U.S. Food and Drug Administration Foreign Supplier Verification Programs (FSVP) Importer Portal for FSVP Records Submission User Guide

Document Version: 1.0
Version Date: June 11, 2021

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1. Creating an FDA Online Account

NOTE: Access to your OAA account must be done through one of the following browsers:

Microsoft Edge, Google Chrome, or Firefox.

An FSVP inspection must be initiated by the FDA to access the FSVP Importer Portal for FSVP Records Submission. At the start of the inspection, FDA will make initial contact with you. FDA will request the name and email address of your Top Management Official (TMO). FDA will send a system generated email notification to the TMO's email address that will include FDA's Unified Registration and Listing System (FURLS) Online Account Administration (OAA) account link and a verification code (Figure 1). Once the TMO logs into the account, they will be able to access the Form 482d Request for FSVP Records and respond with their FSVP documents.
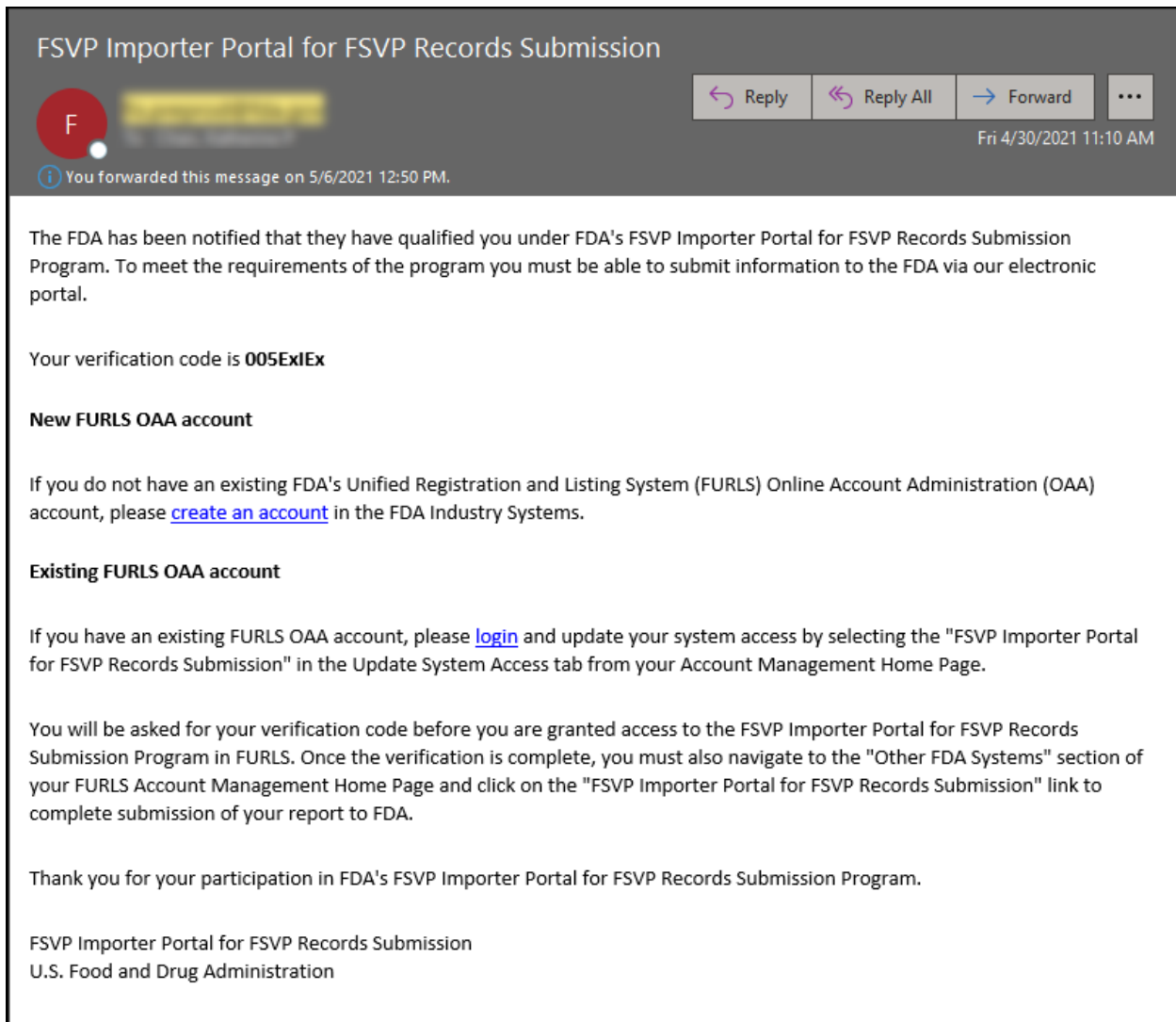
Figure 1 – System Generated Email Notification

To log into the "Online Account Administration" (OAA) system and gain access to FURLS, you will need to create an FDA online account.

To create an FDA online account, you will have two options.

Option 1: Go to https://www.access.fda.gov/oaa/. Click on the "Create New Account" button on the "Online Account Administration (OAA) FDA Industry Systems" page (Figure 2). You will be directed to the "Create New Account" page.

Figure 2 – FDA OAA Page

The system displays the "Create New Account" page (Figure 3). You will see "Step 1: Select Application(s) for Account Creation." Two radio buttons are displayed: "Yes" and "No." Note that "No" is selected by default.

Note: Leave the default value of the selected radio button as "No." The workflow created by selecting "Yes" directs you to a program that is not within the scope of this document.

Figure 3 – Create New Account – Step 1: Select Application(s) for Account Creation

The system will display various FDA programs available in OAA.

Click the "FSVP Importer Portal for FSVP Records Submission" checkbox under the "FSMA Program(s)" section (Figure 4) and continue to the next step by clicking the "Continue" button at the bottom of the page. You will be directed to the "Step 1a: Enter Verification Code for Account Creation" page.

Figure 4 – Create New Account – FSMA Program(s)

Option 2: Click on the "Create an account" link from the system generated e-mail that you received containing the verification code (Figure 1). You will be directed to the "Step 1a: Enter Verification Code for Account Creation" page.

The system will display the "Step 1a: Enter Verification Code for Account Creation" page (Figure 5).

Figure 5 – Step 1a: Enter Verification Code for Account Creation

Enter the verification code in the box and click the "Verify" button. After the code is verified you will be able to create an account for accessing the FSVP Importer Portal for FSVP Records Submission (Figure 5). Note: The email address used to receive the verification code must be used to create new account.

The system displays the "Step 2: Enter Your Account Information" screen. You will need to complete the data entry fields in the "Point of Contact Information," "Account Information," and "Physical Address (Business) of Account Holder" sections (Figure 6).

Note: All fields are required, unless indicated as "Optional."
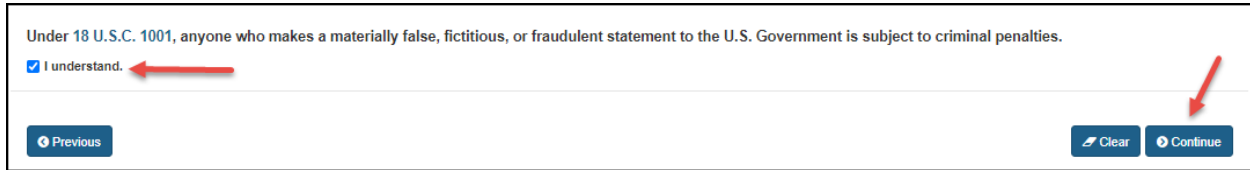
Figure 6 – Create New Account – Step 2: Enter Your Account Information

Click the checkbox for "I understand" at the bottom of the page (Figure 7). Click the "Continue" button after you enter the required account information.
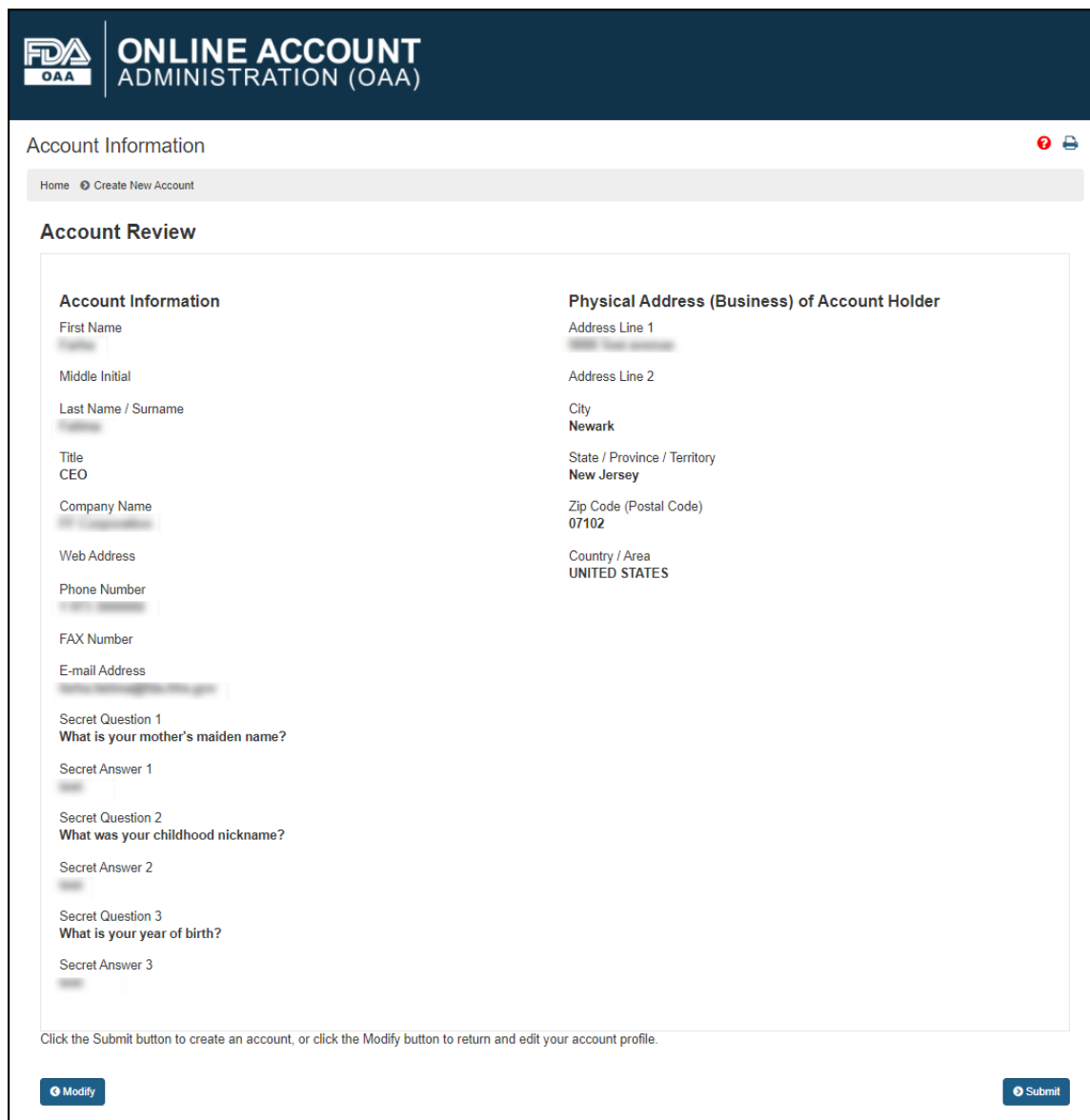
Figure 7 – Checkbox

The "Account Review" page will display (Figure 8). Review the data entered to ensure it is correct. Click the "Modify" button to edit the profile information on the previous page. Click the "Submit" button to complete the process.

Figure 8 – Account Review Page

When you click the "Submit" button, the system will display a message indicating the account was created successfully. The message displays your account ID (Figure 9). You must retain your account ID and password to log into the system in the future.
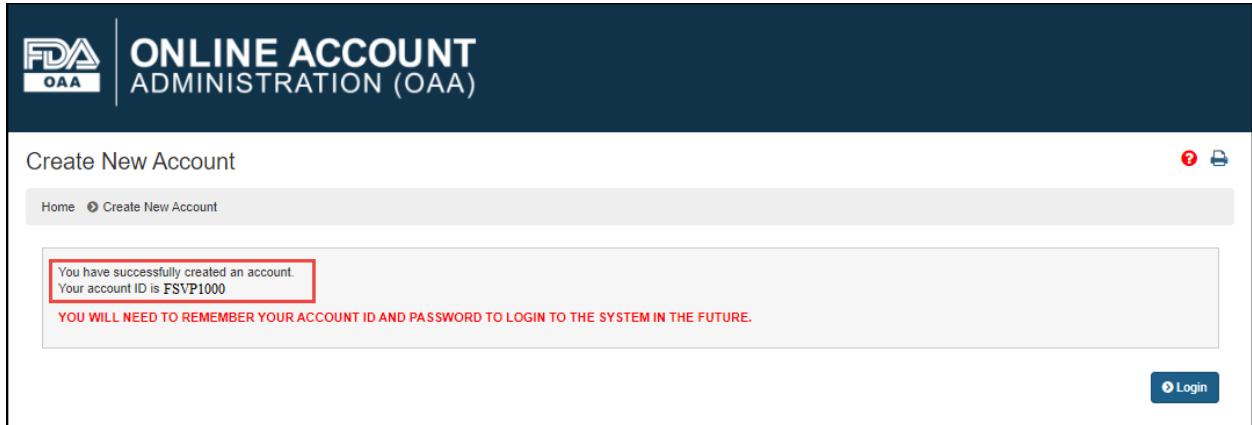
Figure 9 – Successful Account Creation Message Page

Once you create an account, you will receive an e-mail notification sent to the e-mail address entered in the "Account Information" page which contains the account ID (Figure 10).
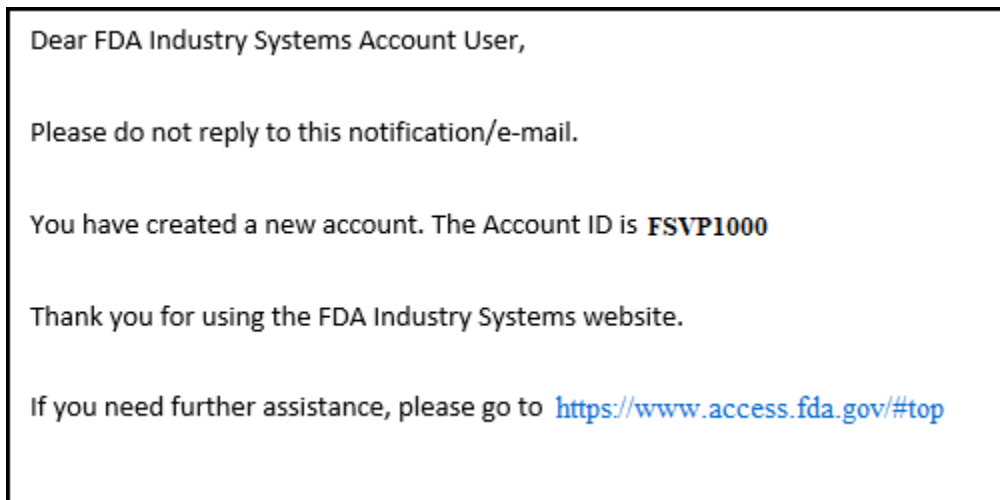
Figure 10 - Account Creation Confirmation E-mail

Click the "Login" button to access the FSVP Importer Portal (Figure 11). Select "FSVP Importer Portal for FSVP Records Submission" under "FSMA Program(s)." Log into the FSVP Importer Portal to ensure the information was successfully submitted to FDA.

Figure 11 - Login

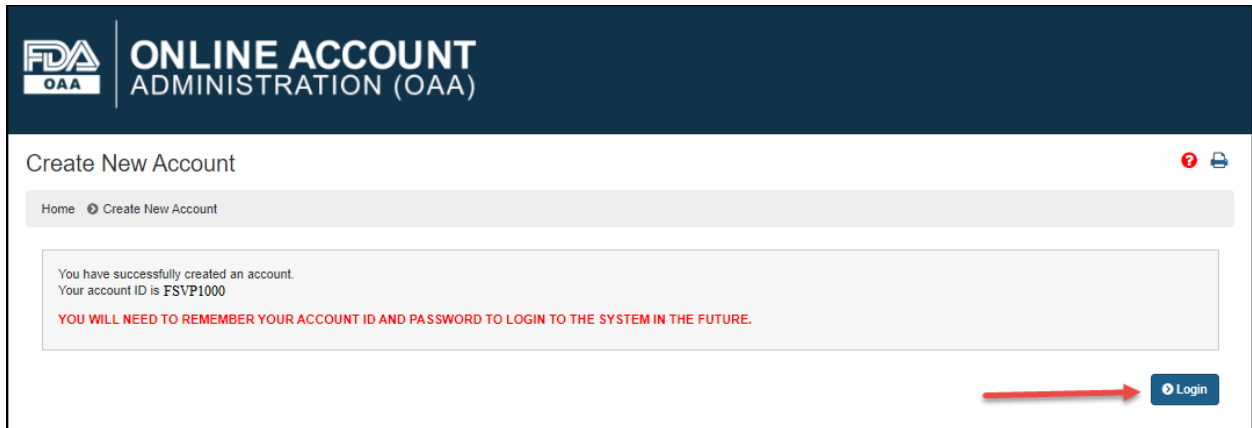If you have previously created an FDA Online Account, you will enter your Account ID and Password to log in (Figure 12).
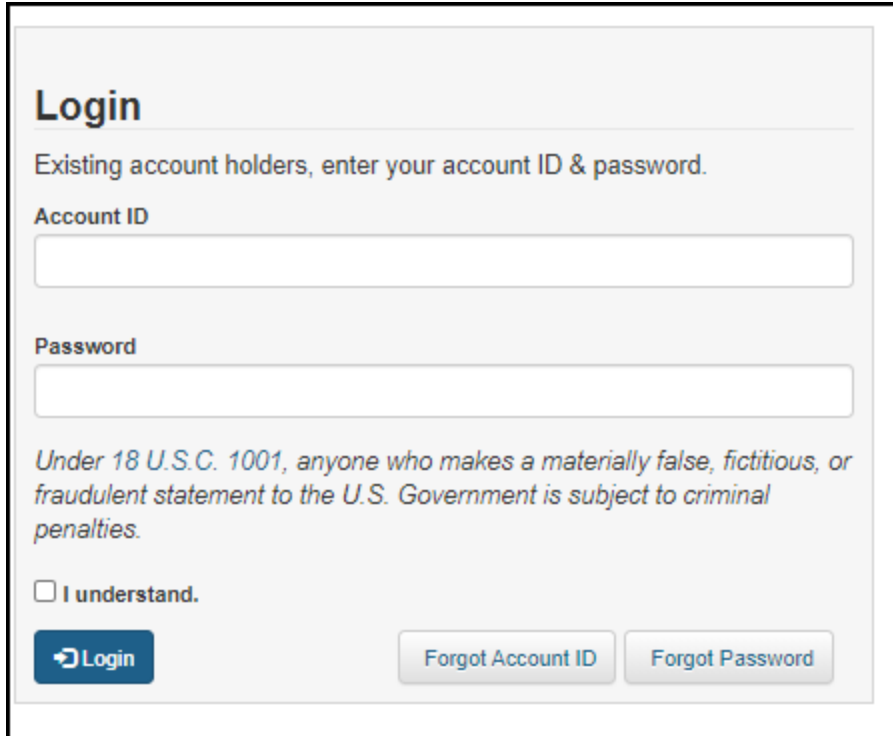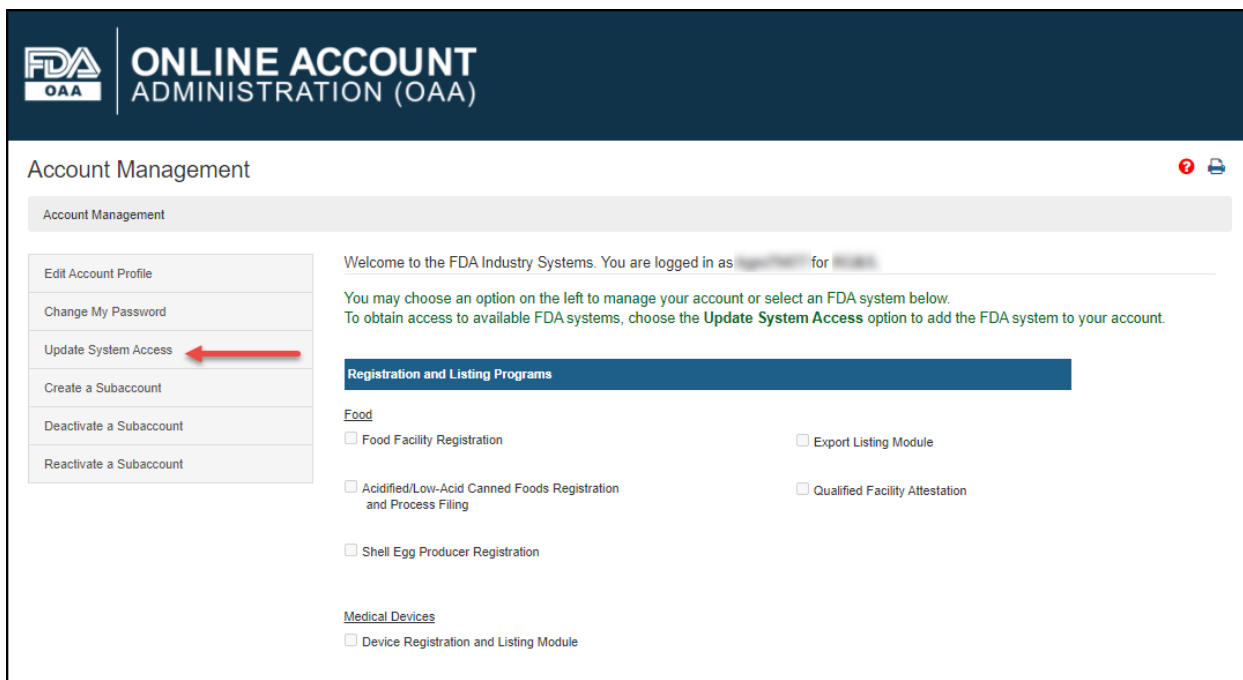

Figure 1 – OAA Login

You will update your system access by selecting the "FSVP Importer Portal for FSVP Records Submission" in the Update System Access tab (Figure 13) from your Account Management Home Page.

Figure 2 - Update System Access

You will be asked for your verification code before you are granted access to the FSVP Importer Portal for FSVP Records Submission Program in FURLS.

1.1 Logging into Your OAA Account

After providing the requested information under "Create new account" you will receive final account set up details via email. A subaccount ID (Figure 14) and temporary password (Figure 15) will be sent in two separate emails to the email account submitted.

Note: Subaccount ID is for the FSVP Importer's account.
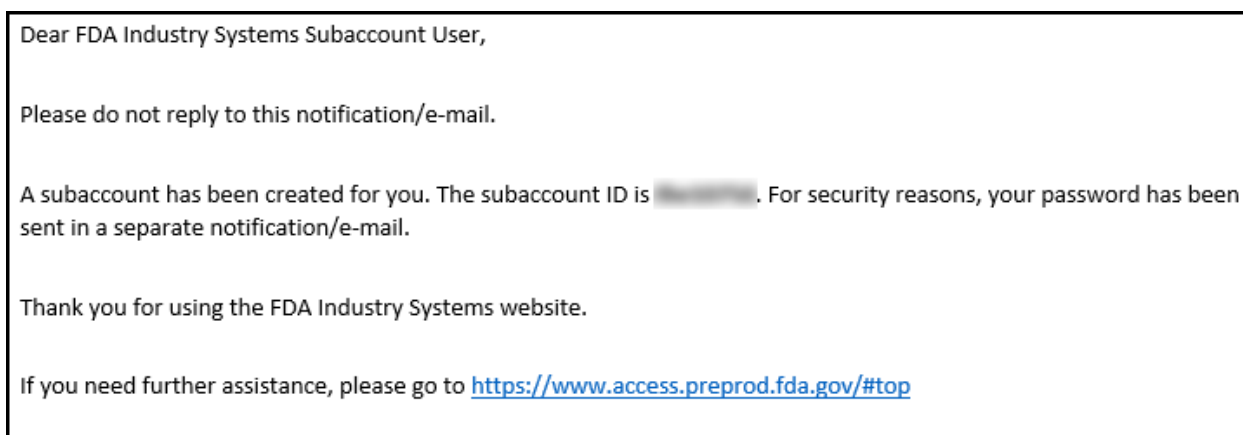
Figure 3 - Subaccount ID Email

Dear FDA Industry Systems Subaccount User,

Please do not reply to this notification/e-mail.

A subaccount has been created for you. For security reasons, your subaccount ID was sent in a separate notification/e-mail. The temporary password is g3R%9qy7

The temporary password will give you access to your existing account. You will be prompted for a new password. Passwords must be at least 8 characters but no more than 32, contain uppercase and lowercase letters, numbers and special characters (e.g ;,%,$).

Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to https://www.access.preprod.fda.gov/#top

Figure 4 – Temporary Password Email

Enter your account ID and temporary password under OAA Login page. The system will take you to the OAA Account Management page where you can view your account ID, change your password, update system access, and create security questions for logging in. Scroll down to "FSMA Program(s)" section and Select "FSVP Industry Portal for FSVP Record Submission" (Figure 16).
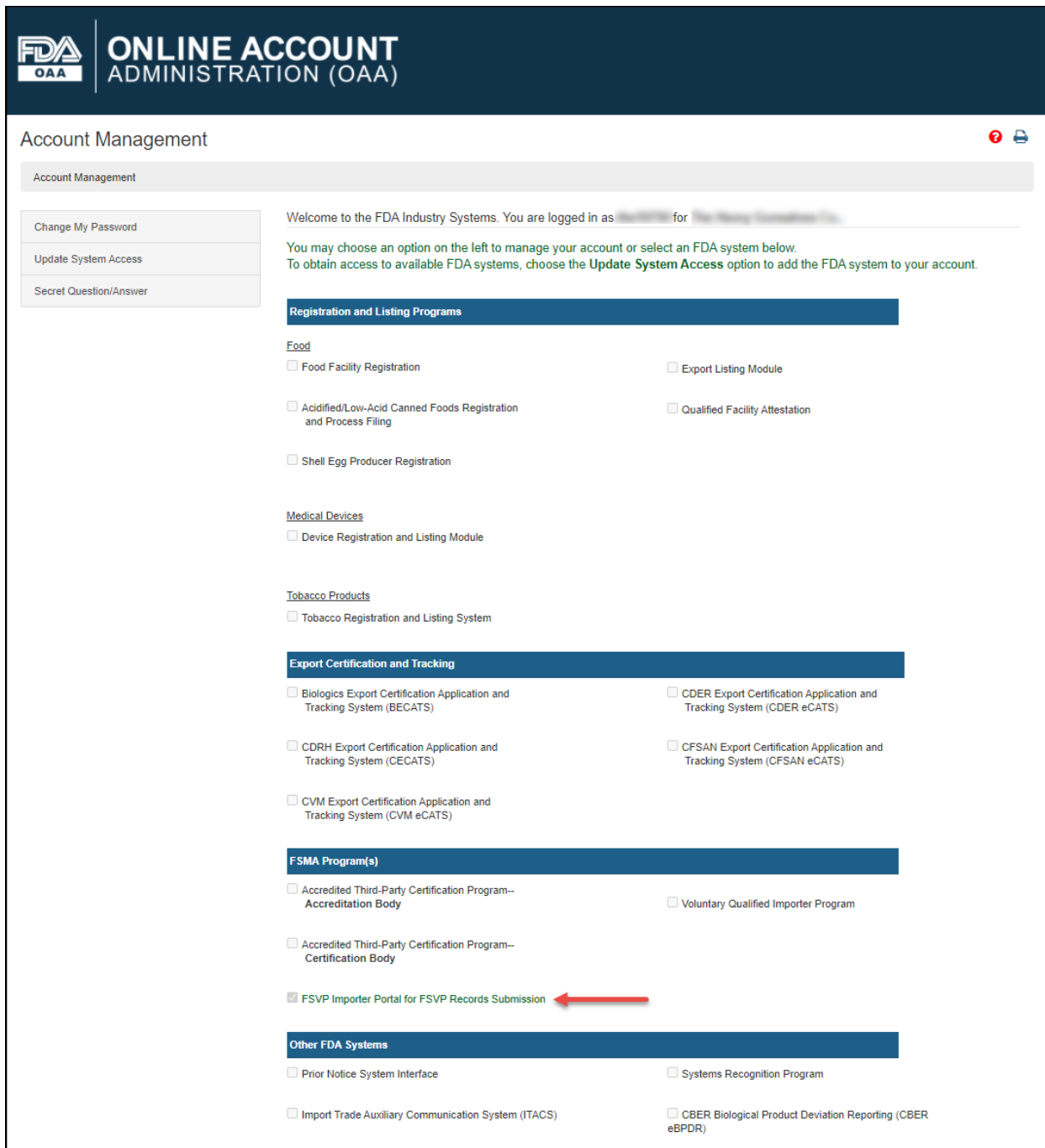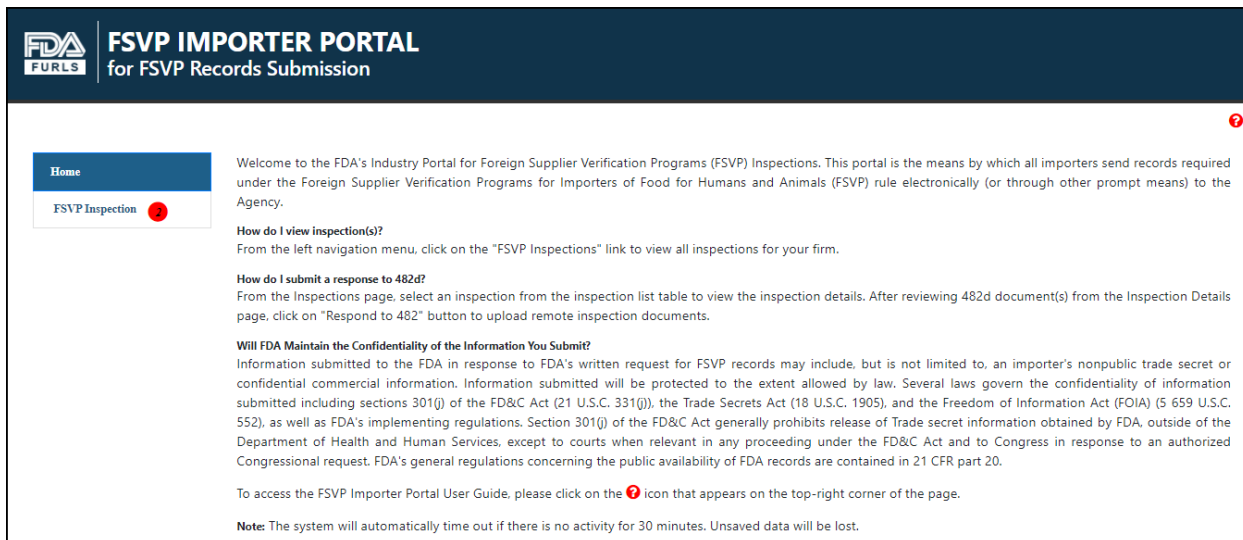
Figure 5 - Account Management

## 2. FSVP Importer Portal for FSVP Records Submission

As an FSVP Importer, you will be directed to the FSVP Importer Portal for FSVP Records Submission Portal home page which outlines frequently asked questions to assist you in navigating the Portal. The left menu consists of "FSVP Inspections" (Figure 17).

Figure 6 - FSVP Importer Portal Home Page

2.1 Inspections Home Page

The Inspections Home Page (Figure 18) depicts all inspections assigned to the FDA Establishment Identification (FEI) number associated with your firm name and address. You have the option to search inspection information based on date, status, etc.
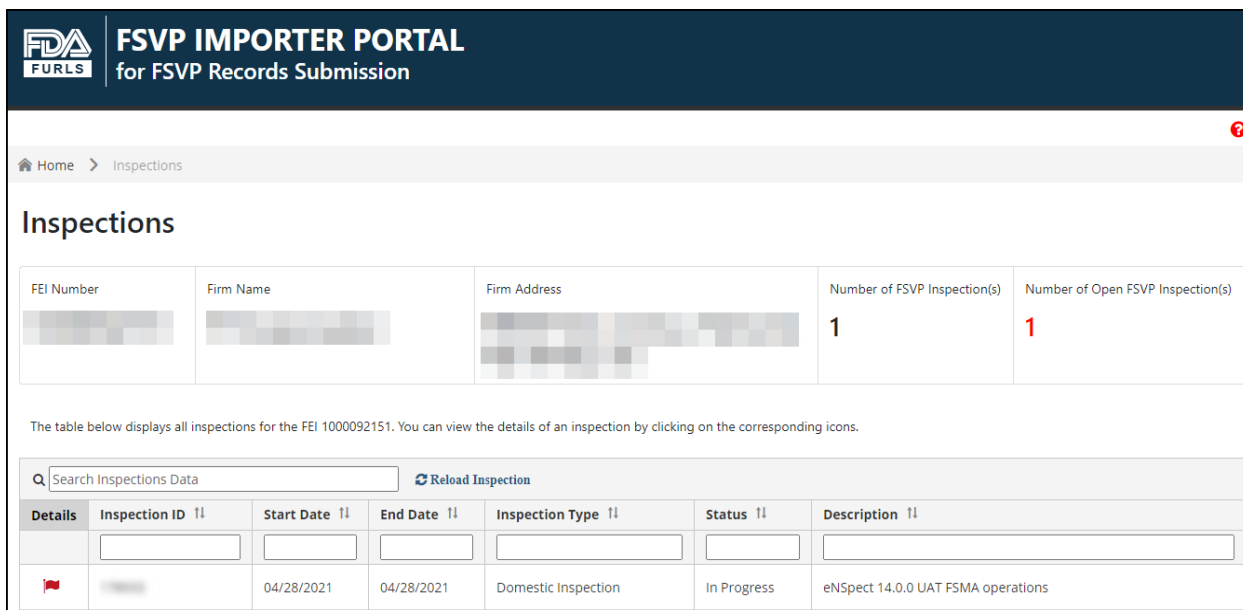
Figure 7 - Inspections Page

The Status Column (Figure 19) will detail the state of each inspection. 'In Progress' means the inspection is active and is in a state of waiting for you to upload information or FDA to request/review uploaded information. When an inspection is complete the status will indicate as such.

Figure 19 – Inspections Table – Status Column

The "Details" column describes what actions can be performed on the displayed information. The **Blue Eye icon represents records that are View only and the Red Flag icon represents records that are View *and* Respond** (Figure 20).

Figure 20 – Inspections Table – Details Column

Selecting the **Blue Eye icon** will display the Inspection Detail (Figure 21).

Figure 21 - Inspections Details Page - When View Only or Blue Eye icon is selected

Selecting the **Red Flag Icon** on an open inspection will display the Inspection Documents section and a table of all documentation sent between the Importer and FDA (Figure 22).

Figure 22 - Inspections Details Page - When View and Respond or Red Flag icon is selected

Select the "Respond to 482d" button from the Inspection Details page to add attachment(s) (Figure 23). The attachment description of the uploaded document is required in order to submit for FDA review. The attachment description of the uploaded document should clearly identify the records required by the FSVP regulation, refer to the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) Regulation Records Requirements document (e.g., hazard analysis, a required written procedure, documentation of a foreign supplier verification activity, documentation of their review and assessment of a foreign supplier verification activity).

Figure 23 - Attachment Upload Page – When 'Respond to 482d' is selected

You will not be able to update the attachment description or delete the document once it has been submitted. Ensure you uploaded and submitted all your FSVP records by clicking back to Inspection Detail to verify all your documents are available. You can open/view the attachment(s) by double clicking the document icon in the document column of the Inspection Details homepage (Figure 22). The system will then notify FDA of your response.

2.2 Manage Sub-Account

Once your FSVP Importer Portal for FSVP Records Submission has been activated, FDA will send a notification email to your sub-account members identified during the initial call. Logging into the FSVP Importer Portal for FSVP Records Submission will return you to the homepage. Select "Manage Sub-Account" on the left menu to edit Sub-Account Access by updating role to: No Access (cannot see any documentation sent back and forth), Full Access (can read and submit documents), or Read Only (can view but cannot submit documents) (Figure 24). A Top Management Official (TMO) can add a sub-account if necessary.
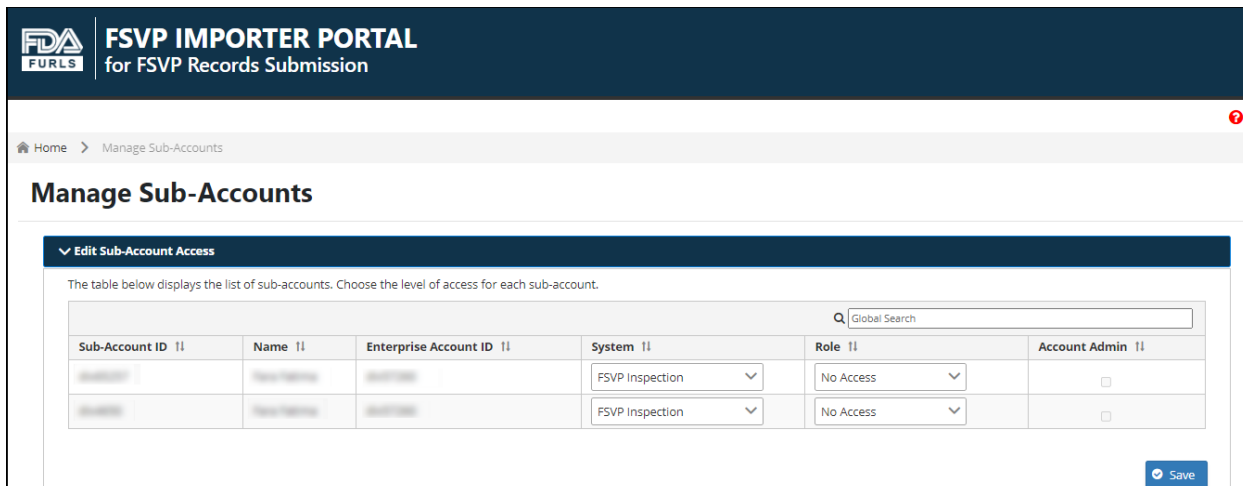
Figure 24 – Manage Sub-Accounts

2.3 Communications from FDA

Any request from FDA for additional/supplemental information will notify you via email, phone or video to log into and view the request on the Inspections Details Page. There will be an option to respond with the requested information, similar to the initial 482d response option.

3. FURLS Portal Troubleshooting

If you encounter a technical issue that cannot be resolved using this document, you may reach out to the FURLS Helpdesk for assistance. Select the "Help Desk" button on the log in page (Figure 25) and scroll down to your specified index.
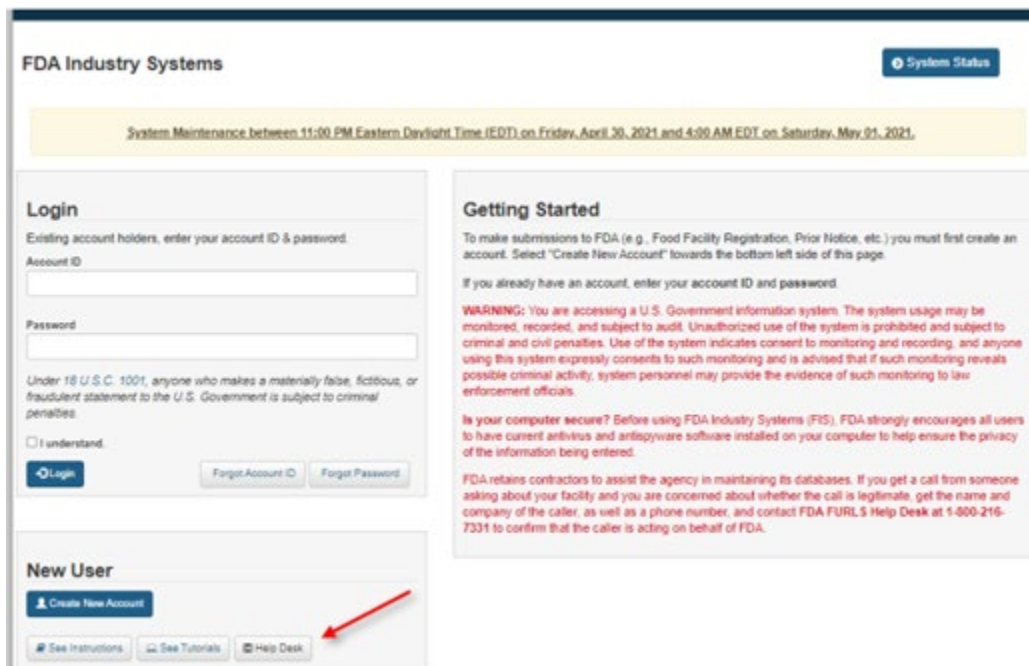

Figure 25 - FURLS Help Desk Navigation Button

Scroll to the bottom to the "Help Desk" Section to find the contact information for technical assistance (Figure 26).

Figure 26 - FURLS Help Desk Contact Information