U.S. Agent Voluntary Identification System (VIS) for Food Facility Registration: Guidance for Industry

You may submit written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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U.S. Agent Voluntary Identification System (VIS) for Food Facility Registration: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) 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 as listed on the title page.

I. Introduction

The purpose of this guidance document is to announce that FDA has established a U.S. Agent Voluntary Identification System (VIS) in conjunction with our food facility registration database, the Food Facility Registration Module (FFRM).The purpose of the VIS is to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. This guidance provides information for U.S. agents and foreign facilities importing food into the U.S. who choose to utilize the VIS.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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 FDA guidances means that something is suggested or recommended, but not required.

II. Background

FDA has established the U.S. Agent Voluntary Identification System (VIS) in conjunction with our food facility registration database to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. The VIS allows a U.S. agent to directly provide FDA with their contact information and the name of the facility or facilities for which the agent agrees to serve. FDA will then provide the U.S. agent with an identification number that the agent can provide to the

[1] This guidance has been prepared by the Office of Compliance Division of Field Programs and Guidance in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

facilities that the U.S. agent agrees to represent. Foreign food facilities now have the option of providing the identification number of their U.S. agent during registration.

Under §§ 1.231(a)(5) and 1.231(b)(7)[2], after a foreign facility submits registration, FDA will verify that the person identified as the U.S. agent for the foreign facility has agreed to serve as the U.S. agent. FDA will not confirm registration or provide the foreign facility with a registration number until the U.S. agent has confirmed that the agent has agreed to serve as the U.S. agent for that facility. The VIS provides a streamlined U.S. agent verification process. When a foreign facility uses a U.S. agent identification number in accordance with the VIS and the name of the facility matches the facility name the U.S. agent has identified, FDA will consider that verification and will provide the facility with a registration number without taking any additional steps to verify the U.S. agent.

III. Questions and Answers

Question: What information will a U.S. agent need to provide to register with VIS?

Answer: The information to be collected from the U.S. agent is specified in 21 CFR 1.232(c)(1), including name, full address, phone number, email address, and emergency contact phone number. U.S. agents have the option provide the name and address of the facility or facilities for which the agent agrees to serve. Inclusion of the facility name and address will assist FDA with validating the facility/agent listing relationship.

Question: How does a U.S. agent enter information in the VIS?

Answer: The U.S. agent must first obtain an account for the FDA Unified Registration and Listing System (FURLS), where they can then obtain access to FFRM. Upon entering FFRM, the U.S. Agent can access the VIS from the main menu where they will be able to enter their information, verify the information provided, and obtain their unique U.S. agent ID number.

Question: What information will a U.S agent need to provide to foreign food facilities they agree to represent?

Answer: When a U.S. agent provides information through the VIS, FDA will issue the U.S. agent an identification number. The U.S. agent can provide this identification number to foreign facilities the agent agrees to represent. Foreign facilities will have the option to provide either the required U.S. agent identification information or the U.S. agent identification number when the foreign facilities register, update, or renew their registration with FDA. Under §§ 1.231(a)(5) and 1.231(b)(7), FDA will not confirm a foreign facility's registration or provide a registration number until the U.S. agent has confirmed that the agent has agreed to serve as the U.S. agent. If

[2] Beginning January 4, 2020, registrants must submit registrations, registration renewals, updates, or cancellations to FDA electronically, unless FDA has granted a waiver under 21 CFR 1.245 (see 21 CFR 1.231(a)(2) and (b), 1.234(d), and 1.235(d)). For more information, see *Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry.* Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition

the U.S. agent identification number and the information that the U.S. agent provides about the facility in VIS match, FDA will consider the use of the identification number as a verification under §§ 1.231 (a)(5) and 1.231(b)(7). When the confirmation notification of a foreign facility registration is sent to the facility, a confirmation will also be sent to the U.S. agent to ensure that the U.S. agent is aware of the connection with each foreign facility registration. In addition, the facility will also be listed under the U.S. agent's VIS account as a facility which they are currently representing, enabling the U.S. agent to see and verify that the agent has agreed to represent all listed facilities.

Question: What is the benefit to U.S. agents and foreign facilities to utilize the VIS?

Answer: The U.S. agent identification number can be used to facilitate verification for purposes of § 1.231(a)(5) and 1.231(b)(7). The speed with which verification can be accomplished provides an incentive for foreign facilities to use U.S. agents who have created a VIS account. The efficiency of this process allows for automatic assignment of a registration number when the U.S. agent adds the facility name and address to their profile and when the foreign facility lists the U.S agent identification number to their registration submission. Additionally, because U.S. agents would have direct access to a list of facilities identifying them as U.S. agent, they would have an incentive to use the identification system, which we anticipate will limit the number of unauthorized and/or fraudulent U.S. agent listings. U.S. agents can also electronically notify FDA that they decline to serve as or no longer serve as the U.S. agent for a foreign facility via the VIS.

Question: How will a foreign facility identify a U.S. agent who is in the VIS?

Answer: It is the responsibility of the U.S. agent to share their identification number with the facilities for whom they agree to serve as U.S. agent. FDA does not intend to publish a list of U.S. agents who are participating in the VIS. The foreign facilities have the option of providing the identification number for the U.S. agent in its registration rather than the specific U.S. agent's contact information required for food facility registrations (, name, address, email address, phone number).[3] After using the identification number, and if the foreign facility name matches a facility name the U.S. agent identified in the system, we consider the use of that identification a verification for purposes of 21 CFR 1.231(a)(5) and 1.231(b)(7). We then provide the facility with a registration number without FDA taking any additional steps to verify the U.S. agent as provided in 21 CFR 1.231(b)(6), and the U.S. agent contact information in the system will then be linked and automatically populated in the foreign facility registration. If the facility does not have the U.S. agent identification number, the facility still has the option to provide the required information (name, full address, phone number, and email address) for the U.S. agent (see 21 CFR 1.232(c)(1)).

Question: What happens if a foreign facility designates a U.S. agent that does not agree to serve as the U.S. agent or who declines the assignment?

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[3] See 21 CFR 1.232(c)(1) (requiring foreign facilities to provide the name, full address, phone number, and email address for the foreign facility's U.S. agent).

Answer: U.S. agents in the VIS system will be notified any time a foreign facility registers with FDA using their U.S. agent identification number. Although we consider the use by a foreign facility of a U.S. agent identification number to be confirmation that the U.S. agent agrees to serve in that capacity for that foreign facility when a facility name matches a facility name the U.S. agent has identified, U.S. agents can nevertheless reject the assignment via the VIS or contact FDA in the event the U.S. agent is falsely identified in a food facility registration. If the U.S. agent does not agree to serve or declines the assignment, FDA will notify the foreign facility that they will need to identify a valid U.S. agent within 30 days for the registration to be confirmed. Once a registration is confirmed and a U.S. agent has been accurately identified, the U.S. agent may decline to serve as the U.S. agent at any time. If the U.S. agent wishes to no longer serve the already-registered foreign facility, the foreign facility will have 60 calendar days to update the facility's registration with a new U.S. agent (21 CFR 1.234(a)).

Question: How often should U.S. agents update information in the VIS?

Answer:. Food facilities must update their registrations within 60 calendar days of any change to any required information, including required U.S. agent information such as the name, full address, phone number, and email address of the U.S. agent (21 CFR 1.234(a)). Because the VIS functions as the repository for U.S. agent information for a foreign facility, the U.S. agent should update required U.S. agent information in the VIS within 60 calendar days of a change to the previously-submitted information. Updates can be submitted online through the VIS. In addition, any updates to the U.S agent's information will be updated on the registration of facilities which they have agreed represent.

Question: Are U.S. agents who utilize the VIS subject to renewal requirements akin to biennial registration renewal requirements for food facilities?

Answer: No. U.S. agents who utilize the VIS do so voluntarily, and there is no requirement for renewing participation in the VIS. However, we encourage U.S. agents who use the VIS to regularly review their information to ensure it is up-to-date and to also review the facilities associated with their identification number in the VIS that they are representing. If the U.S. agent fails to update their information within 60 days of a change, FDA would consider the foreign facility registration to be out-of-date because facilities must update their registration within 60 calendar days of any change to any of the required registration information (21 CFR 1.234(a)).
Question: What is the process for U.S. agents to notify FDA if they are no longer serving as the U.S. agent for a foreign facility?

Answer: The U.S. agent may notify FDA of its intention by sending an e-mail to FURLS@FDA.gov. This e-mail should include the information previously provided on the registration form regarding the U.S. agent (i.e., name, address, phone number, email address) and the name(s) and either address(es) or registration number(s) of the facility or facilities from which the U.S. agent wishes to be removed. Alternatively, U.S. agents who have VIS accounts may decline/reject facility assignments via their VIS profile. The facility will be notified that they are no longer serving as their U.S. agent and asked to find another agent within 60 calendar days.