email
- Firm information
 - Firm name (legal business name and any other names under which you conduct your business.)
 - DUNS number (field will autopopulate if the address is provided)
 - Address, includes street address, city, zip code, country, state/province (field will autopopulate if the DUNS number is provided)
 - Phone number
 - Fax number (if available)
 - Email address
 - Web address (if available)

You may log on and update information in your VQIP User Account at any time.

2. Notice of Intent to Participate in VQIP

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To submit a Notice of Intent to participate in VQIP, you will need your User ID and Password. On FDA's Industry Systems Web page at <http://www.access.fda.gov>, log in to the "Voluntary Qualified Importer Program." Click on the "Notice of Intent" button to submit your Notice of Intent to Participate in VQIP.

3. VQIP Application – First Year

On FDA's Industry Systems Web page at <http://www.access.fda.gov>, log in to the "Voluntary Qualified Importer Program." Click on the "Create a New Application" button to begin creating your VQIP application. To complete your application, you will need the following information:

- User ID and password
- C-TPAT participation information (participation in C-TPAT is not a prerequisite for VQIP, but you should acknowledge any such participation)
- VQIP Quality Assurance Program (see Section F)
- Filer/broker information for each filer/broker who will submit entry documents to U.S. Customs and Border Protection (CBP) for foods you import under VQIP:
 - DUNS number (field will autopopulate if address is provided)
 - Firm name
 - Address, includes street address, city, zip code, country, state/province (field will autopopulate if DUNS number is provided)
 - Phone number
 - Fax number (if available)
 - Email address
 - Web address (if available)
 - Filer/broker code
- Foreign supplier information for each foreign supplier of food for humans or animals that you will import under VQIP:
 - DUNS number (if known)
 - Firm name
 - Address, includes street address, city, zip code, country, state/province
 - Phone number
 - Fax number (if available)
 - Email address
 - Web address (if available)
 - Foreign supplier certification number
- FSVP or HACCP importer for each food, if you are not the FSVP or HACCP importer
 - DUNS number (field will autopopulate if address is provided) Firm name
 - Address, includes street address, city, zip code, country, state/province (field will autopopulate if DUNS number is provided)
 - Phone number
 - Fax number (if available)
 - Email address

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- Web address (if available)
- Food identification information for each food:
 - FDA product code (7 characters)
 - Importer description of food (in English)
 - Food label

You may manually enter information required for each food into your VQIP application or “bulk” upload the information (i.e., provide a list of all food information and copies of all food labels). You should use the FDA templates for the bulk uploads of food information and labels. [Insert links to templates.]

After you fill in the required information in the application, prior to submitting your application, the system will provide you with a summary screen that allows you to review all of the information you provided. You will be prompted to acknowledge that you have reviewed the information and to certify that the information in the application is true and correct.

You will click on the “Submit” button to file your VQIP application with FDA. The system will acknowledge receipt of your application and will provide you with a unique application number. Use your application number in future correspondence with FDA regarding your VQIP application and to identify entries of VQIP foods. (See Question C.4.)

4. VQIP Application – Subsequent Year

If you are a VQIP participant (i.e., you are currently receiving VQIP benefits), you may submit your application to participate in VQIP for the next VQIP year as follows:

- During the VQIP application period (i.e., January 1 - May 31), log on to the “Voluntary Qualified Importer Program” at <http://www.access.fda.gov>.
- Click on the “Notice of Intent” button and submit your Notice of Intent to Participate in VQIP.
- Prior to beginning the process for creating a new application, you should ensure that your current application is accurate. Click on the “Create a New Application” button to begin the process for creating your application for the next fiscal year. You will be prompted to identify whether you intend to cut-and-paste from your current application or begin a new application and manually fill in all required fields. (See Appendix 1, Number 3.)

5. VQIP Application Amendments

You should promptly amend your VQIP application to provide information or documentation that is necessary to maintain your eligibility to participate in VQIP. (See Question C.1 and I.1.) You also may amend your VQIP application to add or remove a filer/broker; to add or remove a food label; to remove a food, the foreign supplier of a food, or the FSVP or HACCP importer for a food; or to change the

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foreign supplier or FSVP or HACCP importer for a food that is already listed in your VQIP application. (See Questions I.2 and I.3.)

When you amend your application, you will be prompted to enter a brief explanation of the reason for the amendment.