FDA's ITACS Account Management

Import Trade Auxiliary Communications System

January 2017
Food and Drug Administration
Division of Systems Solutions
Import Systems Branch

Topics

- Background and Overview
- Creating a New Account
- Retrieving Notices of FDA Action from ITACS
- Managing your Account, Users, and Groups

Background and Overview

ITACS web access currently provides the Import Trade Community with 4 functions:

- the ability to check the status of FDA-regulated entries and lines
- the ability to submit entry documentation electronically
- the ability to electronically submit the location of goods availability for those lines targeted for FDA exam
- the ability to check the estimated laboratory analysis completion dates

No login accounts are necessary to access these functions. All that is needed is a valid Customs entry number that has been successfully transmitted to FDA.

Background and Overview

ITACS Account Management allows users to:

- Receive Notices of FDA Action via email*
- Retrieve Notices of FDA Action as downloads from within ITACS
- View the details of specific information requests, which are currently delivered via hard copy Notices of FDA Action
- Will also allow for future enhancements requested by the Import Trade Community which require user verification

*Receipt of Notices of FDA Action via email is optional and will take the place of paper Notices if chosen. Account users will be able to retrieve Notices by downloading them from within ITACS regardless of whether they opt to receive them via email or regular mail.

Creating an ITACS Account

- NOTE – If you already have an FDA FURLS account you do not need to set up a new account. You can update your existing account access to include ITACS.

- Existing account types may include:
  - Food Facility Registration
  - Prior Notice System Interface
  - Acidified/Low-Acid Canned Foods Registration
  - Device Registration
  - Voluntary Qualified Importer Program
  - Tobacco Registration and Listing

Creating an ITACS Account

User Roles

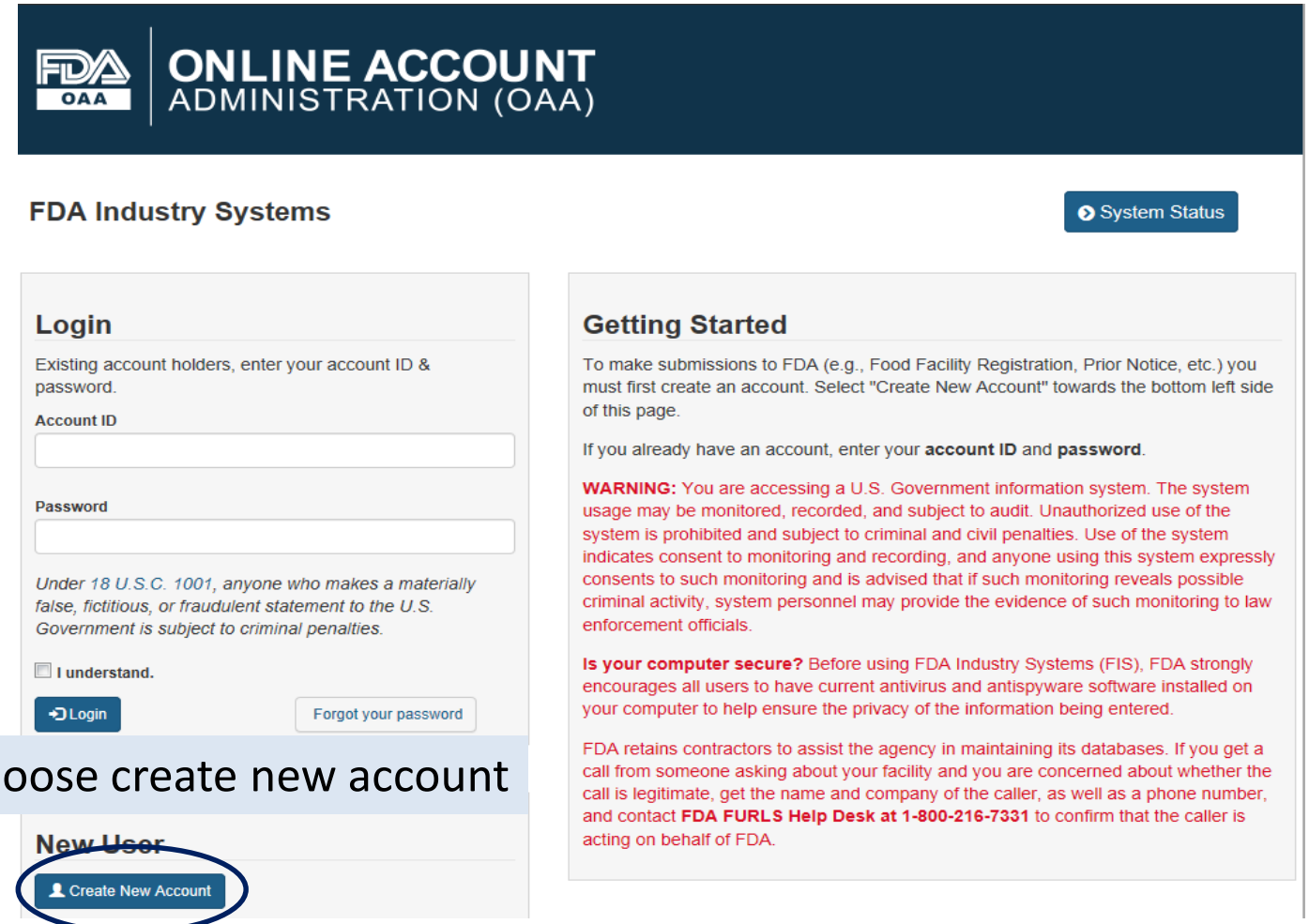
Only one Firm Account is allowed per firm. A Firm Account should be created by the person who is authorized to act as the Firm Administrator

- **Firm Administrator** can:
  - Create, Deactivate, Reactivate Firm Users
  - Create, Modify, Delete Groups
  - Grant/Transfer Group Admin and Firm Admin privileges
- **Group Administrator** can:
  - Create new Users
  - Add/Remove Users to their own group
  - Modify Group settings
- **Firm User** can:
  - Modify own user account
  - Access to ITACS account functionality

Creating an ITACS Account

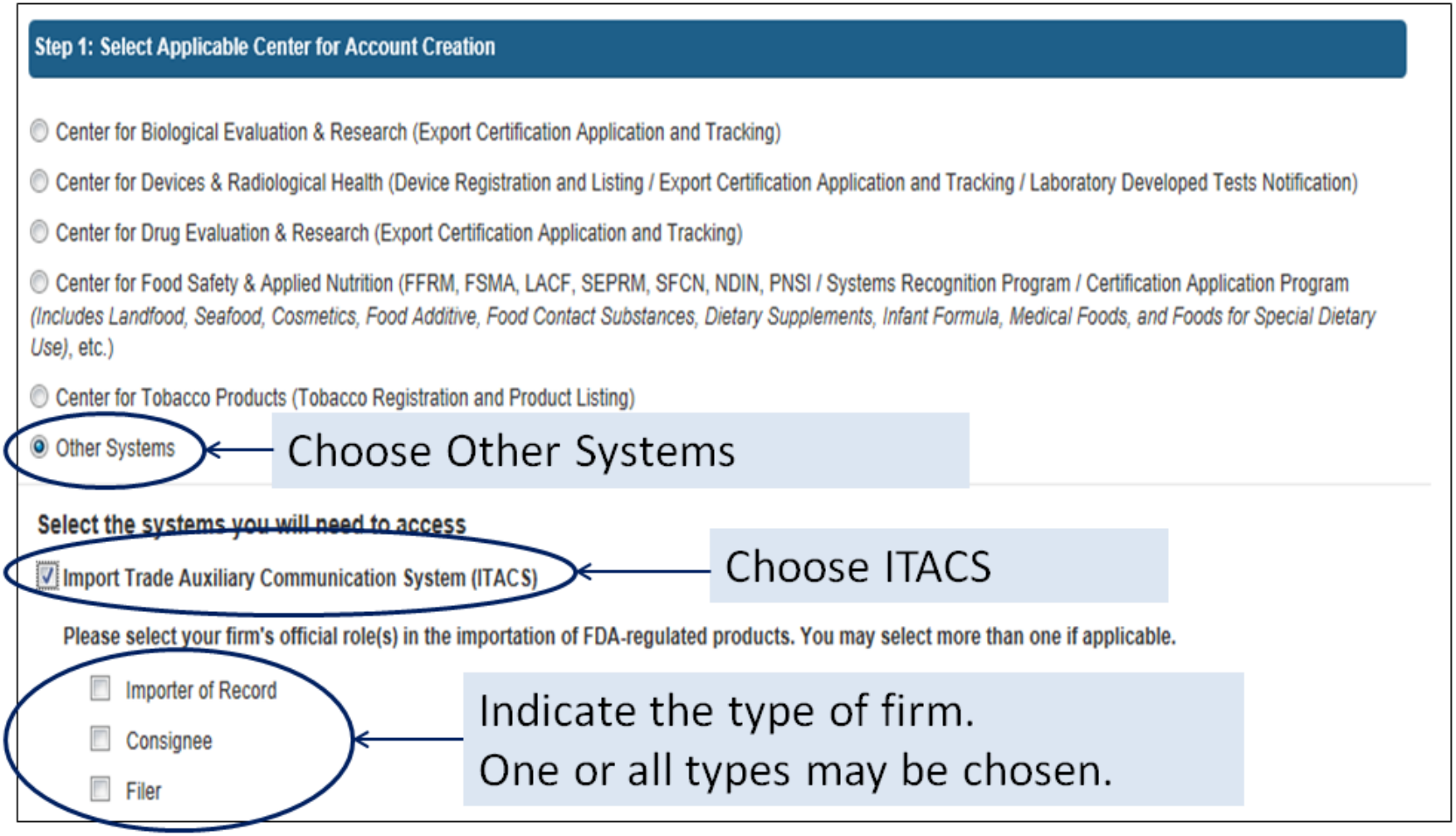
- Click on the Create Account link on the ITACS Home page
- Or go directly to FURLS: https://www.access.fda.gov/oaa

Creating an ITACS Account

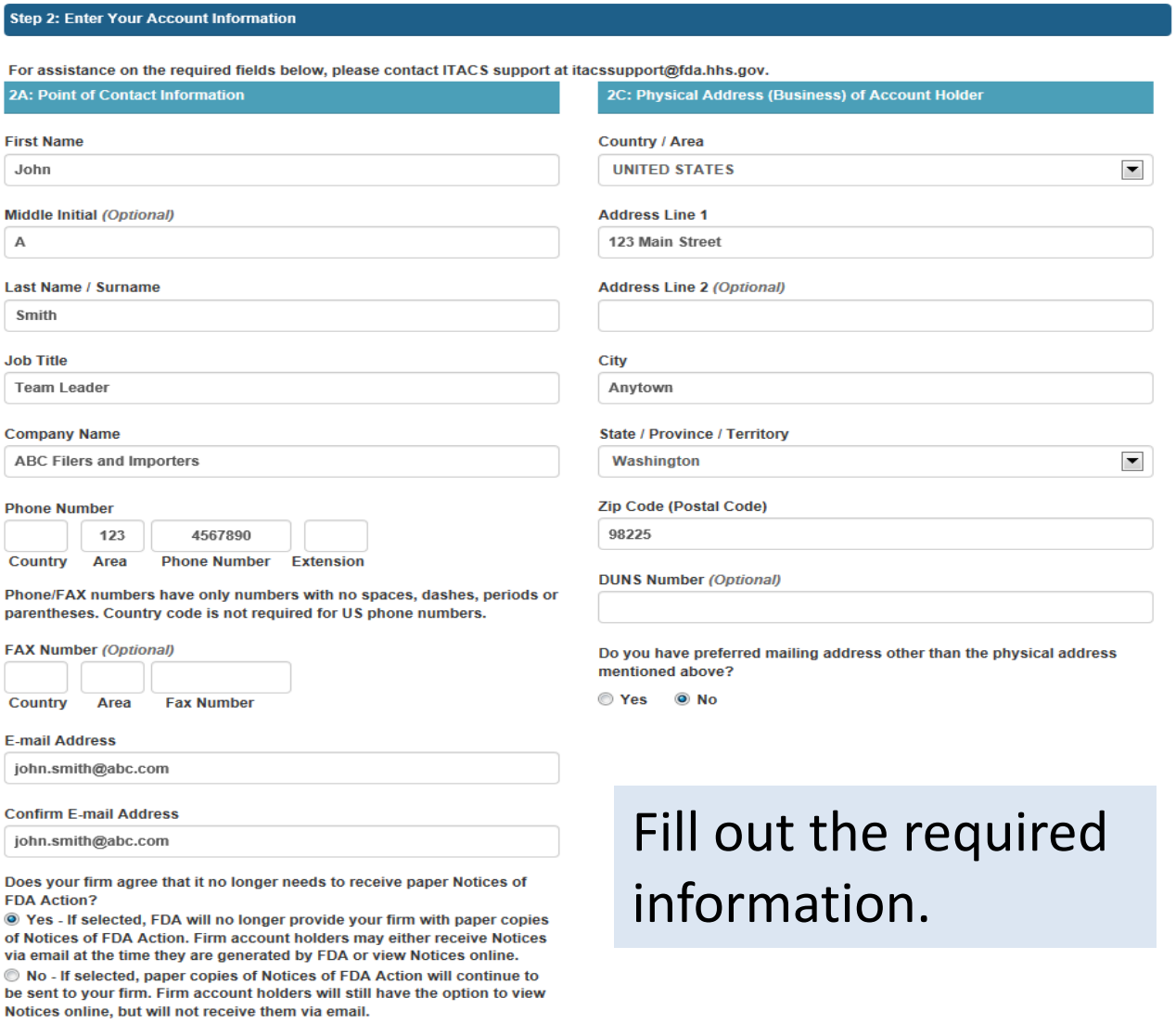


Choose create new account

Creating an ITACS Account



Creating an ITACS Account



Step 2: Enter Your Account Information

For assistance on the required fields below, please contact ITACS support at itacssupport@fda.hhs.gov.

2A: Point of Contact Information

First Name: John

Middle Initial *(Optional)*: A

Last Name / Surname: Smith

Job Title: Team Leader

Company Name: ABC Filers and Importers

Phone Number

Country	Area	Phone Number	Extension
	123	4567890	

Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.

FAX Number *(Optional)*

Country	Area	Fax Number

E-mail Address: john.smith@abc.com

Confirm E-mail Address: john.smith@abc.com

Does your firm agree that it no longer needs to receive paper Notices of FDA Action?

- (●) Yes - If selected, FDA will no longer provide your firm with paper copies of Notices of FDA Action. Firm account holders may either receive Notices via email at the time they are generated by FDA or view Notices online.
- ( ) No - If selected, paper copies of Notices of FDA Action will continue to be sent to your firm. Firm account holders will still have the option to view Notices online, but will not receive them via email.

2C: Physical Address (Business) of Account Holder

Country / Area: UNITED STATES

Address Line 1: 123 Main Street

Address Line 2 *(Optional)*:

City: Anytown

State / Province / Territory: Washington

Zip Code (Postal Code): 98225

DUNS Number *(Optional)*:

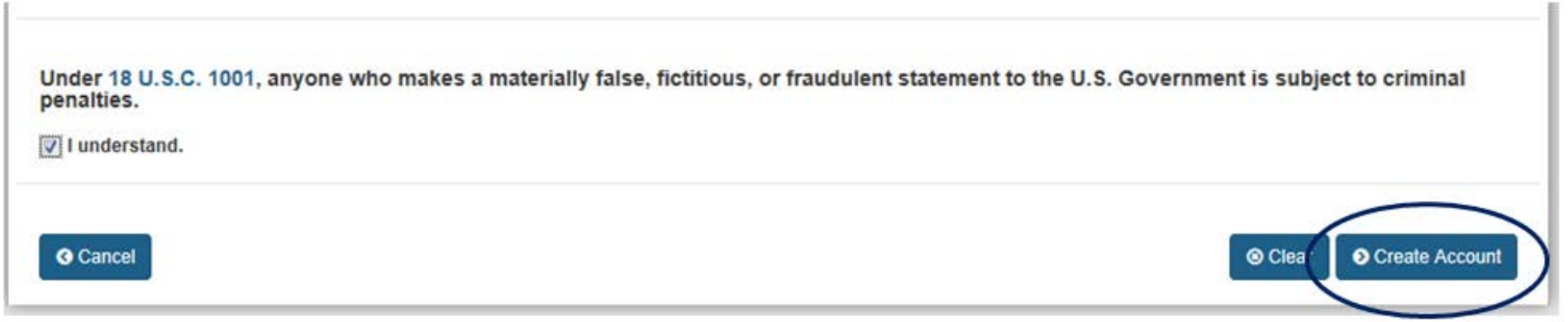
Do you have preferred mailing address other than the physical address mentioned above?

( ) Yes (●) No

Fill out the required information.

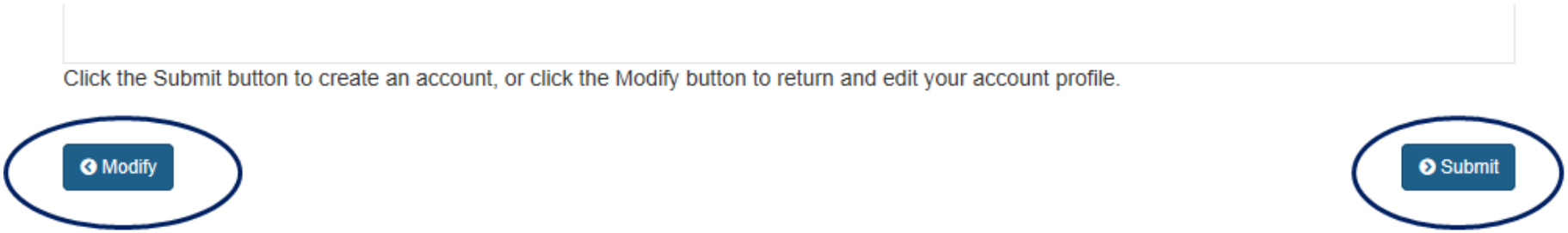
Creating an ITACS Account

When the required information has been completely filled out, Click ‘Create Account’ at the bottom of the page.



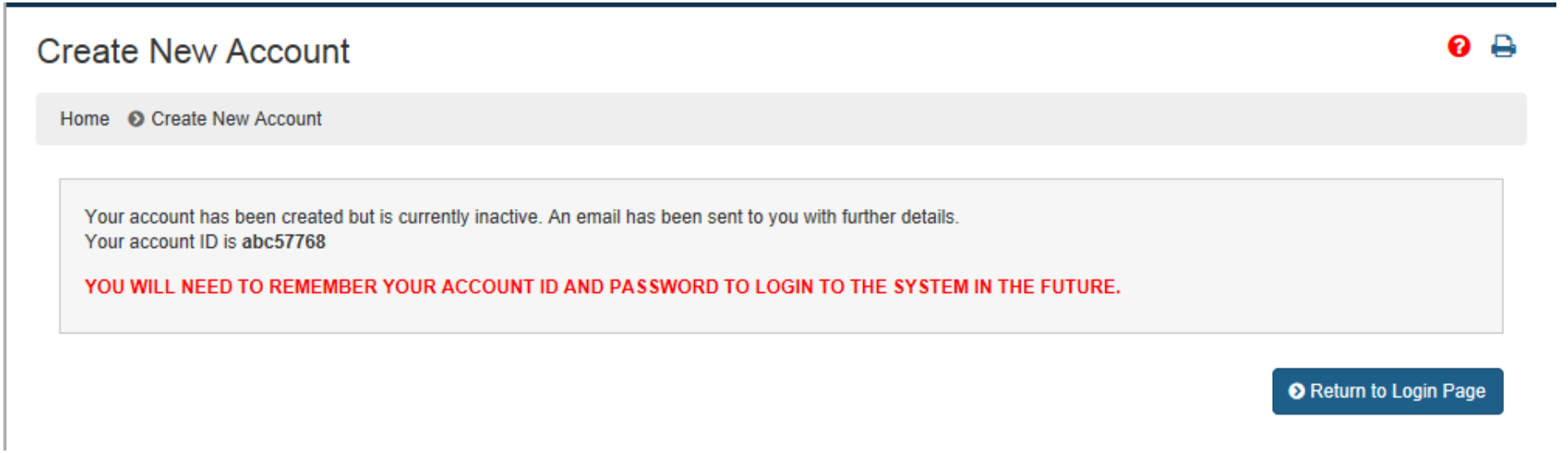
Creating an ITACS Account

Review the account information for accuracy and Click ‘Modify’ to edit the information or click ‘Submit’ to submit the account information for review.



Creating an ITACS Account

You will be provided with an account ID, but will need to await approval of your account to log into ITACS. You will also receive an email with this information.



Creating an ITACS Account

- Your account may be temporarily rejected pending further information. Please provide the requested information to ITACSSupport@fda.hhs.gov.

Department of Health and Human Services

Food and Drug Administration

February 17, 2016

Dear John Smith,

Your request for access to the Import Trade Auxiliary Communication System (ITACS) for account **abc57768** has been rejected at this time.

The request has been rejected for the following reason(s):

Comments: Please provide additional entry numbers for verifcation.

For general ITACS questions, please review the information posted at http://www.fda.gov/ForIndustry/ImportProgram/ucm296314

Please contact us at itacssupport@fda.hhs.gov if you have any specific questions about this rejection.

FDA ITACS Support Team

Please do not reply to this email. Emails sent to this address cannot be answered. Thank you.

Creating an ITACS Account

Reasons an account might be rejected:

- Your firm already has an account
- FDA is unable to verify the entry numbers provided
- Firm is not part of FDA's firm inventory

Your account may be temporarily rejected pending further information. If so, please provide the requested information to ITACSSupport@fda.hhs.gov.

Creating an ITACS Account

If your account has been approved you may log into your account to retrieve Notices via ITACS and manage your account users and groups.

Department of Health and Human Services

Food and Drug Administration

February 17, 2016

Dear John Smith,

Your ITACS Firm Adminstrator account (**abc57768**) request has been approved.

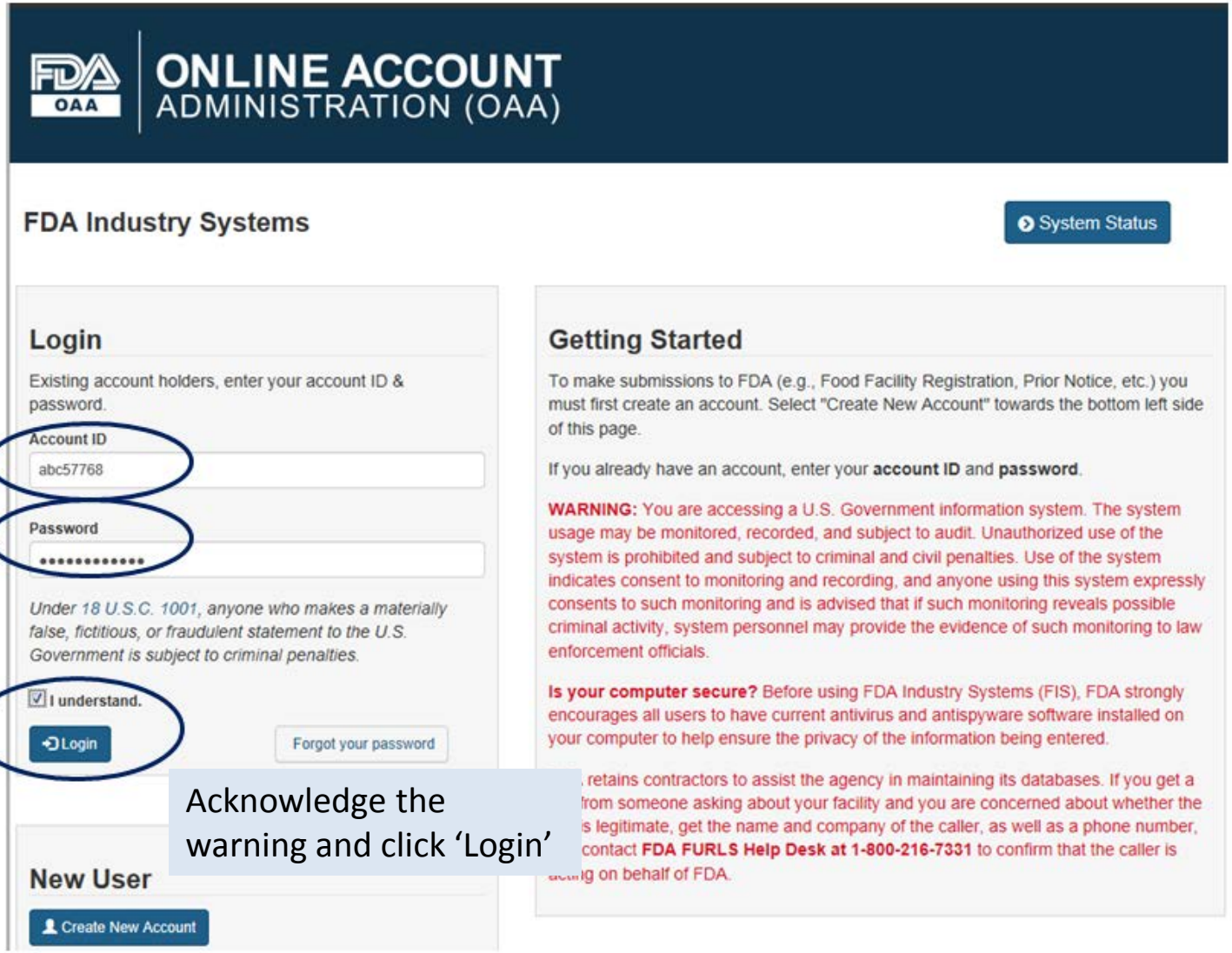
As Firm Administrator, you may now log into FURLS at https://www.access.fda.gov/oaa. Once logged in, you can create groups and designate Group Administrators. For assistance with this functionality, please refer to the help link within the application or posted here: http://www.fda.gov/ForIndustry/ImportProgram/ucm296314

You may also contact FDA with questions at itacssupport@fda.hhs.gov

FDA ITACS Support Team

Please do not reply to this email. Emails sent to this address cannot be answered. Thank you.

Logging into Your ITACS Account



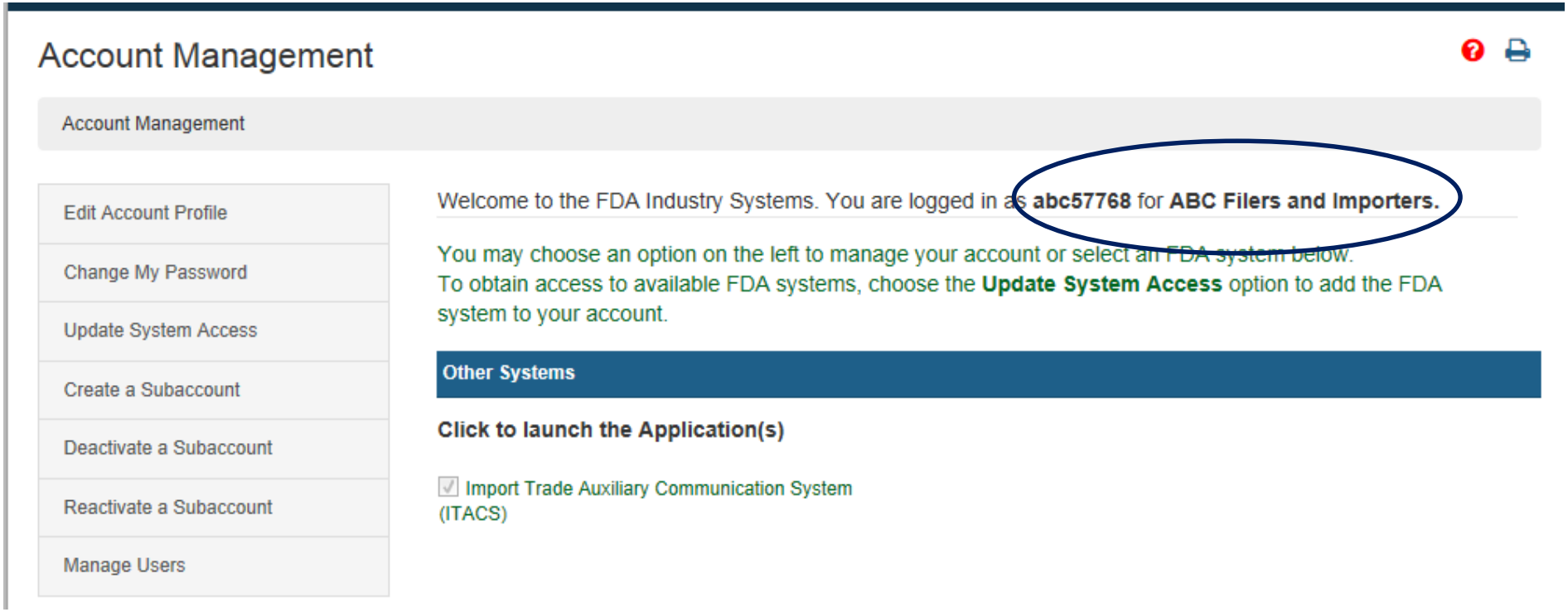
Enter your Account ID and Password

Acknowledge the warning and click ‘Login’

Logging into Your ITACS Account

Firm Administrator

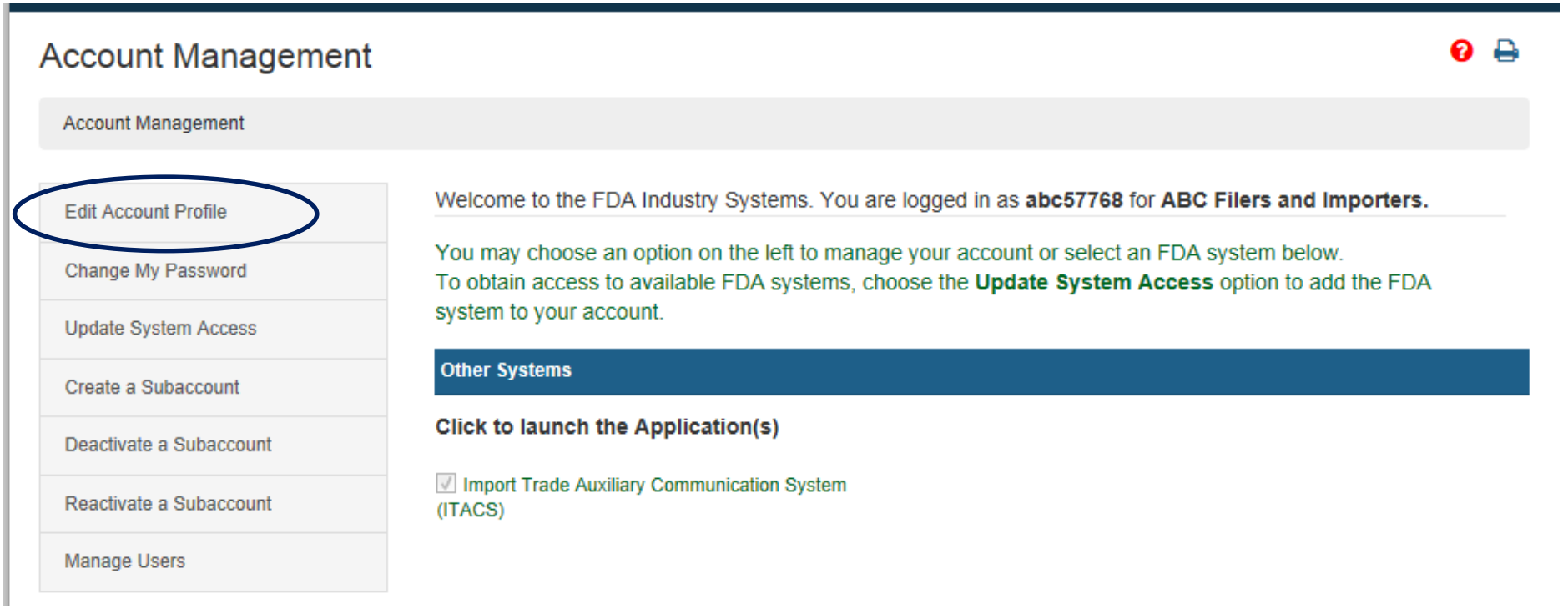
Your Account Home Page



Managing your ITACS Account

Firm Administrator

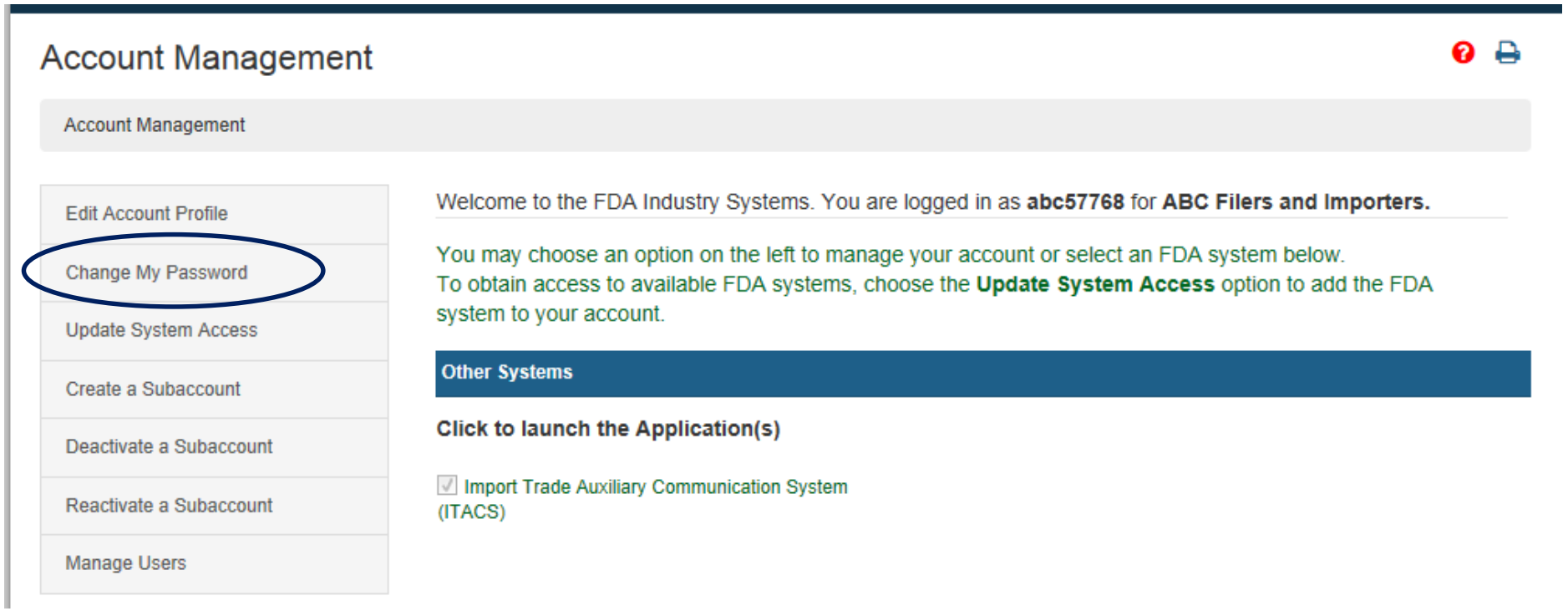
Edit Account Profile allows you to edit your account information and subaccount information.



Managing your ITACS Account

Firm Administrator

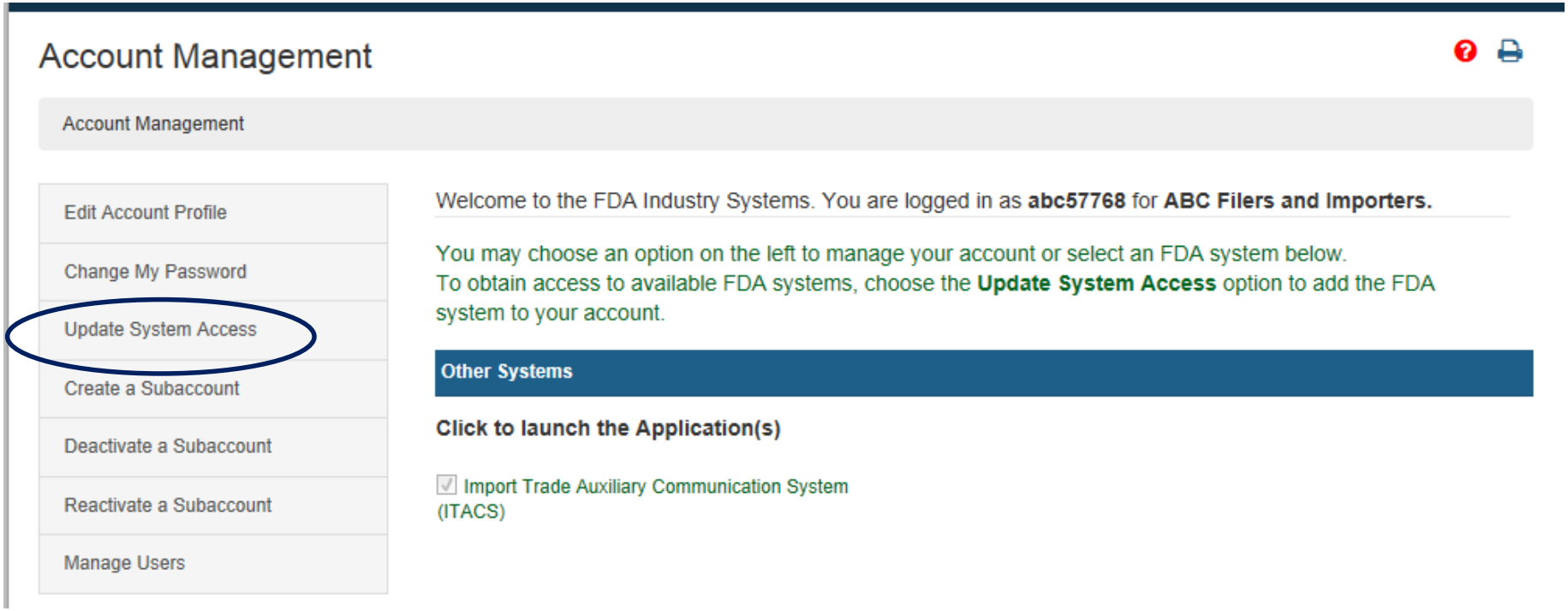
Change My Password allows you to change your account Password.



Managing your ITACS Account

Firm Administrator

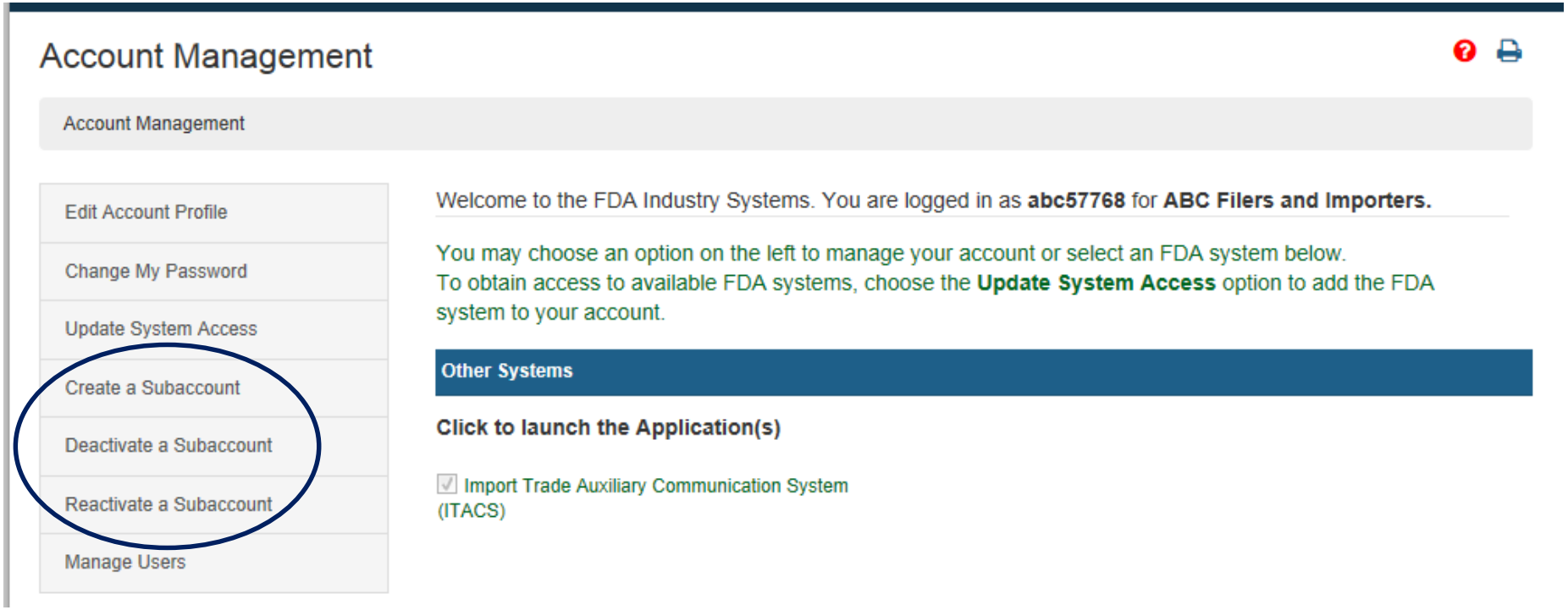
Update System Access allows you to add or remove firm types, Filer, Importer, Consignee.



Managing your ITACS Account

Firm Administrator

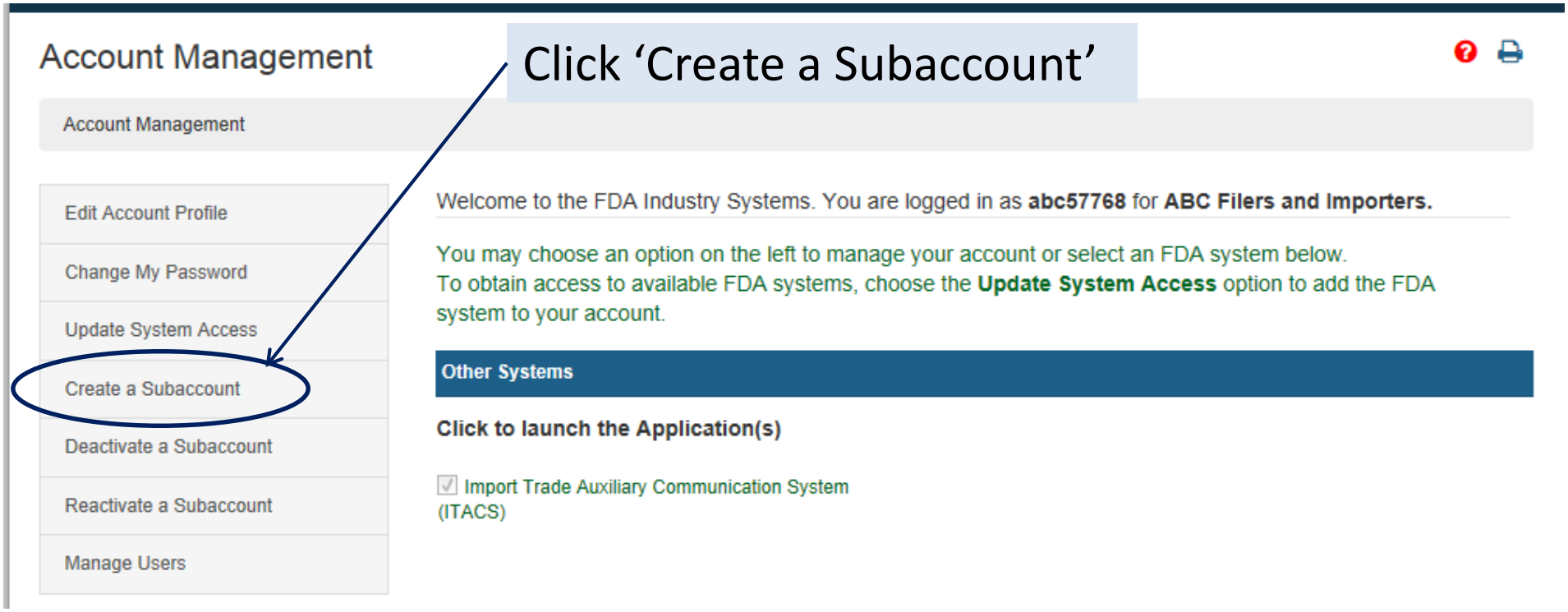
Create, Deactivate and Reactivate Subaccount allows you to manage your user subaccounts.



Managing your ITACS Account

Firm Administrator

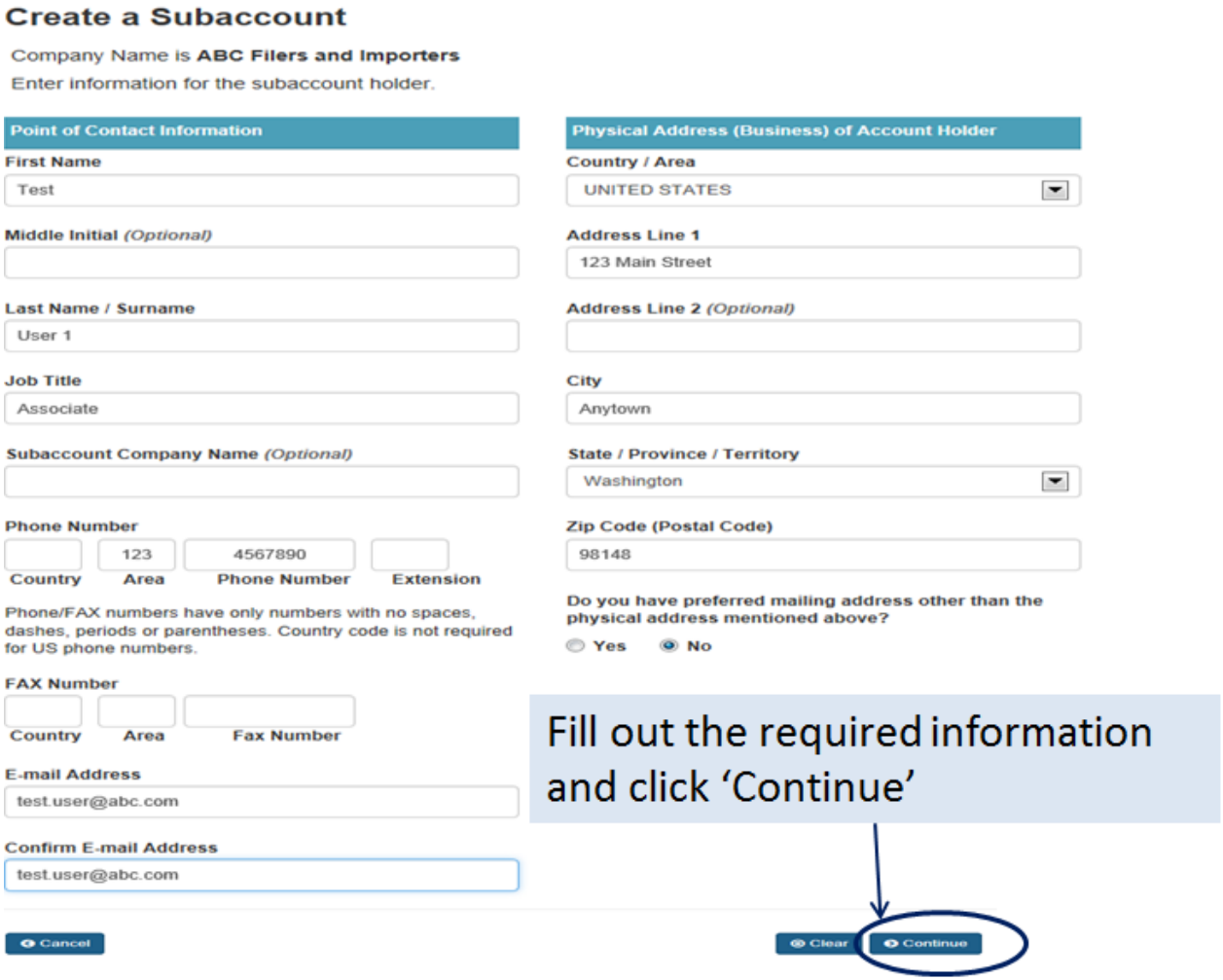
Creating Subaccounts



Managing your ITACS Account

Firm Administrator

Creating Subaccounts

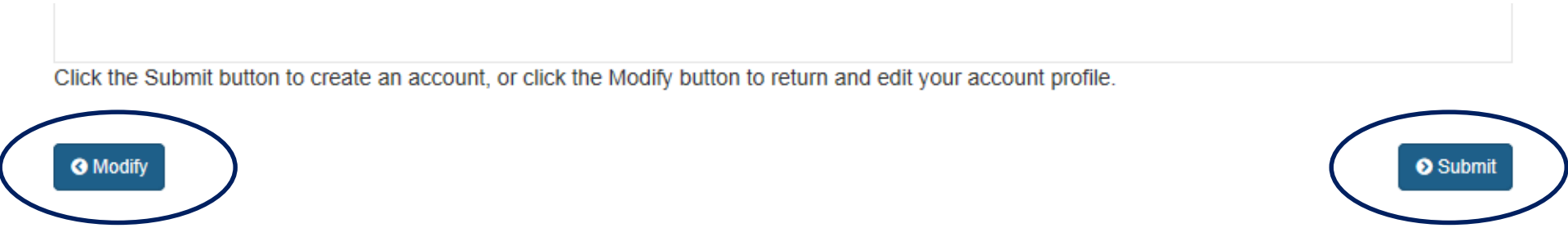


Managing your ITACS Account

Firm Administrator

Creating Subaccounts

Review the account information for accuracy and Click Modify to edit the information or click Submit to submit the account information for review.

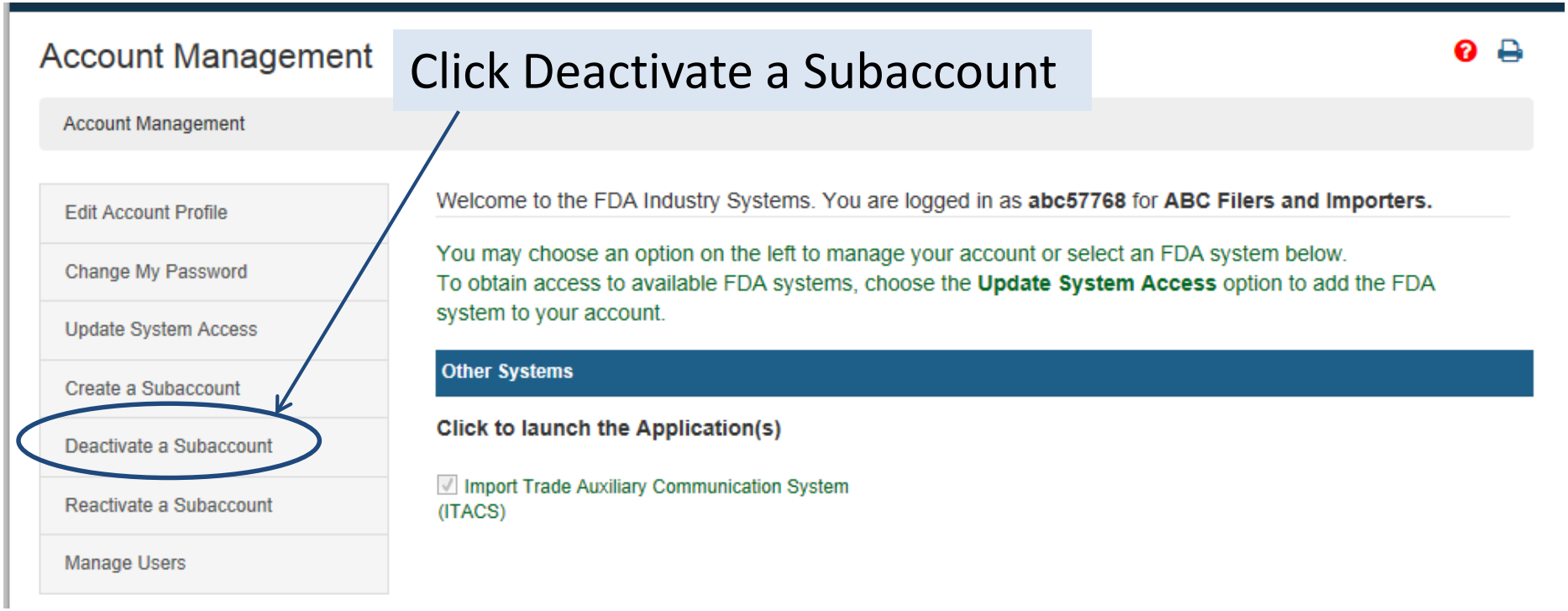


The new user will receive separate emails with their user name and temporary password.

Managing your ITACS Account

Firm Administrator

Deactivating Subaccounts

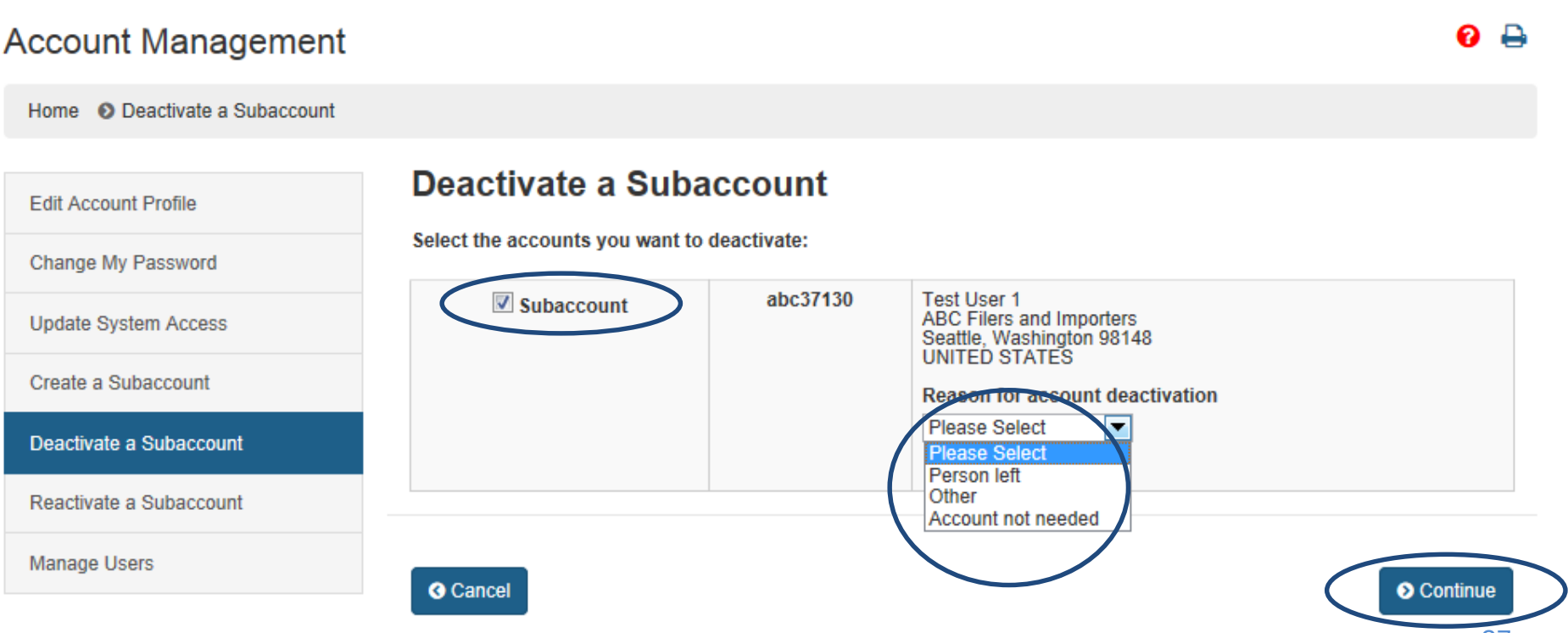


Managing your ITACS Account

Firm Administrator

Deactivating Subaccounts

Select the subaccount you would like to deactivate, select a reason for account deactivation from the pull down menu and click Continue.

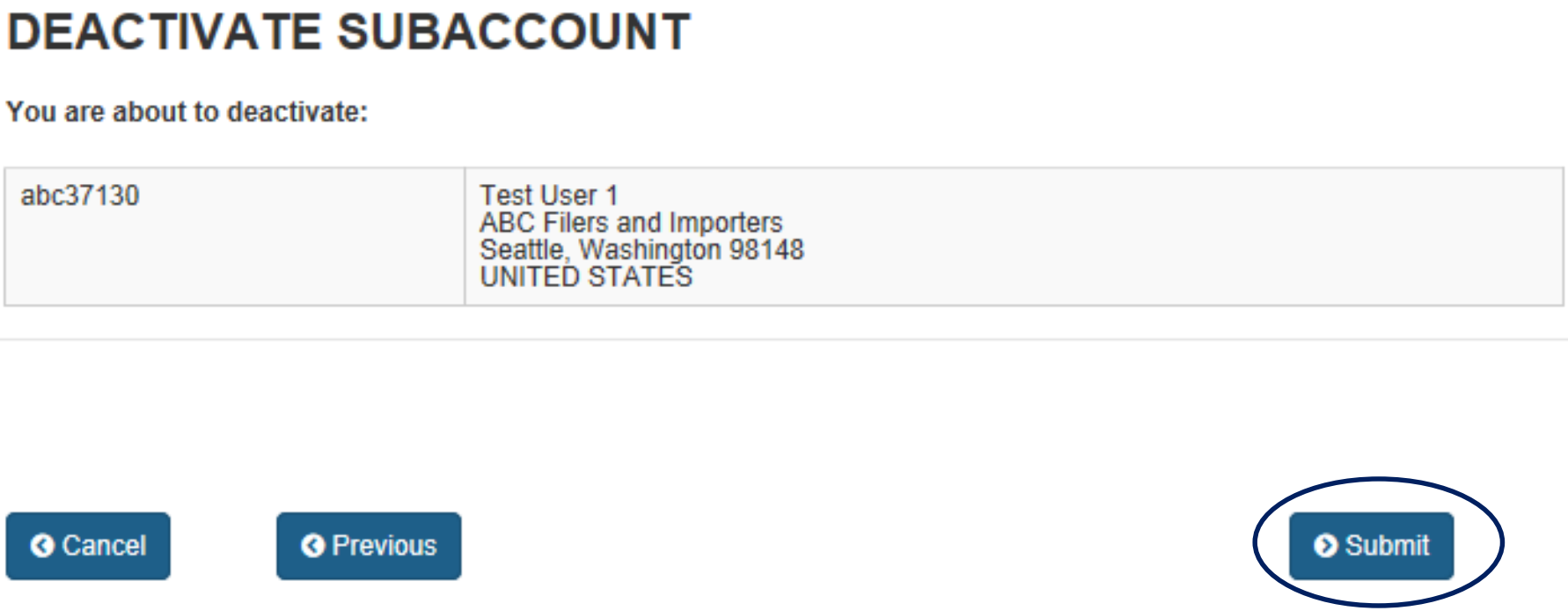


Managing your ITACS Account

Firm Administrator

Deactivating Subaccounts

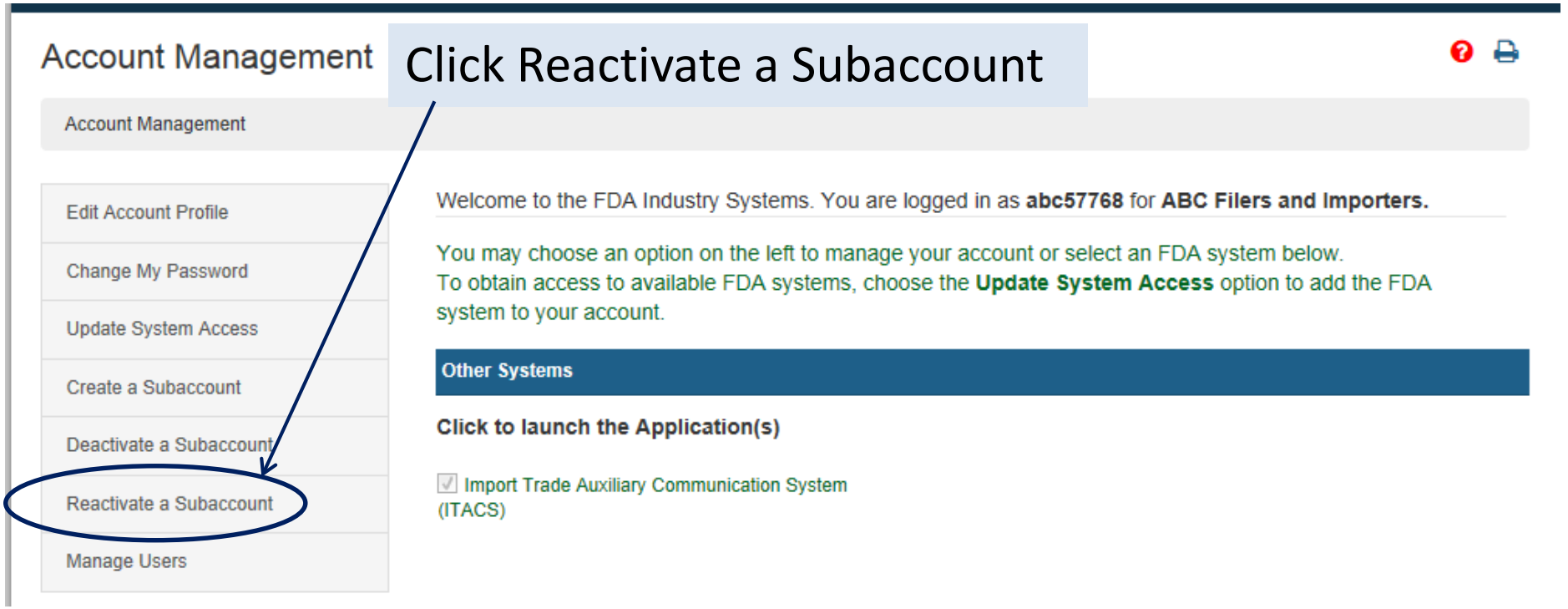
Verify that you would like to deactivate the account and click ‘Submit’.



Managing your ITACS Account

Firm Administrator

Reactivating a Deactivated Subaccount

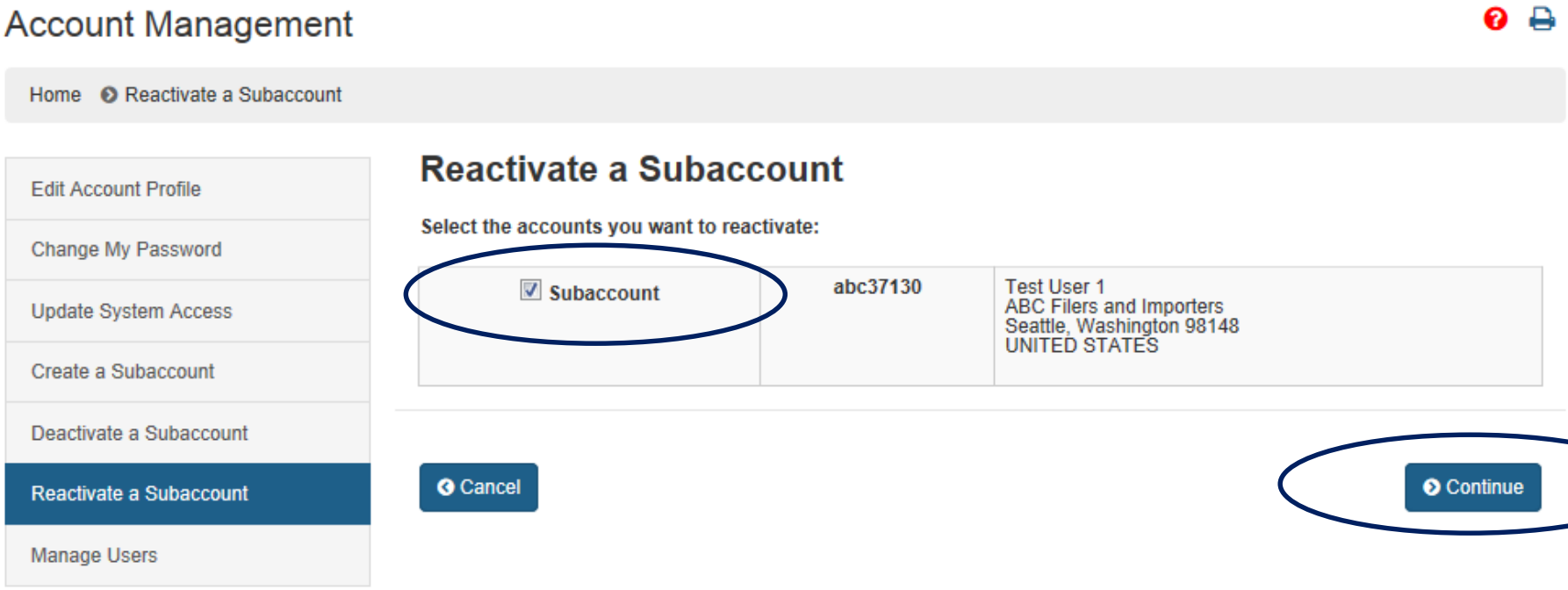


Managing your ITACS Account

Firm Administrator

Reactivating a Deactivated Subaccount

Select the deactivated account you would like to reactivate and click ‘Continue’.

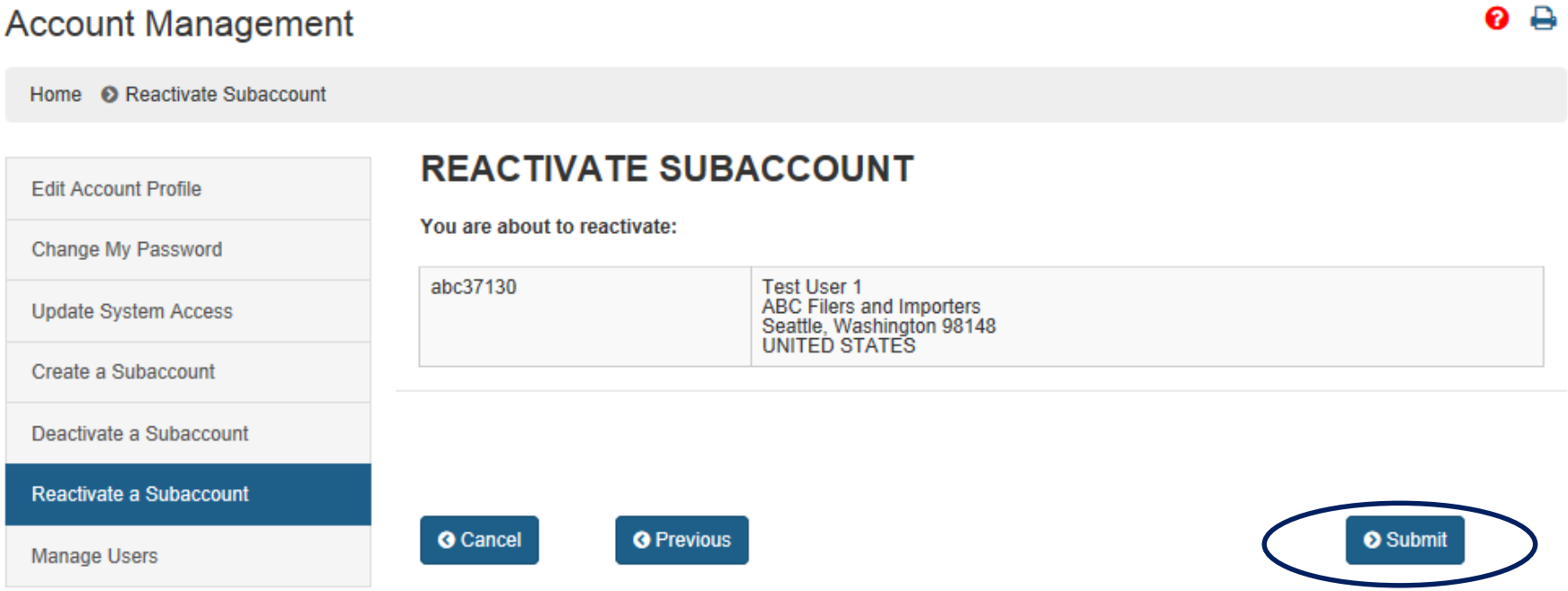


Managing your ITACS Account

Firm Administrator

Reactivating a Deactivated Subaccount

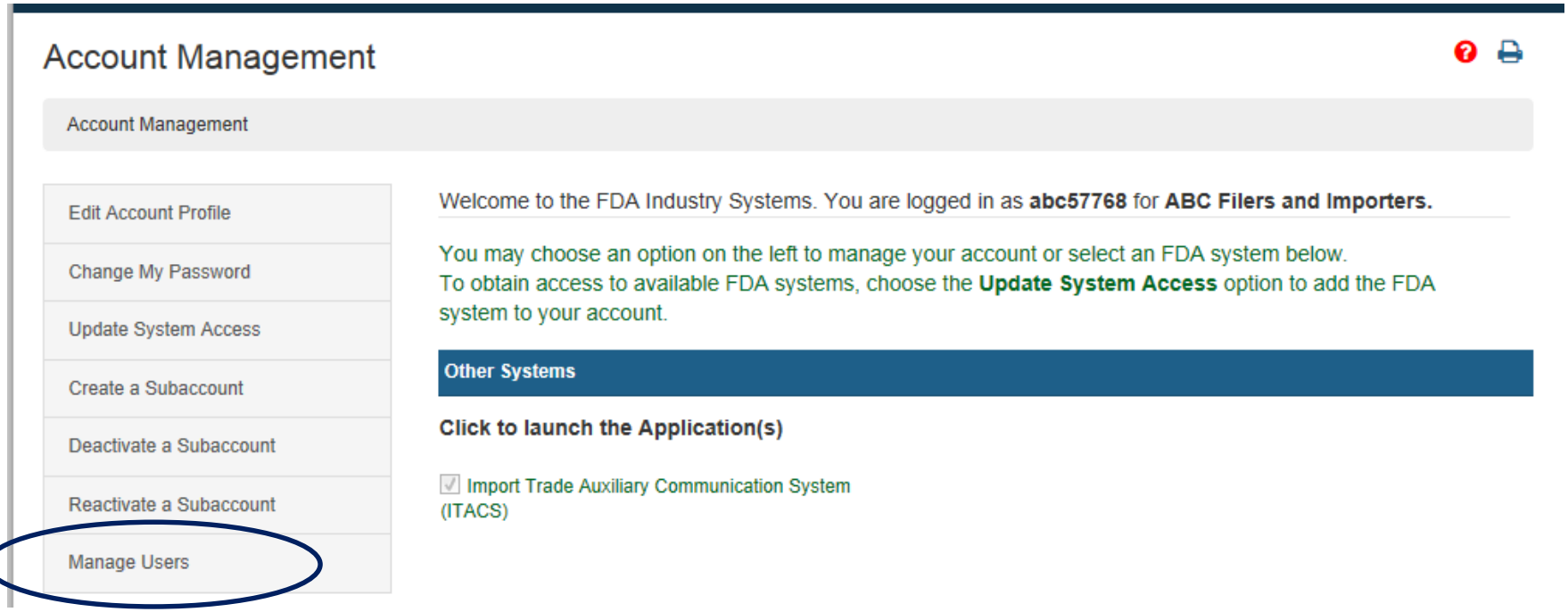
Verify the deactivated account you would like to reactivate and click ‘Submit’.



Managing your ITACS Account

Firm Administrator

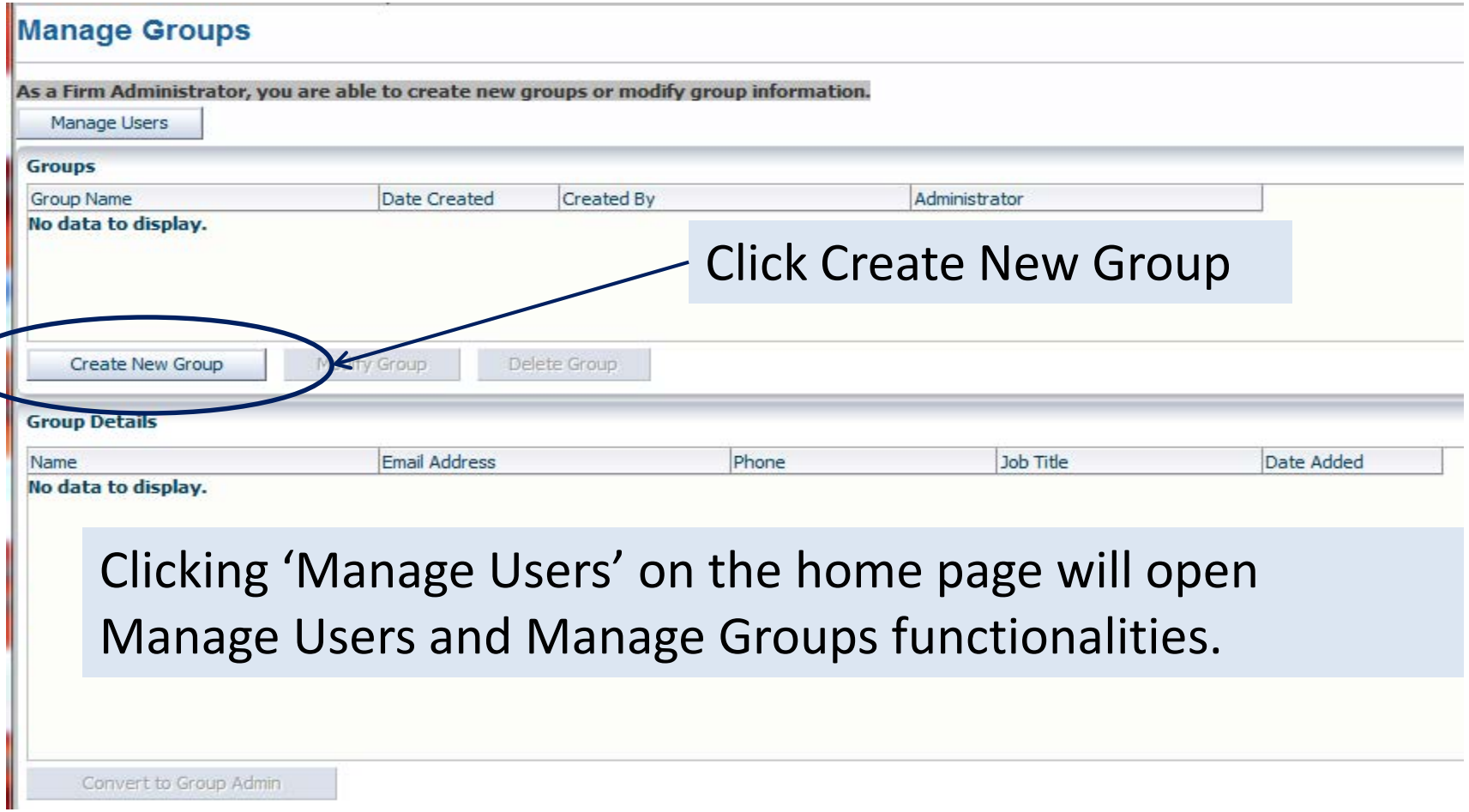
Manage Users will navigate to the screen that allows you to manage user information and create and manage your firm's groups.



Managing your ITACS Account

Firm Administrator

Creating Groups



Managing your ITACS Account

Firm Administrator

Creating Groups

Managing your ITACS Account

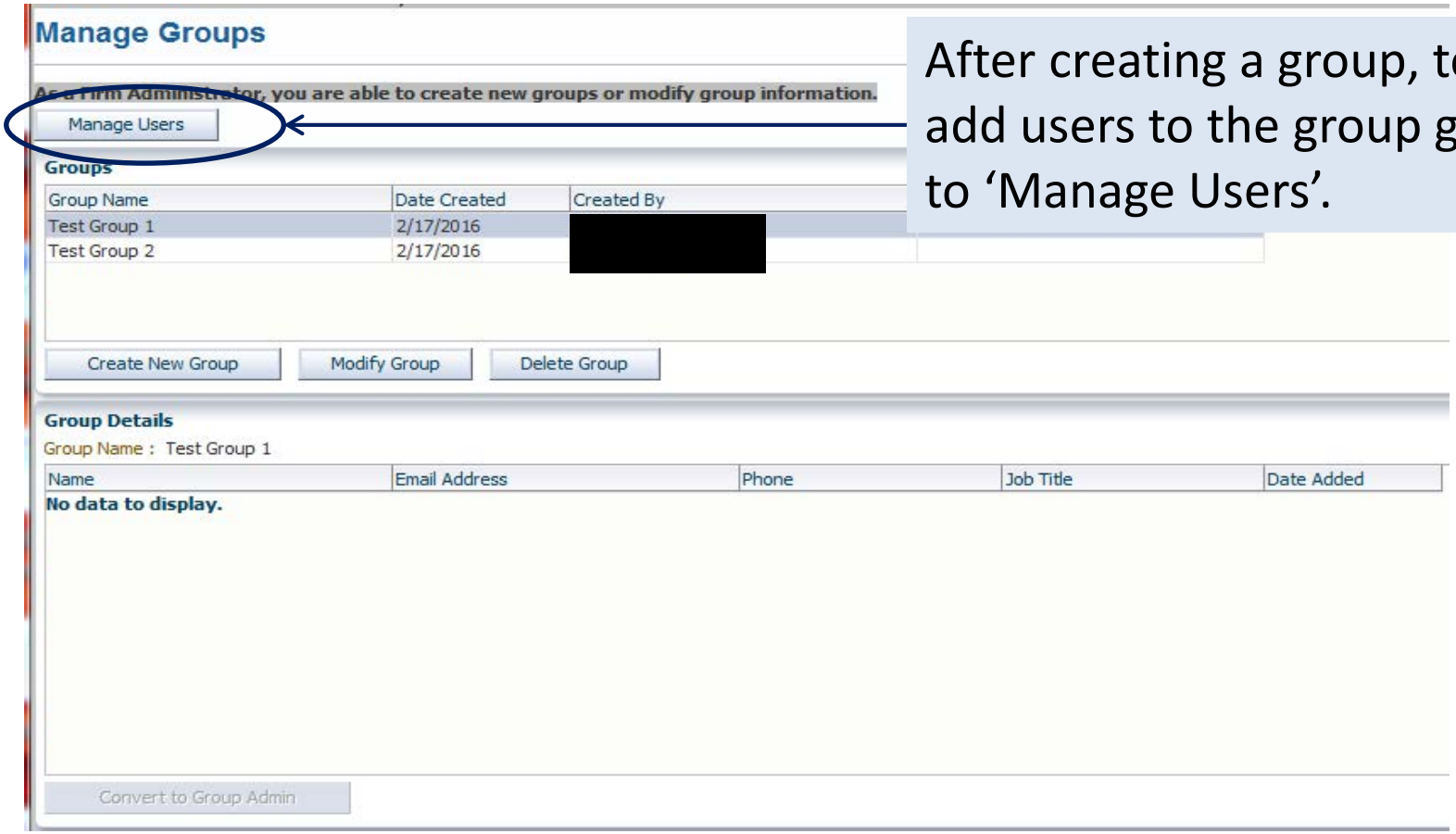
Firm Administrator

- Filers may specify which ports of entry for which a particular Group should receive Notices of FDA Action.
- All Ports should be selected if it is not desired to limit a Group's access to Notices.
- Importers of Record and Consignees will receive all Notices of FDA Action

Managing your ITACS Account

Firm Administrator

Creating Groups

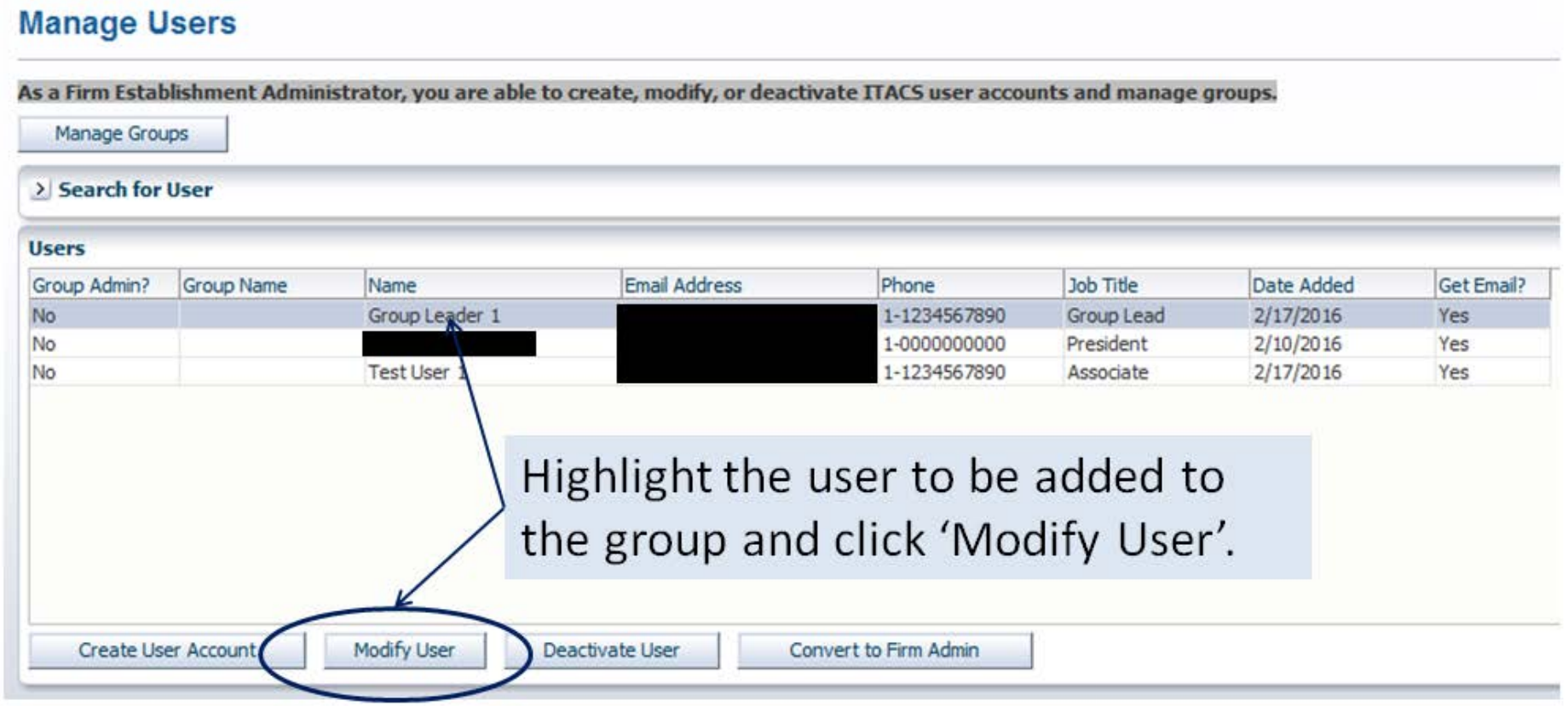


After creating a group, to add users to the group go to 'Manage Users'.

Managing your ITACS Account

Firm Administrator

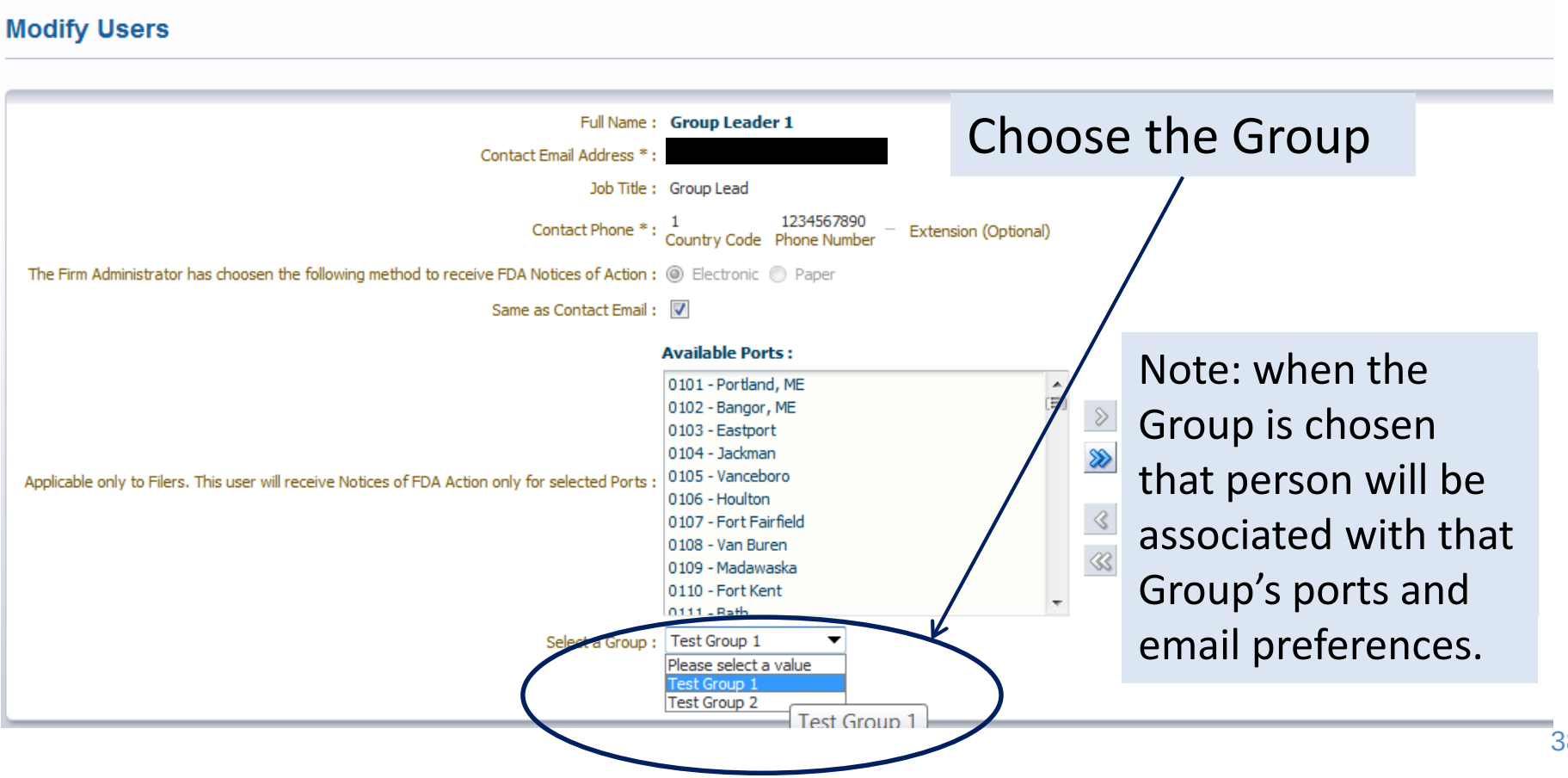
Creating Groups



Managing your ITACS Account

Firm Administrator

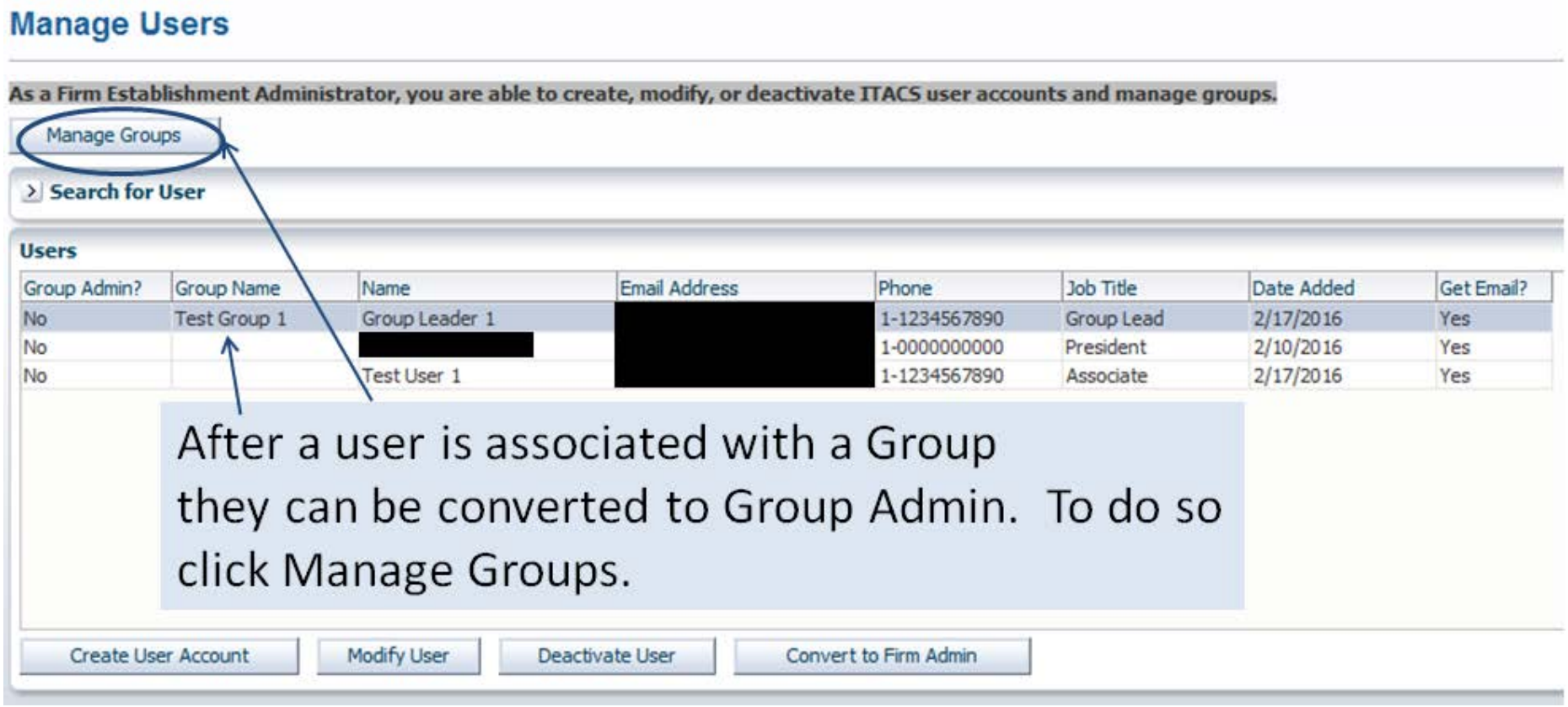
Creating Groups



Managing your Account

Firm Administrator

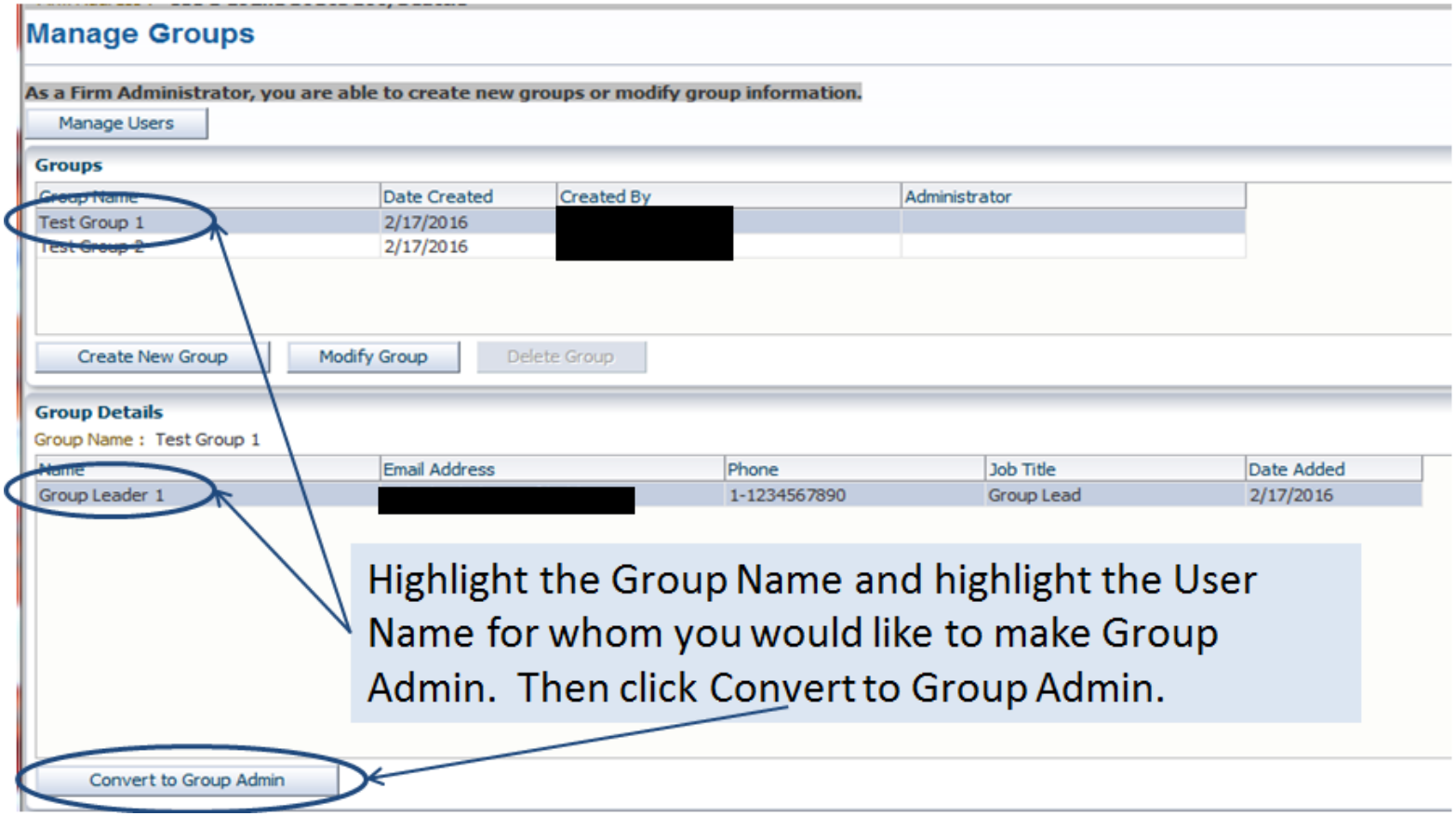
Creating Groups



Managing your Account

Firm Administrator

Creating Groups



Managing your Account

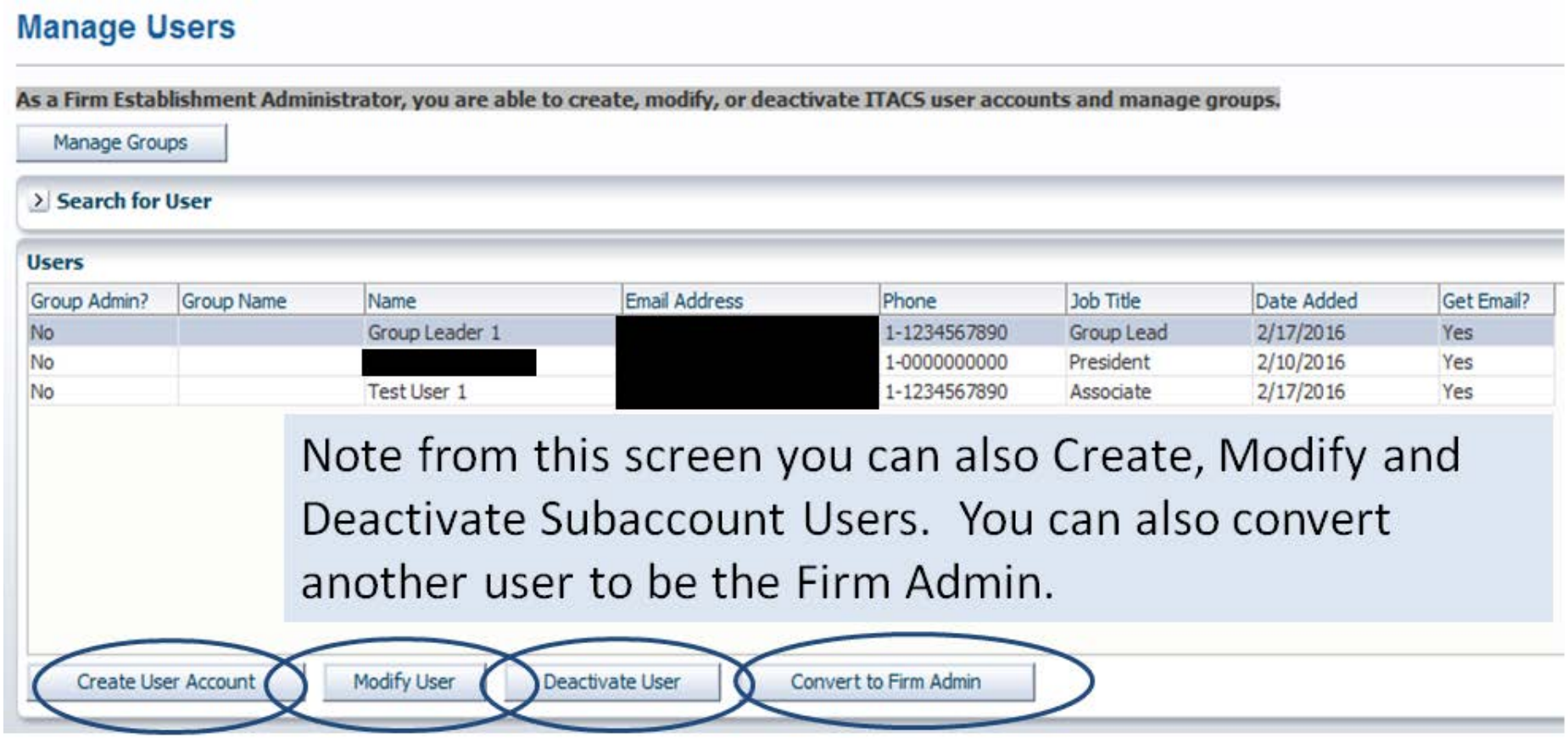
Firm Administrator

- After groups and Group Administrators are established, Group Administrators can create subaccounts and add/remove users to their group and can manage group settings.

- Firm Administrators can continue to manage all users/groups if needed.

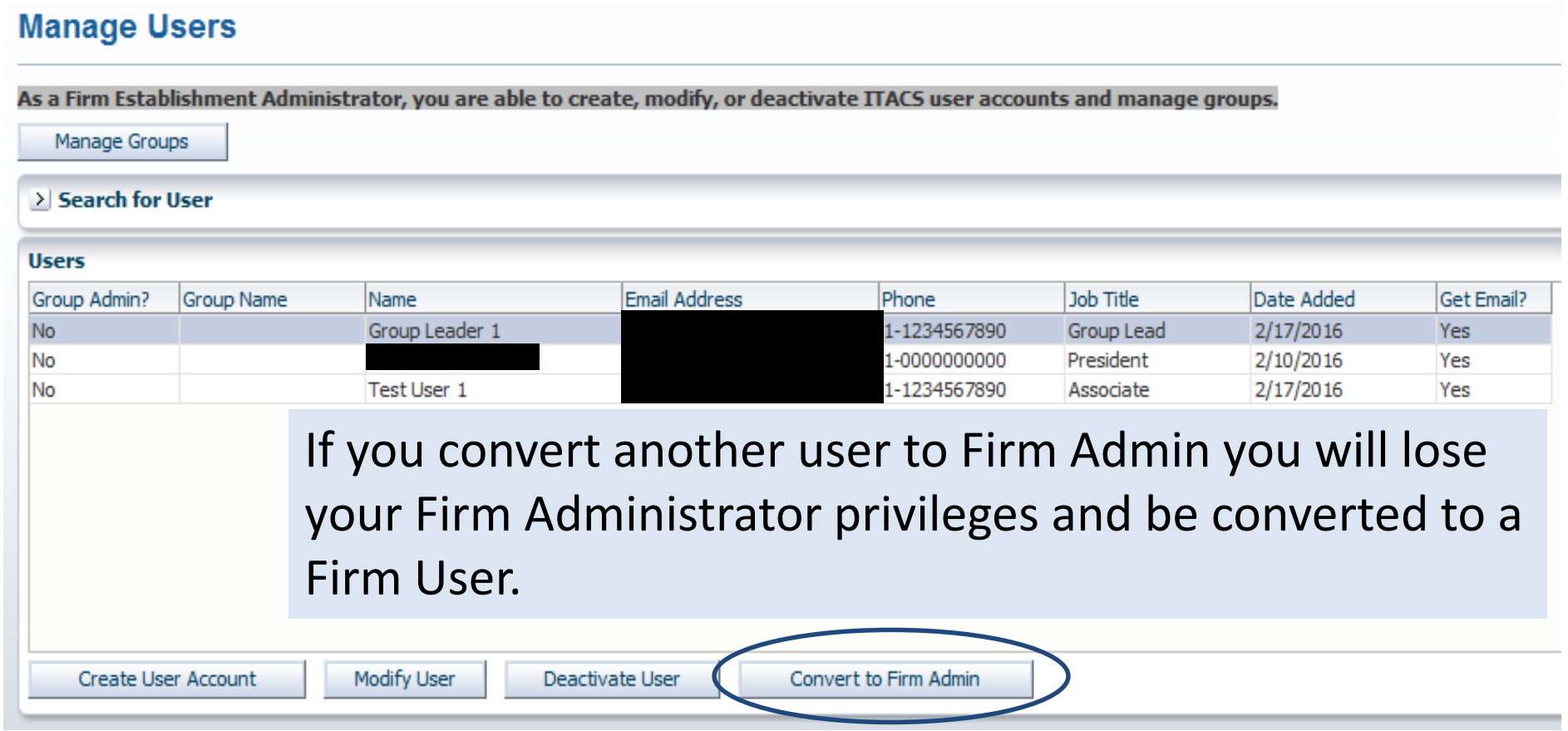
Managing your Account

Firm Administrator



Managing your Account

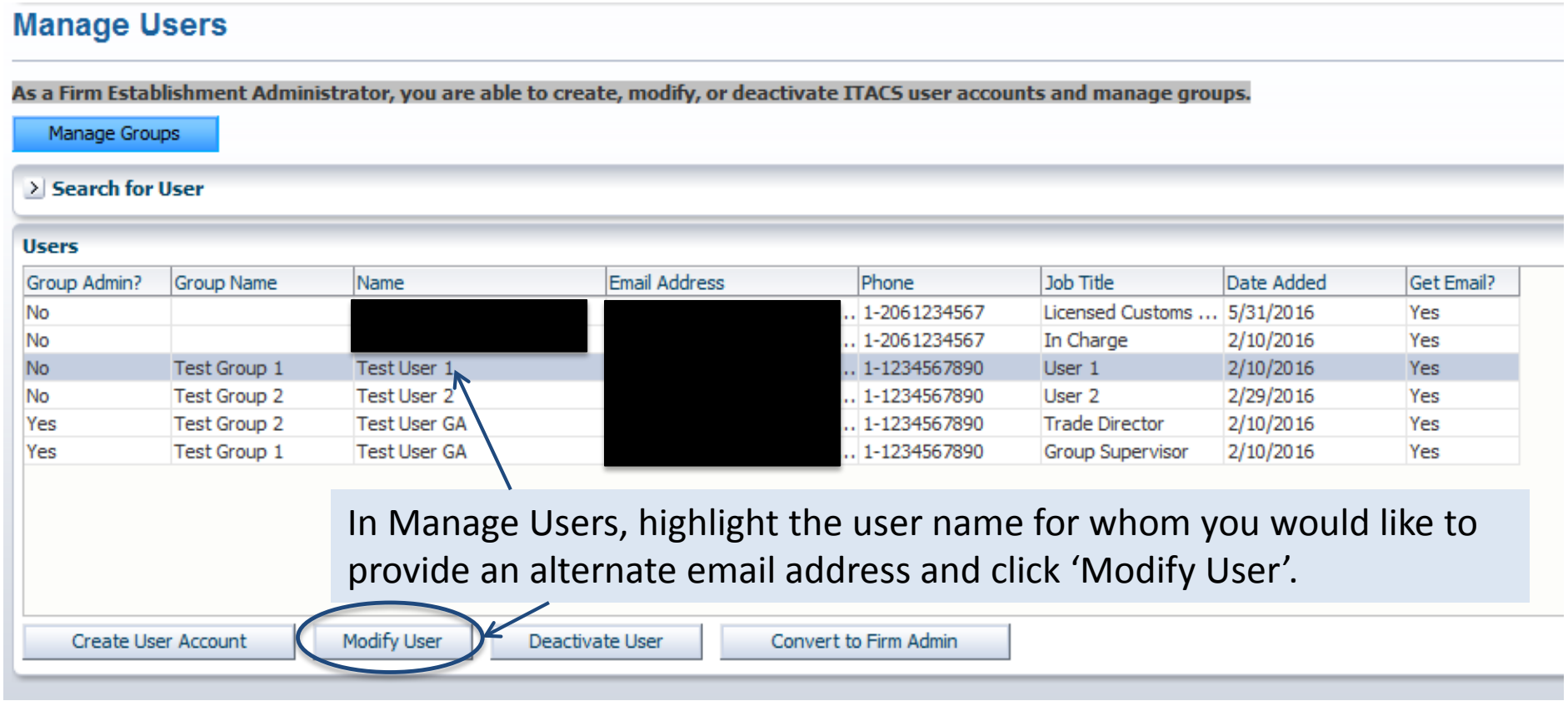
Firm Administrator



Managing your Account

Firm Administrator

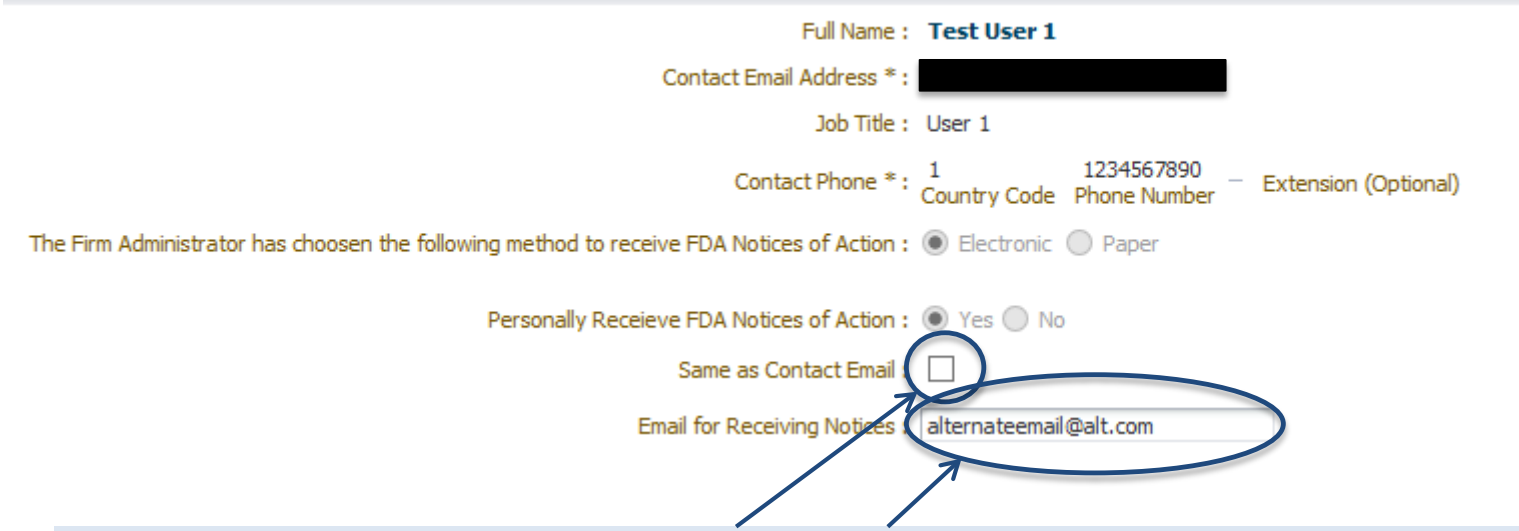
Updating email to receive Notices of FDA Action



Managing your Account

Firm Administrator

Updating email to receive Notices of FDA Action

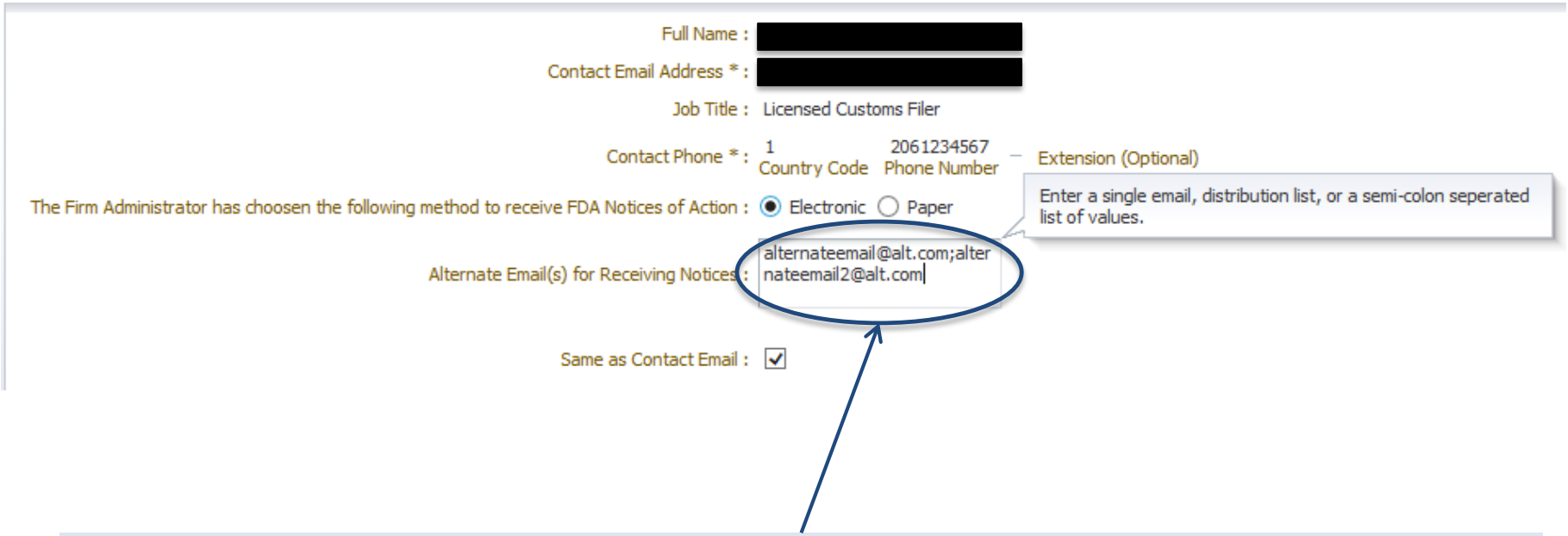


Uncheck 'Same as Contact Email'. This will open the text box for 'Email for Receiving Notices'. Enter one or more emails (separated by a semicolon if more than one).

Managing your Account

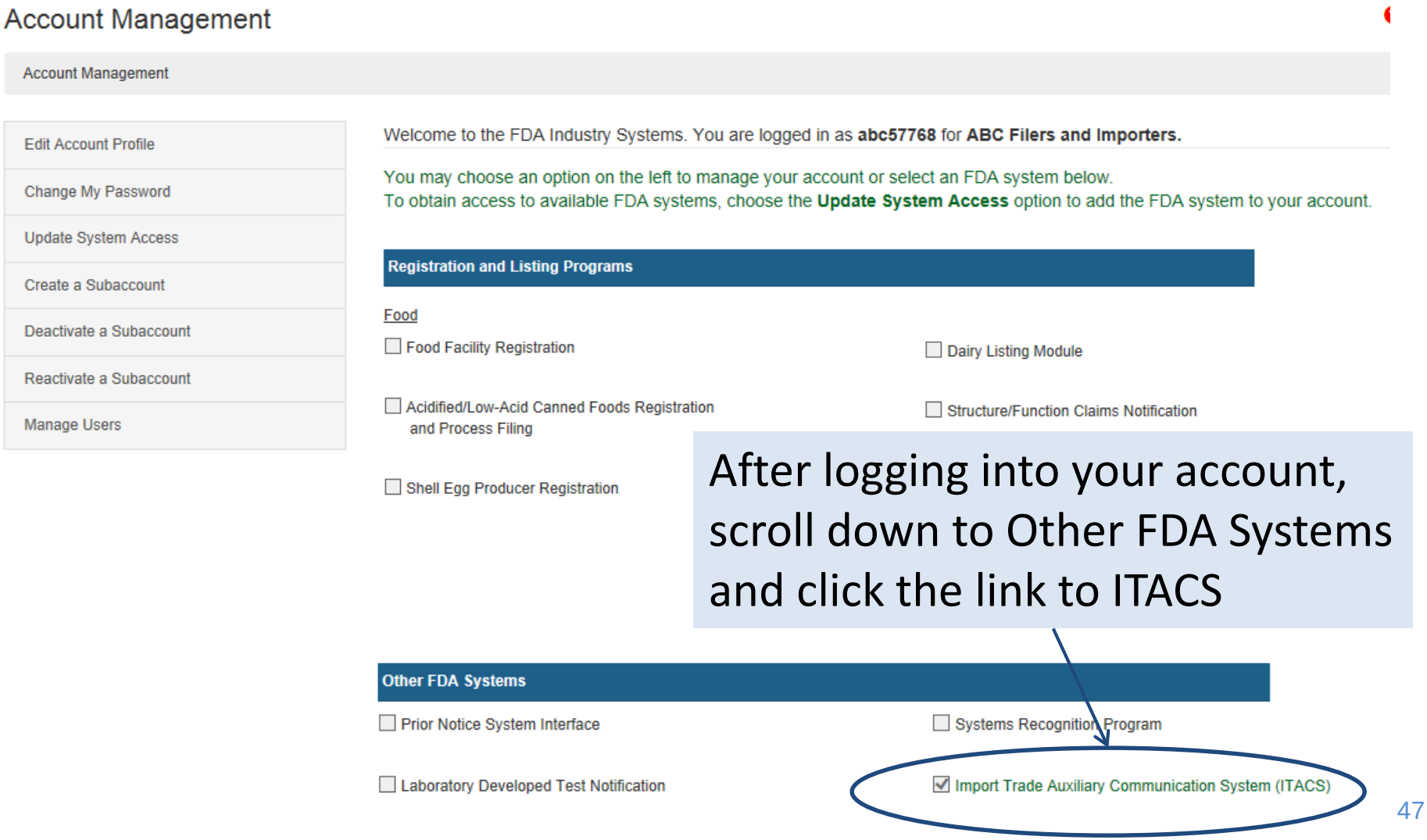
Firm Administrator

Updating email to receive Notices of FDA Action

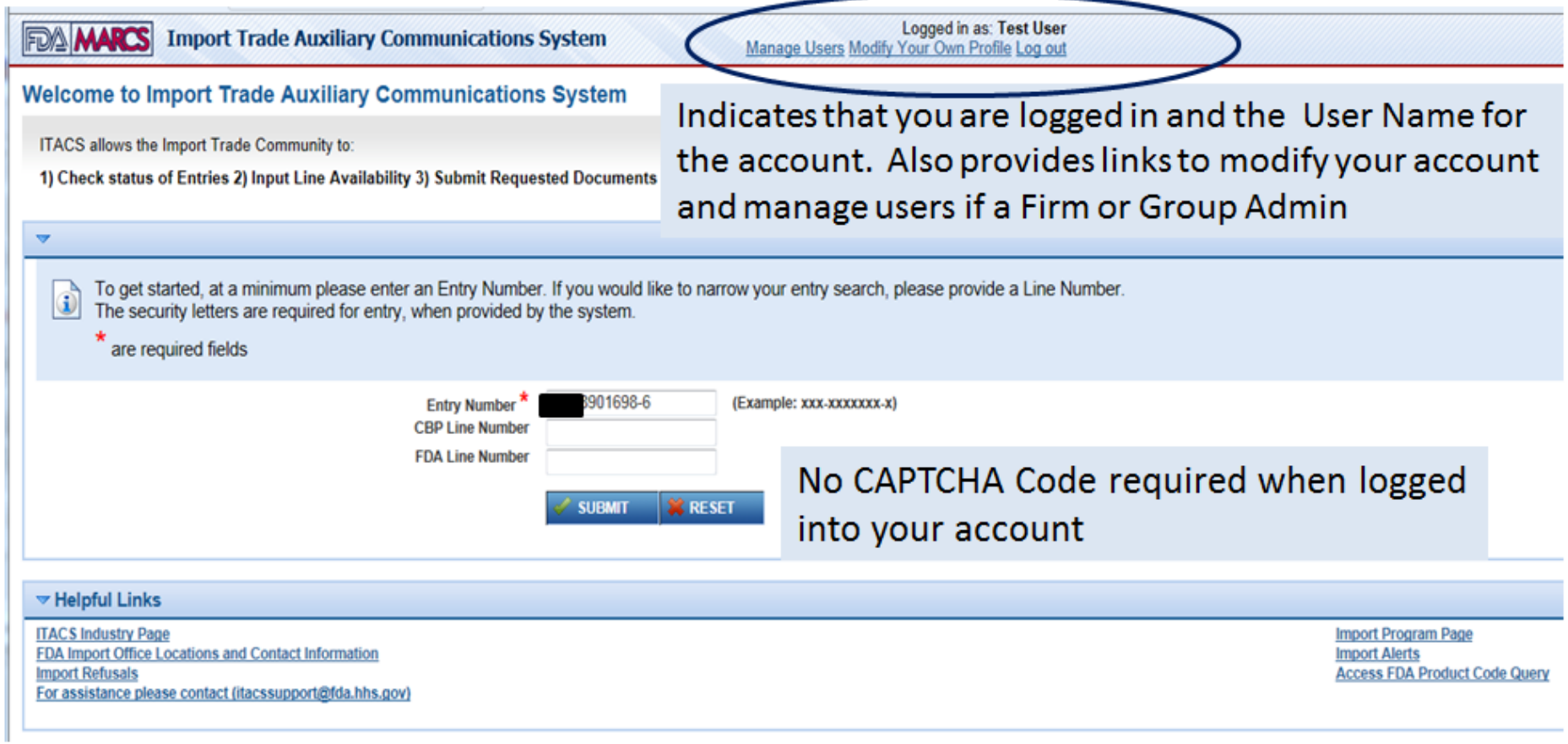


As Firm Administrator you can add alternate emails for receiving Notices (i.e. add a group distribution email and also receive Notices at your contact email address.

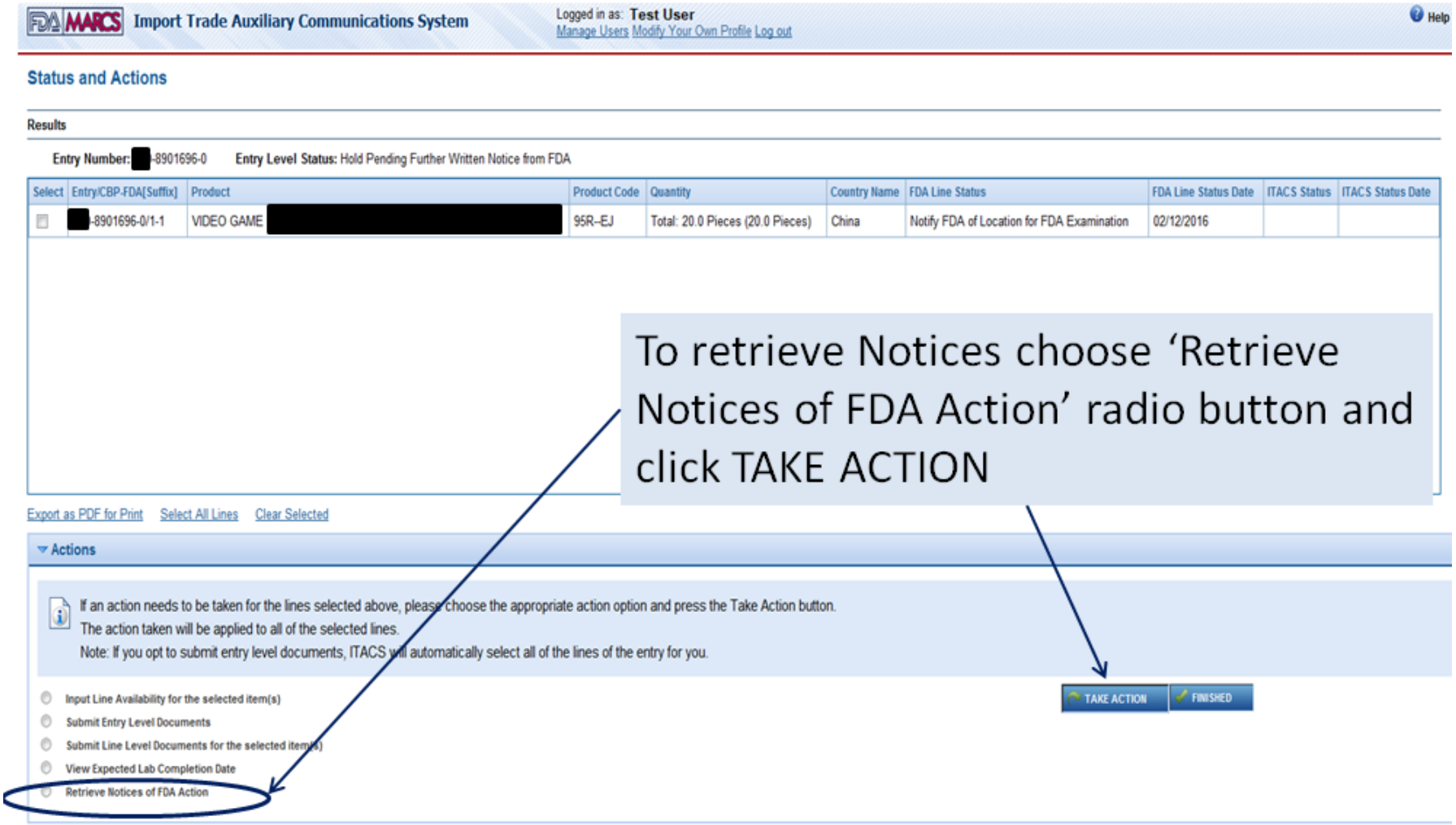
Retrieving Notices of FDA Action from ITACS



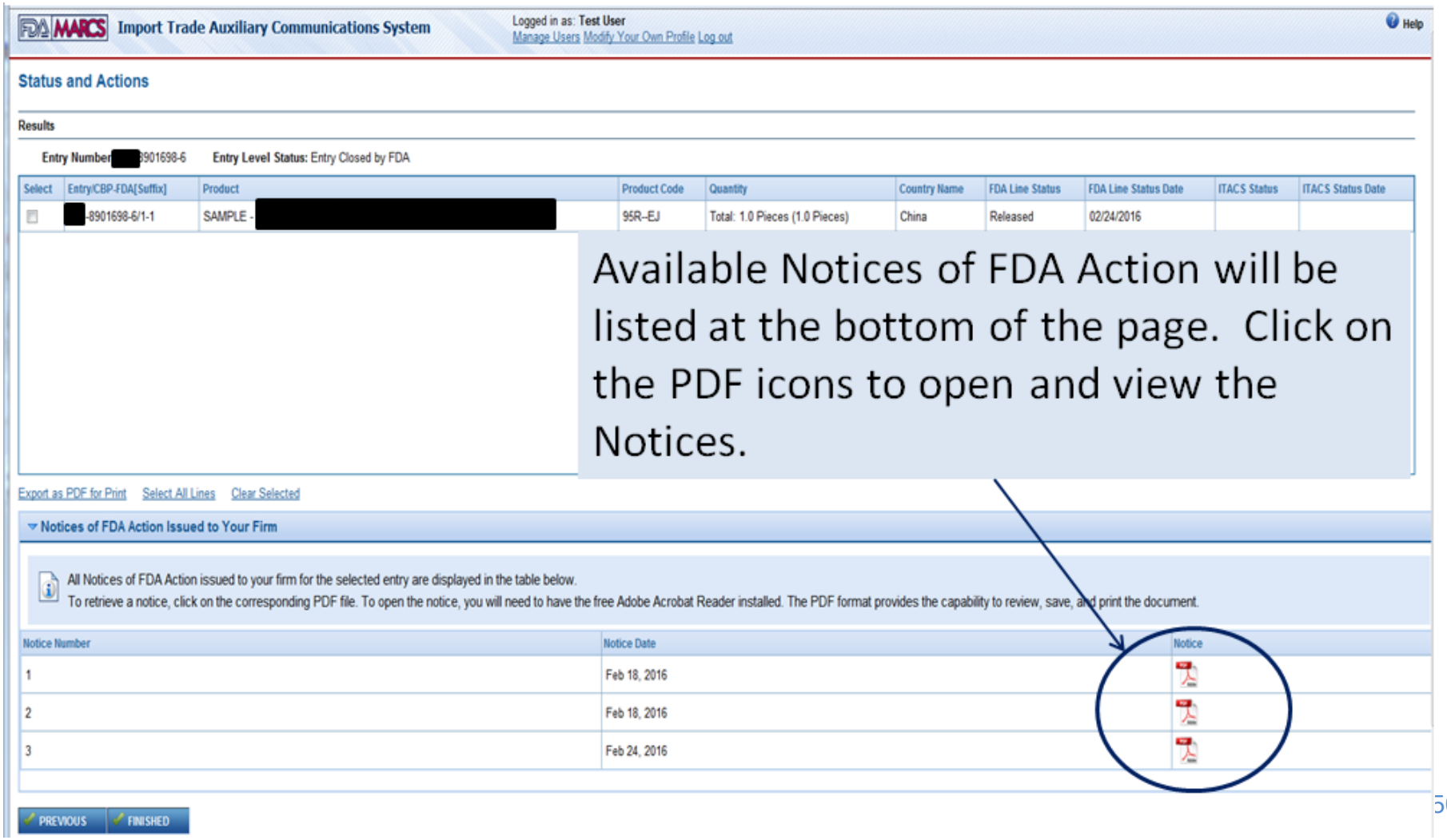
Retrieving Notices of FDA Action from ITACS



Retrieving Notices of FDA Action from ITACS

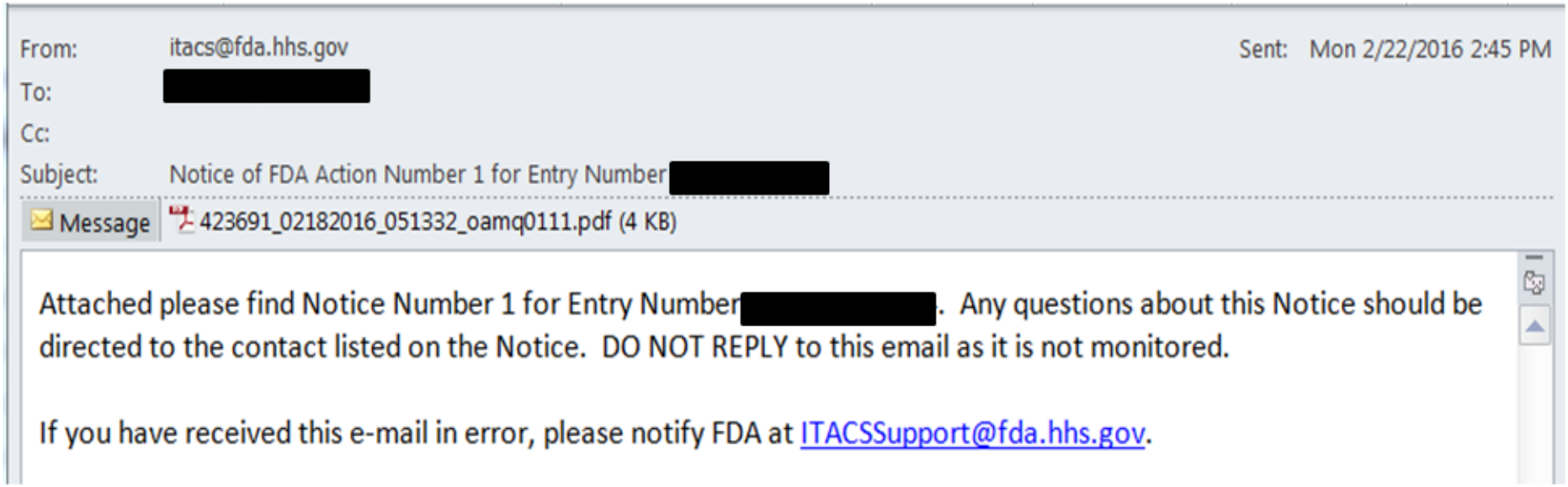


Retrieving Notices of FDA Action from ITACS



Emailed Notices of FDA Action

Example email received by the account holder with the Notice of FDA Action attached.

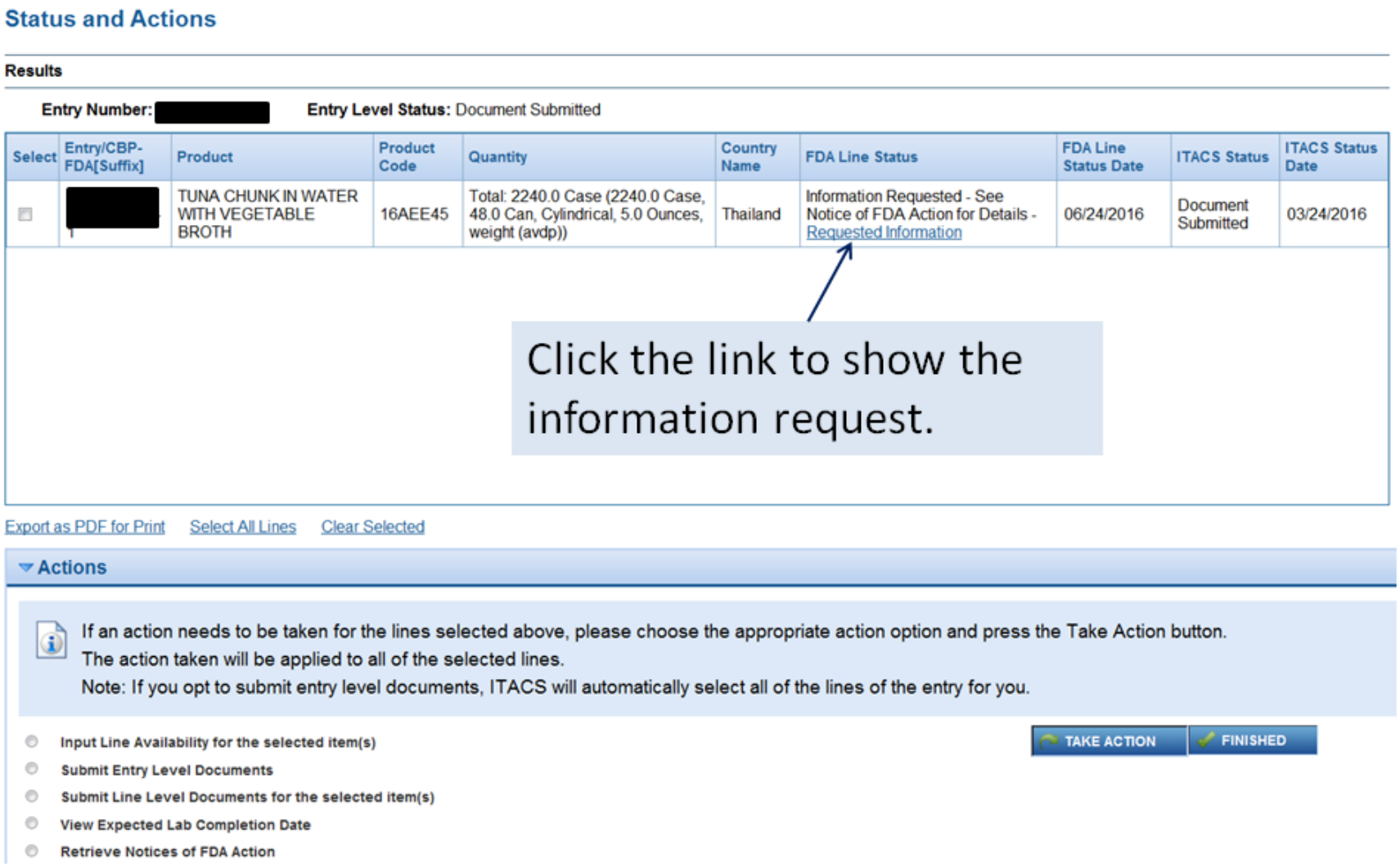


From: itacs@fda.hhs.gov Sent: Mon 2/22/2016 2:45 PM
To: [redacted]
Cc:
Subject: Notice of FDA Action Number 1 for Entry Number [redacted]
Message 423691_02182016_051332_oamq0111.pdf (4 KB)

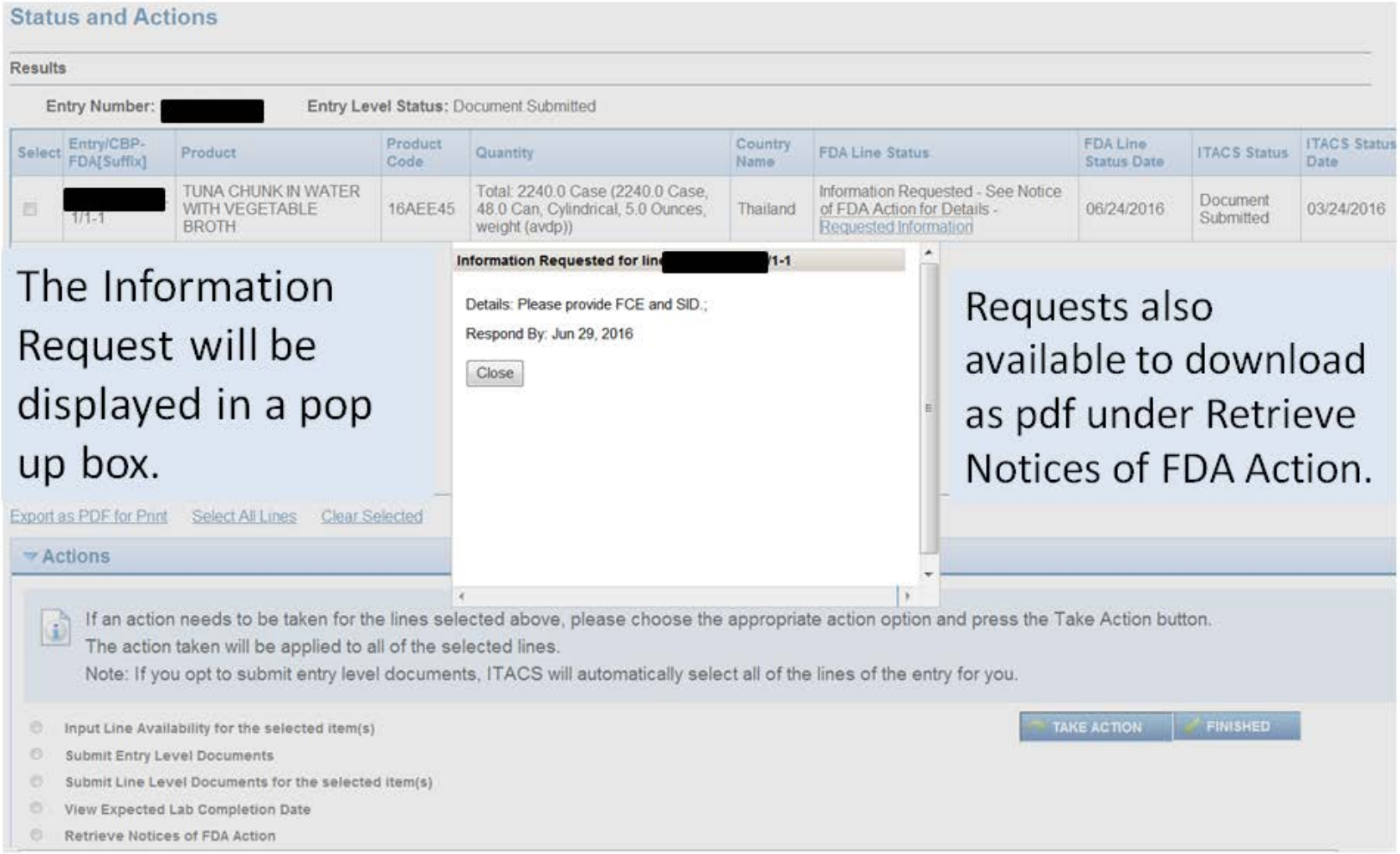
Attached please find Notice Number 1 for Entry Number [redacted]. Any questions about this Notice should be directed to the contact listed on the Notice. DO NOT REPLY to this email as it is not monitored.

If you have received this e-mail in error, please notify FDA at ITACSSupport@fda.hhs.gov.

Retrieving Information Requests from ITACS



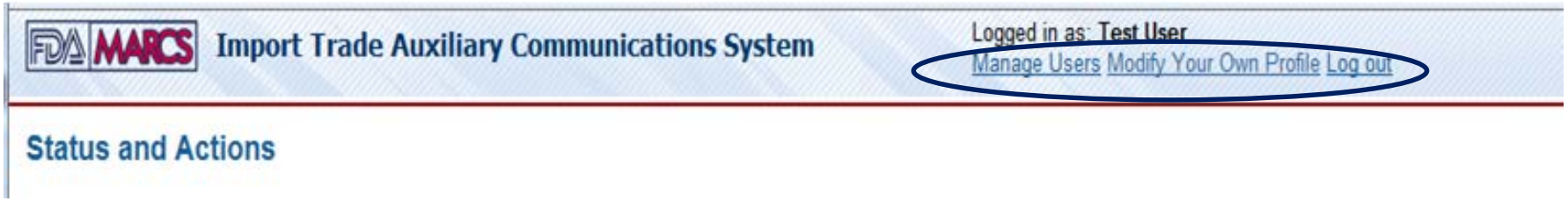
Retrieving Information Requests from ITACS



Managing your Account

Firm Administrator

Links to Manage your account and manage users found at the top of the screen



ITACS Links

ITACS: https://itacs.fda.gov

ITACS Support – for technical assistance regarding ITACS or to suggest additional functionality please email:

ITACSSupport@fda.hhs.gov

To view the ITACS Presentation to Industry PP and this ITACS Account Management PP visit:

http://www.fda.gov/forindustry/importprogram/entryprocess/importsystems/ucm480953.htm

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