

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.



- 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



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



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





FDA Industry Systems

New User

Create New Account



Existing account holders, enter your account ID & password. Account ID Password Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I understand. Togot your password Choose create new account

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your account ID and password.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.



Step 1: Select Applicable Center for Account Crea	tion	
Center for Biological Evaluation & Research (Expo	t Certification Application and Tracking)	
Center for Devices & Radiological Health (Device F	Registration and Listing / Export Certification Application and Tra	acking / Laboratory Developed Tests Notification)
Center for Drug Evaluation & Research (Export Ce	rtification Application and Tracking)	
	FSMA, LACF, SEPRM, SFCN, NDIN, PNSI / Systems Recogni re, Food Contact Substances, Dietary Supplements, Infant Form	
Center for Tobacco Products (Tobacco Registration	n and Product Listing)	
Other Systems Choose Other Systems		
Select the systems you will need to access		
Import Trade Auxiliary Communication System	Chaosa ITAC	:S
Please select your firm's official role(s) in the i	mportation of FDA-regulated products. You may select mo	re than one if applicable.
Importer of Record Consignee Filer	Indicate the type of firm. One or all types may be chosen.	



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	2C: Physical Address (Business) of Account Holder
First Name	Country / Area
John	UNITED STATES
Middle Initial (Optional)	Address Line 1
Α	123 Main Street
Last Name / Surname	Address Line 2 (Optional)
Smith	
Job Title	City
Team Leader	Anytown
Company Name	State / Province / Territory
ABC Filers and Importers	Washington
Phone Number	Zip Code (Postal Code)
123 4567890	98225
Country Area Phone Number Extension	DUNS Number (Optional)
Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.	Don's Number (Optional)
FAX Number (Optional)	Do you have preferred mailing address other than the physical address mentioned above?
Country Area Fax Number	⊚ Yes
E-mail Address	
john.smith@abc.com	
Confirm E-mail Address	
john.smith@abc.com	Fill out the required
Does your firm agree that it no longer needs to receive paper Notices of	
FDA Action? West If selected FDA will no longer provide your firm with paper copies	information.

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

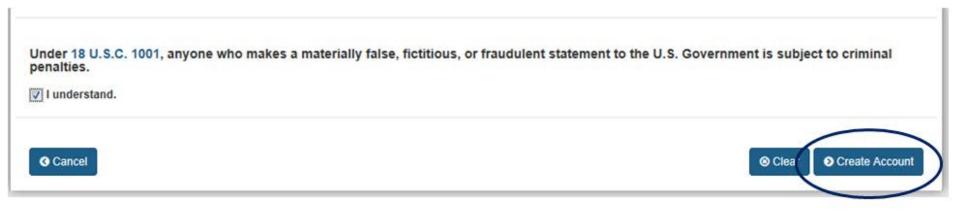
be sent to your firm. Firm account holders will still have the option to view

Notices online, but will not receive them via email.

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





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

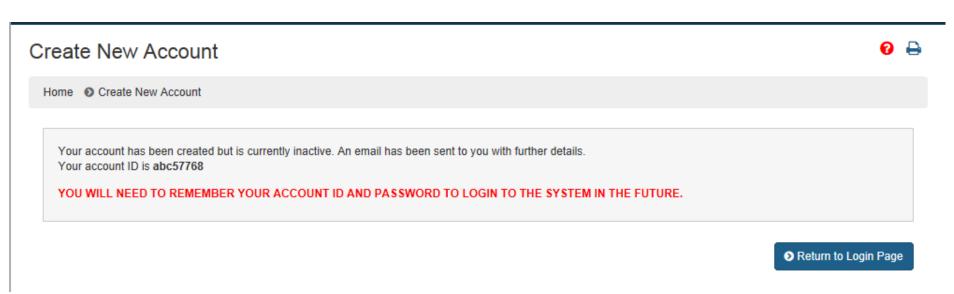
Click the Submit button to create an account, or click the Modify button to return and edit your account profile.







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.





 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 verification.

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.



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.



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.

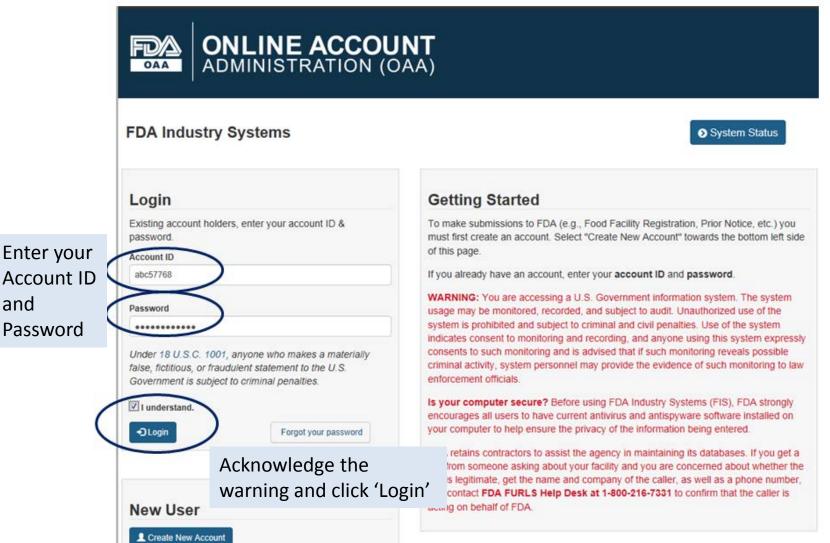
As Firm Administrator, you may now log into FURLS at https://www.access.fda.gov/oaa. Once logged in, you can create groups and designate Group Administrators. For assistance with this functionality, please refer to the help link within the application or posted here: http://www.fda.gov/ForIndustry/ImportProgram/ucm296314

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

FDA ITACS Support Team

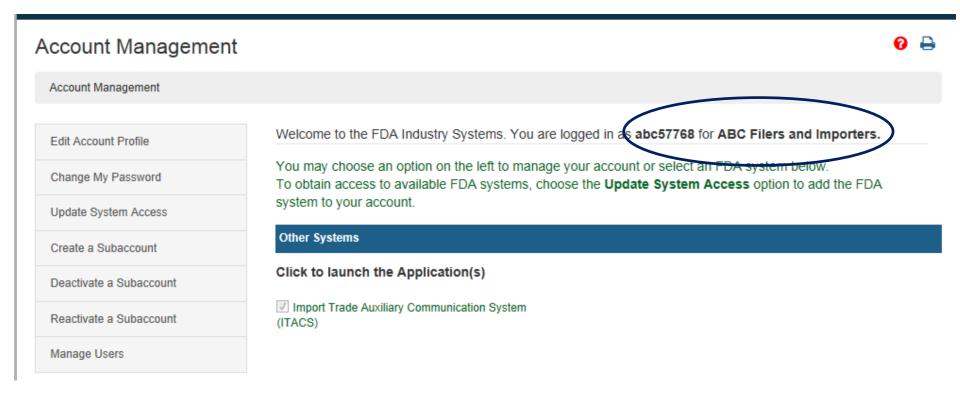


Logging into Your ITACS Account





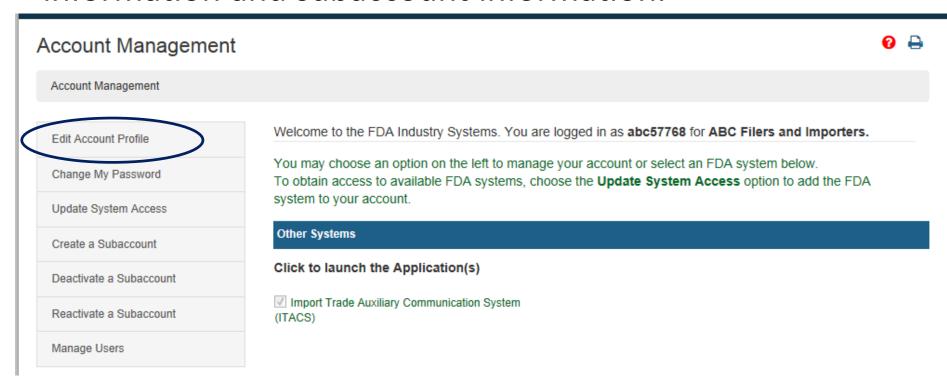
Logging into Your ITACS Account Firm Administrator Your Account Home Page





Firm Administrator

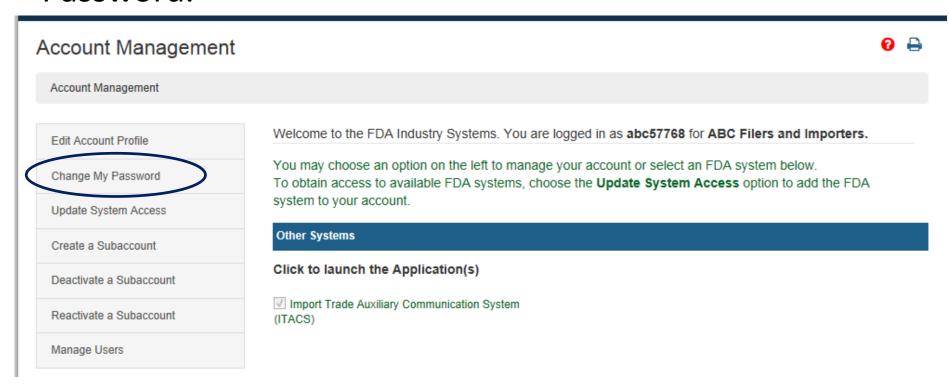
Edit Account Profile allows you to edit your account information and subaccount information.





Firm Administrator

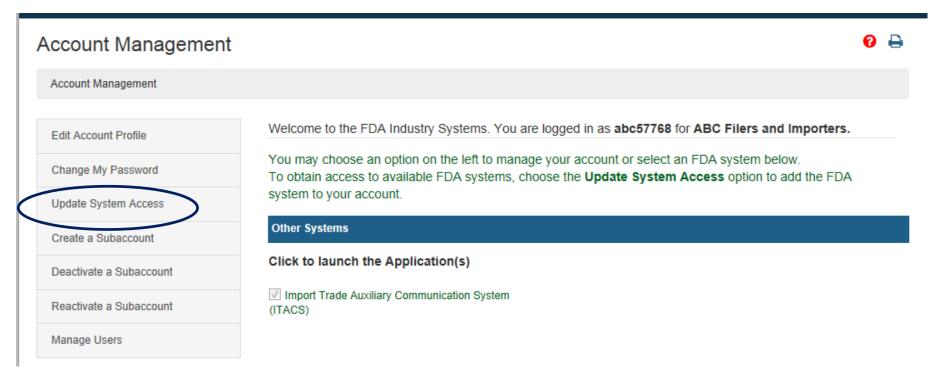
Change My Password allows you to change your account Password.





Firm Administrator

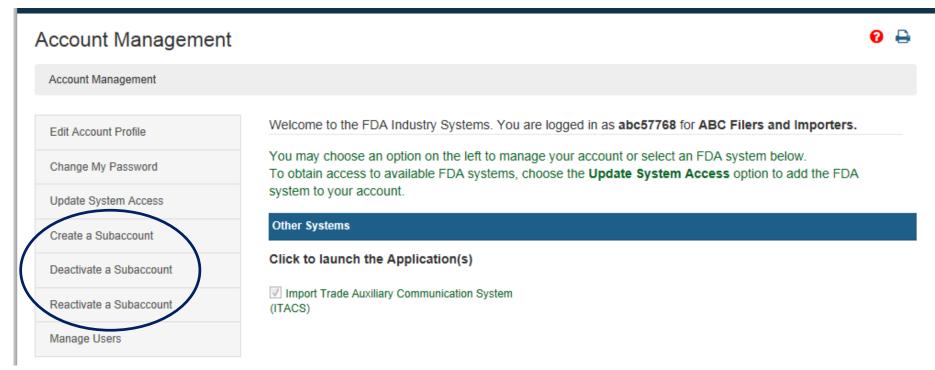
Update System Access allows you to add or remove firm types, Filer, Importer, Consignee.





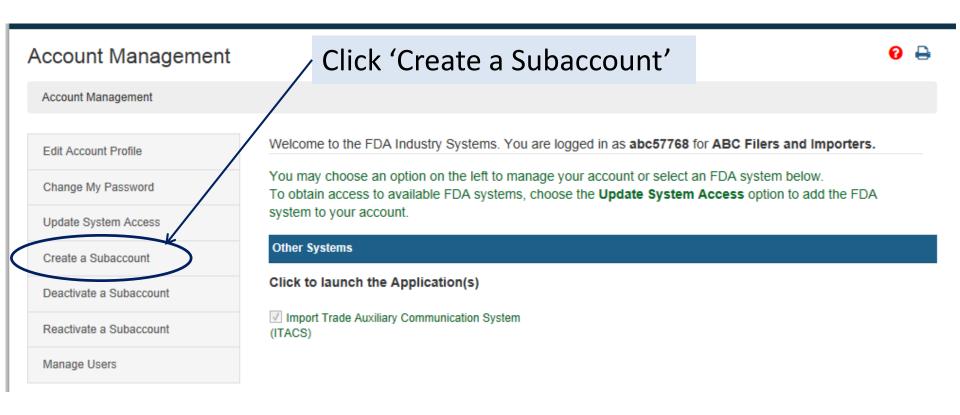
Firm Administrator

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





Managing your ITACS Account Firm Administrator Creating Subaccounts





Firm Administrator Creating Subaccounts

Create a Subaccount

Point of Contact Information	Physical Address (Business) of Account Holder
First Name	Country / Area
Test	UNITED STATES
Middle Initial (Optional)	Address Line 1
	123 Main Street
ast Name / Surname	Address Line 2 (Optional)
User 1	
Job Title	City
Associate	Anytown
Subaccount Company Name (Optional)	State / Province / Territory
	Washington
Phone Number	Zip Code (Postal Code)
123 4567890 Country Area Phone Number Extension	98148
Country Area Phone Number Extension Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required or US phone numbers.	Do you have preferred mailing address other than the physical address mentioned above? — Yes No
FAX Number	
Country Area Fax Number	Fill out the required information
-mail Address	and click 'Continue'
test.user@abc.com	und chek continue
Confirm E-mail Address	
test.user@abc.com	



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.

Click the Submit button to create an account, or click the Modify button to return and edit your account profile.

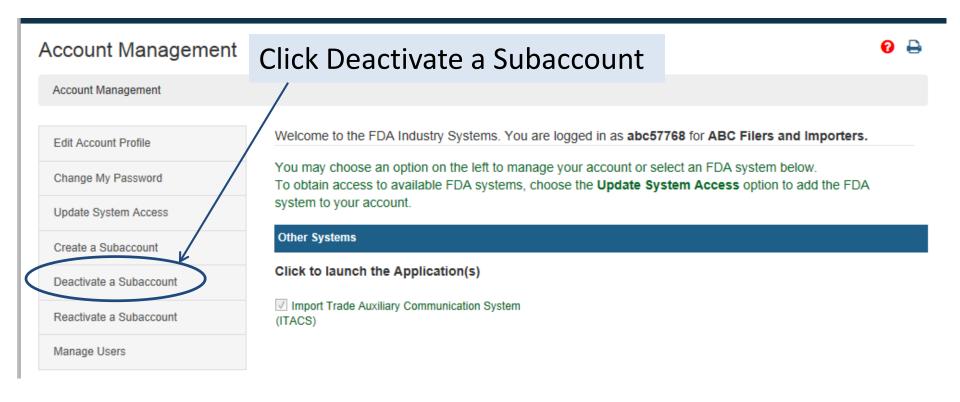




The new user will receive separate emails with their user name and temporary password.



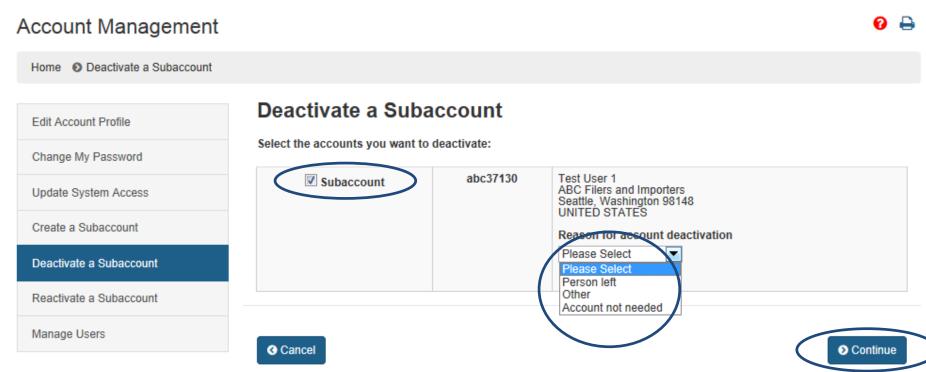
Managing your ITACS Account Firm Administrator Deactivating Subaccounts





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.





Deactivating Subaccounts

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

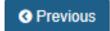
DEACTIVATE SUBACCOUNT

You are about to deactivate:

abc37130

Test User 1 ABC Filers and Importers Seattle, Washington 98148 UNITED STATES

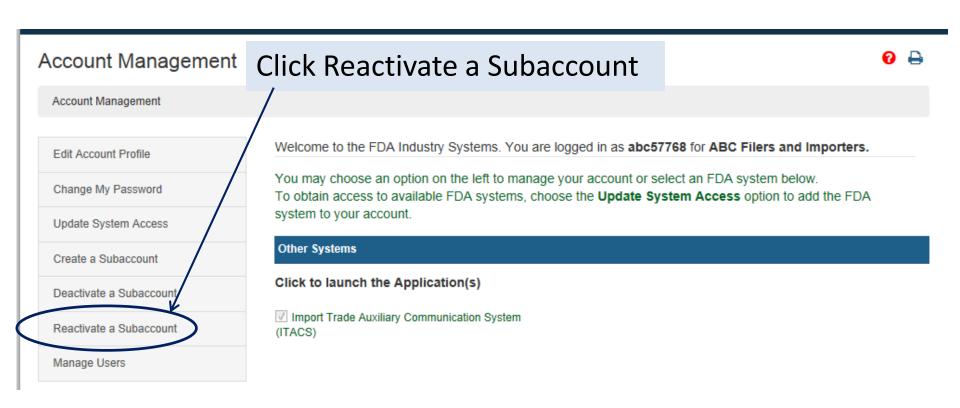






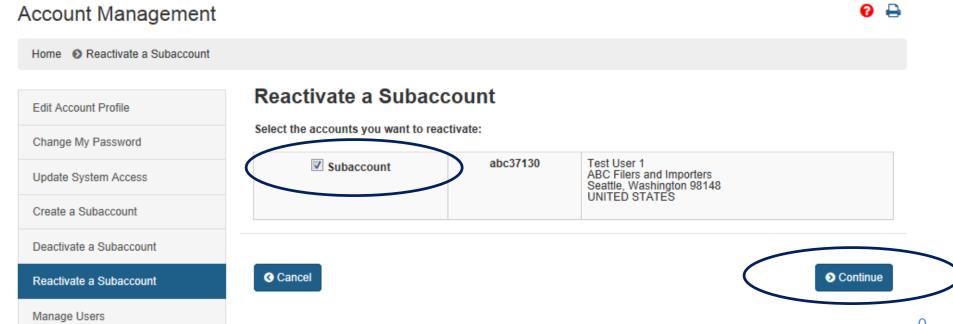


Reactivating a Deactivated Subaccount





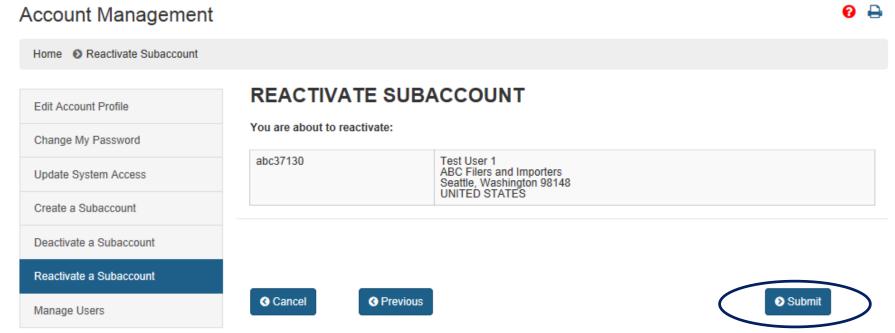
Reactivating a Deactivated Subaccount Select the deactivated account you would like to reactivate and click 'Continue'.





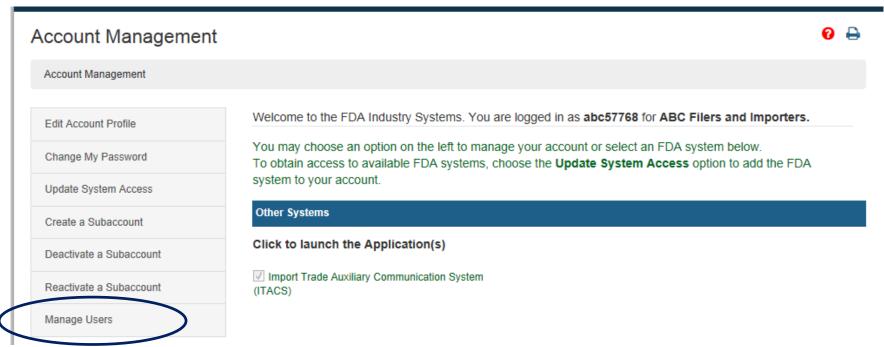
Reactivating a Deactivated Subaccount

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





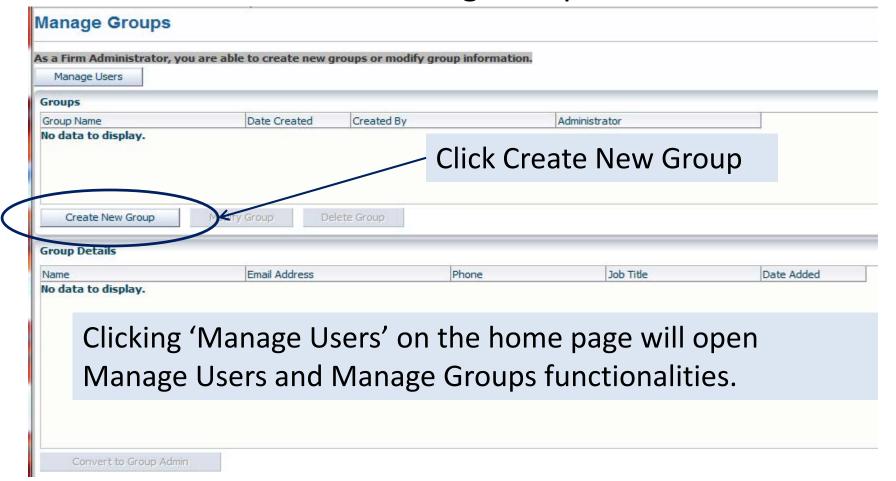
Manage Users will navigate to the screen that allows you to manage user information and create and manage your firm's groups.





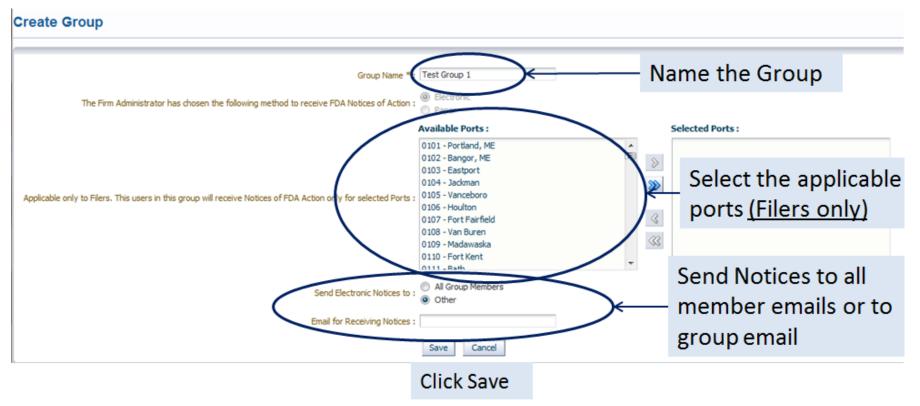
Firm Administrator

Creating Groups





Firm Administrator Creating Groups



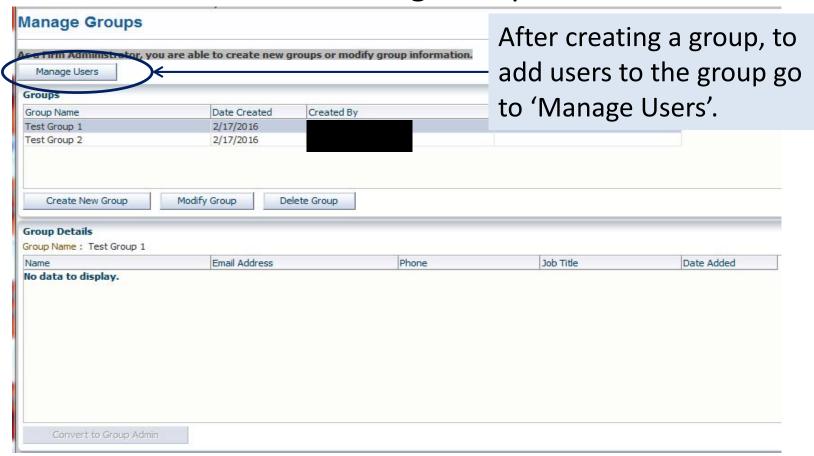
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- Filers may specify which ports of entry for which a particular Group should receive Notices of FDA Action.
- All Ports should be selected if it is not desired to limit a Group's access to Notices.
- Importers of Record and Consignees will receive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



Firm Administrator Creating Groups

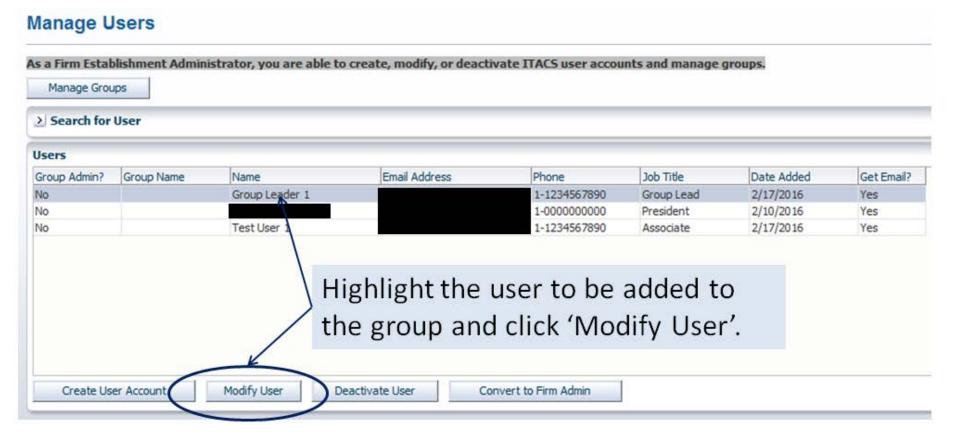




Managing your ITACS Account

Firm Administrator

Creating Groups

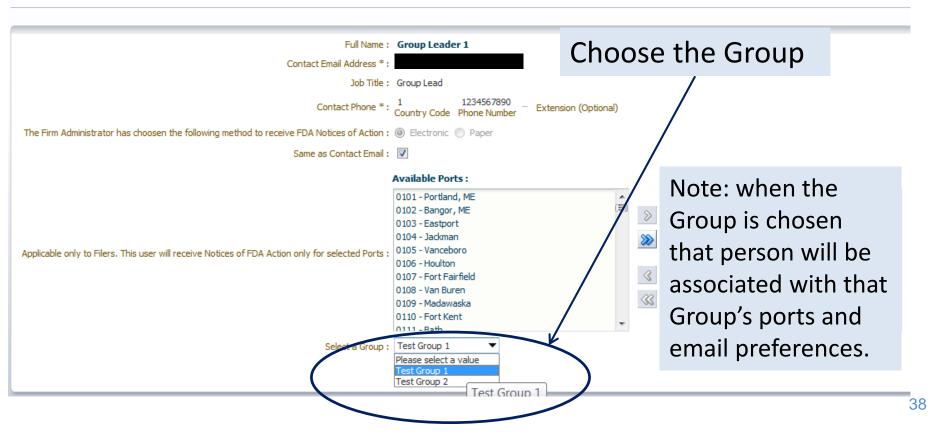




Managing your ITACS Account

Firm Administrator Creating Groups

Modify Users





Managing your Account Firm Administrator Creating Groups

Manage Users





Managing your Account Firm Administrator Creating Groups

s a Firm Administrator, you a	re able to create new	groups or modify group info	rmation.		
Manage Users					
Groups					
Croop Name	Date Created	Created By	Admir	nistrator	
Test Group 1	2/17/2016				
Test Group 2	2/17/2016				
\					
\					
1					
		1.1.0			
Create New Group	Modify Group	elete Group			
\	Modify Group	elete Group			
Group Details	Modify Group	elete Group			
Group Details					
Group Details Group Name: Test Group 1	Modify Group D Email Address	Phone		Job Title	Date Added
Group Details Group Name: Test Group 1		Phone	4567890	Job Title Group Lead	Date Added 2/17/2016
Group Details Group Name: Test Group 1 Hame		Phone			
Group Details Group Name : Test Group 1	Email Address	Phone 1-123	4567890	Group Lead	2/17/2016
Group Details Group Name : Test Group 1	Email Address	Phone 1-123	4567890	Group Lead	2/17/2016
Group Details Group Name: Test Group 1 Hame	Email Address Highlight	t the Group Na	1567890 1me and h	nighlight the	2/17/2016 e User
Group Details Group Name: Test Group 1	Email Address Highlight	t the Group Na	1567890 1me and h	nighlight the	2/17/2016 e User
\	Highlight Name fo	t the Group Na	ime and h	nighlight the	e User Dup
Group Details Group Name : Test Group 1	Highlight Name fo	t the Group Na	ime and h	nighlight the	e User Dup



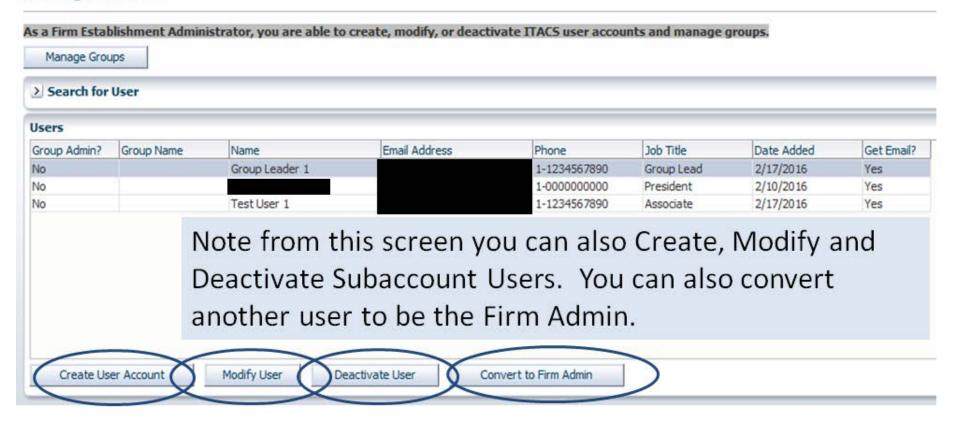
Managing your Account Firm Administrator

- 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.



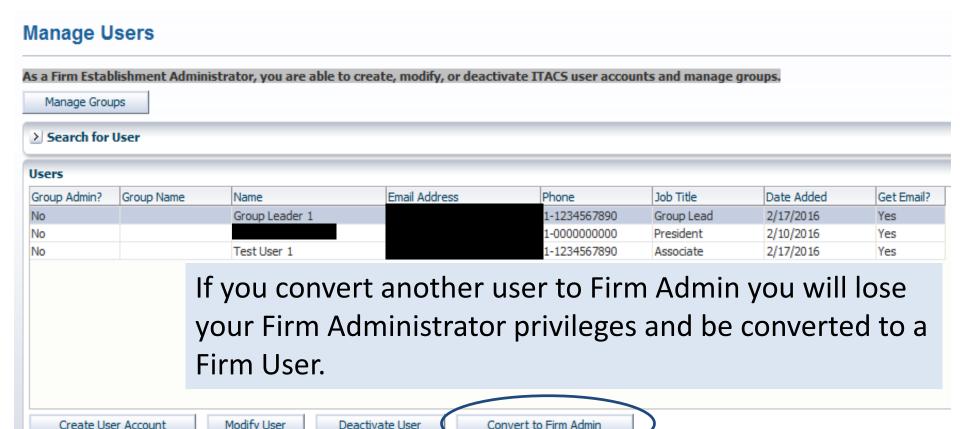
Managing your Account Firm Administrator

Manage Users





Managing your Account Firm Administrator



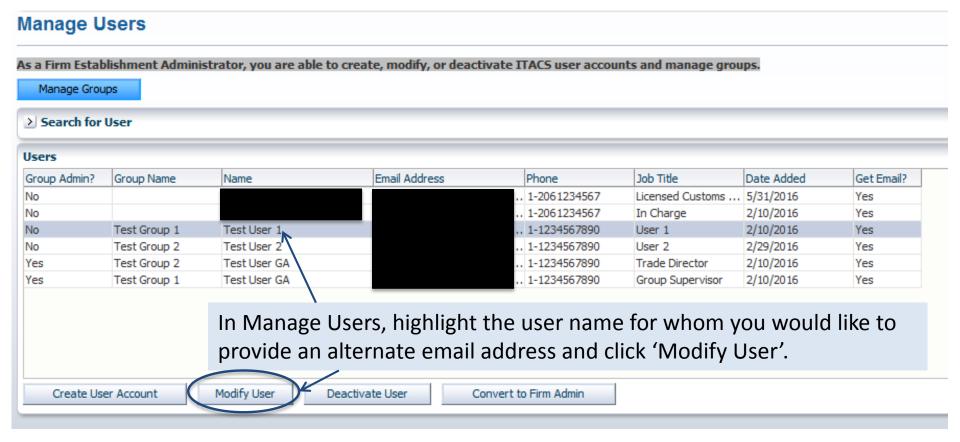
Modify User

Create User Account



Managing your Account

Firm Administrator Updating email to receive Notices of FDA Action





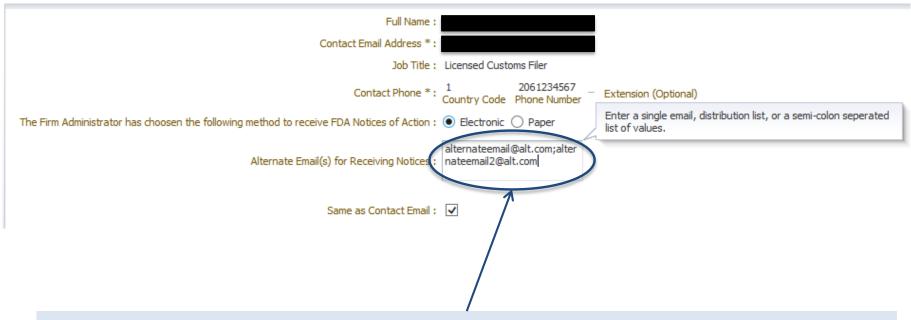
Managing your Account Firm Administrator Updating email to receive Notices of FDA Action

Test User 1
User 1
1 1234567890 - Extension (Optional)
Electronic Paper
alternateemail@alt.com

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

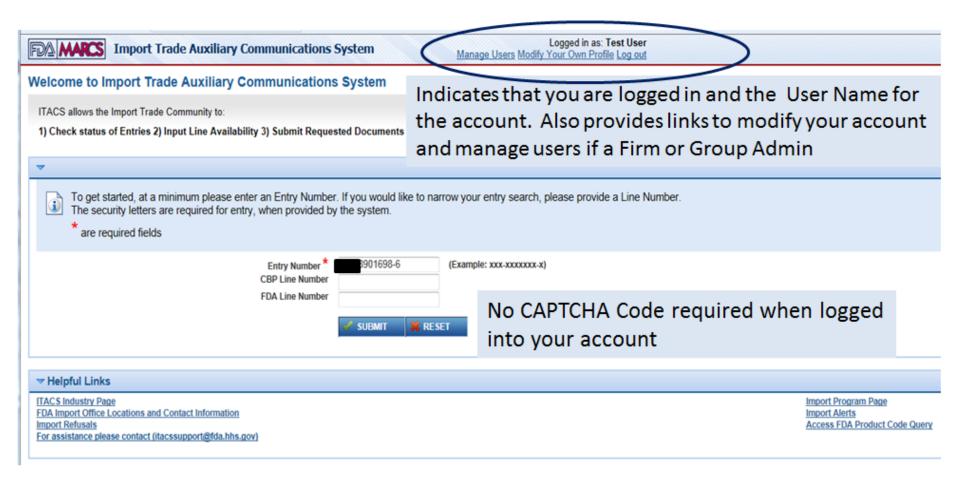


As Firm Administrator you can add alternate emails for receiving Notices (i.e. add a group distribution email and also receive Notices at your contact email address.

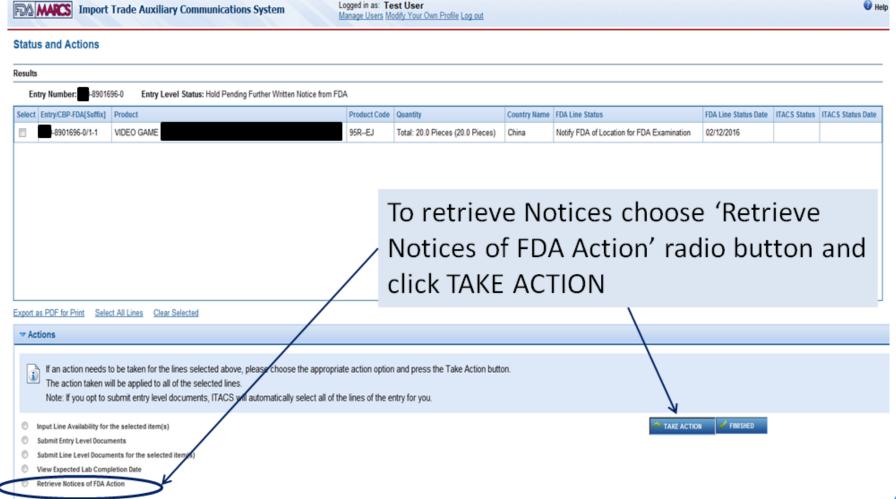


Account Management Account Management Welcome to the FDA Industry Systems. You are logged in as abc57768 for ABC Filers and Importers. Edit Account Profile You may choose an option on the left to manage your account or select an FDA system below. Change My Password To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account. Update System Access **Registration and Listing Programs** Create a Subaccount Food Deactivate a Subaccount Food Facility Registration Dairy Listing Module Reactivate a Subaccount Acidified/Low-Acid Canned Foods Registration Structure/Function Claims Notification Manage Users and Process Filing After logging into your account, Shell Egg Producer Registration scroll down to Other FDA Systems and click the link to ITACS Other FDA Systems Systems Recognition Program Prior Notice System Interface Laboratory Developed Test Notification ✓ Import Trade Auxiliary Communication System (ITACS)

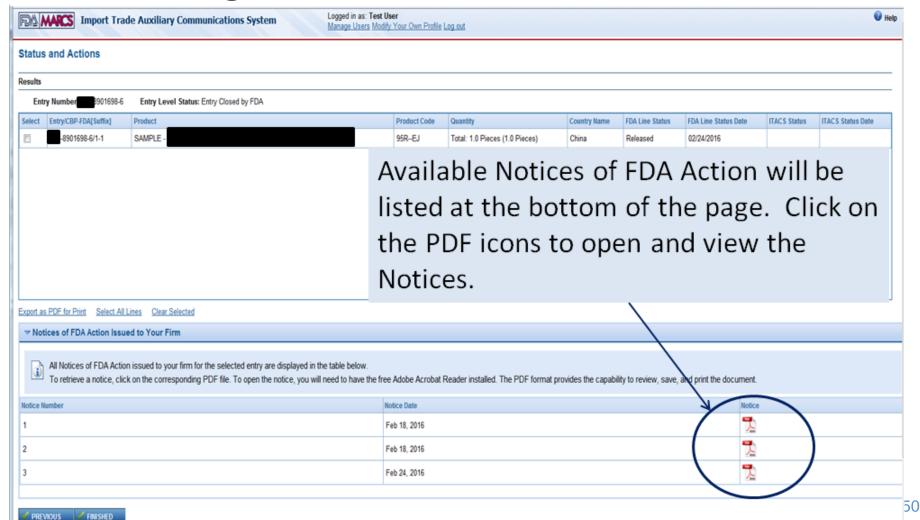








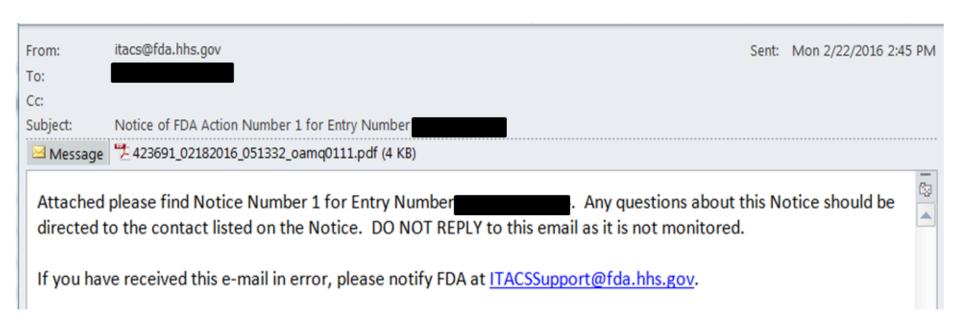






Emailed Notices of FDA Action

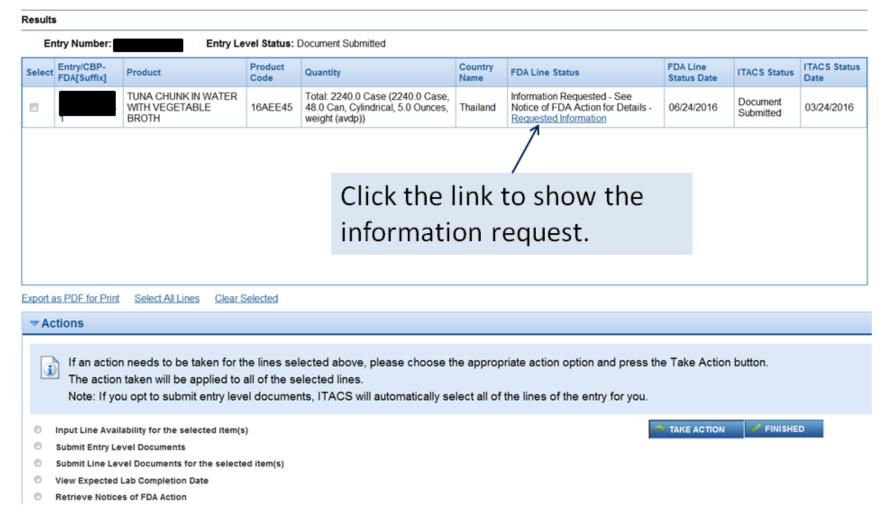
Example email received by the account holder with the Notice of FDA Action attached.





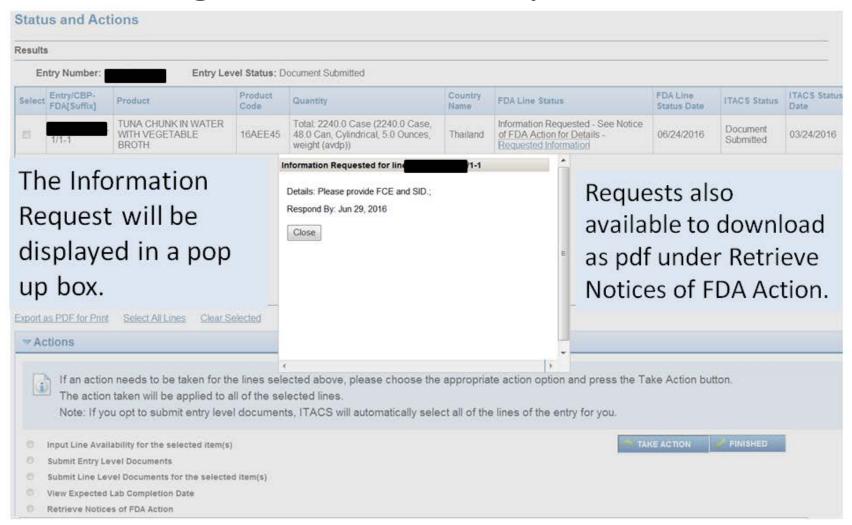
Retrieving Information Requests from ITACS

Status and Actions





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



Status and Actions



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

