

FDA's ITACS Account Management

Import Trade Auxiliary Communications System

January 2025 Food and Drug Administration Division of Import Business Informatics & Solutions Import Business Solutions Branch



Topics

- Background and Overview
- Creating a New Account
- Retrieving Notices of FDA Action from ITACS
- View line by line status history report
- 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
- View line by line status history report

ITACS accounts 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.

Background and Overview

- ITACS Account Management functionality may be used by customs brokers (entry filers), importers of record, and consignees with an approved ITACS account.
- ITACS accounts are limited to one individual per firm at the corporate level. This person should be a high-ranking individual within the firm as they will have the responsibility to create and manage ITACS subaccounts for other users within their firm.
- Note that an ITACS account is not required to import FDA regulated goods. To be granted an ITACS account a firm must have been a party (Filer, Importer of Record, and/or Consignee) to at least one previously transmitted, non-disclaimed FDA entry.



Benefits of ITACS Accounts

Benefits of ITACS accounts include:

- Faster receipt of Notices of FDA Action either via e-mail or via download from within ITACS
- No need to wait for hard copy mailed Notices of FDA Action
- No need to maintain paper copies of Notices of FDA Action as they will continue to be available in ITACS even after an entry is closed
- Receipt of requests for specific information sent via email or via download within ITACS
- Can view/download line by line status history report



- 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 but are not limited to:
 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 Administrator Account is allowed per firm. A Firm Administrator Account should be created by the person who is authorized to act as the Firm Administrator

Firm Administrator can:

- Create, Deactivate, Reactivate Firm subaccounts
- Create, Modify, Delete groups
- Grant/Transfer Group Admin and Firm Admin privileges

Group Administrator can:

- Create new subaccounts
- Add/Remove Users to their own group
- Modify group settings
- Firm User can:
 - Modify own user account
 - Access ITACS account functionality



- Click on the <u>ITACS Account Log-in(FURLS)</u> link on the ITACS Home page
- Or go directly to FURLS: <u>https://www.access.fda.gov/oaa/</u>



ONLINE ACCOUNT ADMINISTRATION (OAA)

FDA Industry Systems



Login

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.

Login

Forgot Account ID Forgot 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: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

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.



Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Other FDA Systems	her FDA Systems
Prior Notice System Interface Import Trade Auxiliary Communication System (ITAC S) Please select your mon's ornicial role(s) in the importation of FDA	A-regulated products, rowing select more than one in appricable.
Importer of Record Consignee Filer (Licensed Customs Broker) Indication One of	ate the type of firm. or all types may be chosen if applicable.
CDER Office of manufacturing Quality (CDER OMQ e-Portal)	



FDA

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Step 2: Enter Your Account Information

2A: Point of Contact Information	2C: Physical Address (Business) of Account Holder
First Name	Country / Area
Jane Smith	UNITED STATES
Middle Initial (Optional)	Address Line 1
A	123 Main Street
Last Name / Surname	Address Line 2 (Optional)
Smar	Optional
Job Title	City
Team Lead	Anytown
Company Name	State / Drawings / Tarritany
ABC Filers	Washington
Web Address (Optional)	aagan ington
	Zip Code (Postal Code)
(Example: http://www.name.domain.or.http://name.domain)	98123
Phone Number	DUNS Number (Optional)
Country 123 4567890 Ext	Optional
Country Area Phone Number Extension	Do you have preferred mailing address other than the physical address mentioned above?
Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Cour	^{itry} O Yes ® No
code is not required for US phone numbers.	
FAX Number (Optional)	
Country Area Fax Number	Fill out the required information
Country Area Fax Number	r in out the required information.
E-mail Address	
jane.smith@abc.com	
Confirm E-mail Address	Salact 'Vac' hard to receive
jane.smith@abc.com	Select les liere to receive
 Poes your firm agree that it no longer needs to receive paper Notices of FDA Action? Yes Inselected, FDA will no longer provide your firm with paper copies of Notices of 	Notices of FDA Action via email
Action. Firm account holders may either receive Notices via email at the time they are	
O No - If selected, paper copies of Notices of FDA Action will continue to be sent to your	when they are concreted by EDA
firm. Firm account holders will still have the option to view Notices online, but will not	when they are generated by FDA



When the required information has been completely filled out, Click Continue 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.

Create New Account

Home O Create New Account

Your account has been created but is currently inactive. An email has been sent to you with further details. Your account ID is abc27781

YOU WILL NEED TO REMEMBER YOUR ACCOUNT ID AND PASSWORD TO LOGIN TO THE SYSTEM IN THE FUTURE.

Return to Login Page



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

October 15, 2024

Dear Jane Smith,

Your request for access to the Import Trade Auxiliary Communication System (ITACS) for account abc27781 has been rejected at this time.

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

Other

Invalid entry numbers provided

FDA Comments: The entry numbers provided are invalid or have not been transmitted to FDA. Please provide at least one valid entry, that has been transmitted to FDA, naming your firm as the Filer, Importer of Record, and/or Consignee.

For general ITACS questions, please review the information posted at http://www.fda.gov/forindustry/importprogram/entryprocess/importsystems/ucm480953.htm

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.



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 firm has not been named as an Importer of Record, Consignee, or Filer in an entry previously transmitted to FDA

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

October 15, 2024

Dear Jane Smith,

Your ITACS Firm Administrator account (abc27781) request has been approved.

As Firm Administrator, you may now log into FURLS at <u>https://www.access.fda.gov/oaa/</u>. 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: <u>http://www.fda.gov/forindustry/importprogram/entryprocess/importsystems/ucm480953.htm</u>

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



ONLINE ACCOUNT ADMINISTRATION (OAA)

FDA Industry Systems



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ation or cy. Any

3 all users 3 privacy

Login Existing account holders, enter your account ID & password. Account ID abc27781 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. I understand. I create New Account			
Existing account holders, enter your account ID & password. Account ID abc27781 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. Torgot Account ID Forgot Password New User Create New Account	Login		
Account ID abc27781 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. I understand. Forgot Account ID Forgot Password New User Create New Account	Existing account holders, enter	r your account ID & pa	ssword.
abc27781 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. I understand. I understand. I create New Account	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. Torgot Account ID Forgot Password New User Create New Account	abc27781		
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. Degin Forgot Account ID Forgot Password New User Create New Account	\ge		
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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. Degin Forgot Account ID Forgot Password New User Create New Account			
fraudulent statement to the U.S. Government is subject to criminal penalties. I understand. Login Forgot Account ID Forgot Password New User Create New Account	Under 18 U.S.C. 1001, anyone	e who makes a materia	lly false, fictitious, or
Periatites. I understand. I create New Account Image: Create New Account	fraudulent statement to the U.S	S. Government is subje	ect to criminal
I understand. Login Forgot Account ID Forgot Password New User Create New Account	penaities.		
Forgot Account ID Forgot Password New User Create New Account	I understand.		
New User Create New Account	DLogin	Forgot Account ID	Forgot Password
New User Create New Account			
New User Create New Account			
New User			
Create New Account	New User		
Create New Account			
	Create New Account		
B See Instructions D See Tutorials D Hole Deck	B San Instructions	itariala 🖉 Hala Daala	

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: This warning banner provides privacy and security notices consistent with applicable federal

To log in, enter your account id and the password entered during the account set up; acknowledge the warning, and click Login.

bi the information period 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.



Your Account Home Page

Account Management

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Account Management		
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged in	es abc27781 for ABC Filers.
Change My Password	You may choose an option on the left to manage your according to obtain access to available FDA systems, choose the Up	ount or select an FDA system below. Date System Access option to add the FDA system to your account.
Update System Access		
Create a Subaccount	Registration and Listing Programs	
Deactivate a Subaccount	Food Food Facility Registration	Export Listing Module
Reactivate a Subaccount		
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation

The system will show you logged in and display your account id and company name.



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

Account Management			0 🔒
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logge	ed in as abc27781 for ABC Filers.	
Change My Password	You may choose an option on the left to manage you To obtain access to available FDA systems, choose th	[·] account or select an FDA system below. ne Update System Access option to add the FDA system to your accoun	ıt.
Update System Access			
Create a Subaccount	Registration and Listing Programs		
Deactivate a Subaccount	Food Food Facility Registration	Export Listing Module	
Reactivate a Subaccount			
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	

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Change My Password allows you to change your account Password.

Account Management		8	Ð
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logg	ed in as abc27781 for ABC Filers.	
Change My Password	You may choose an option on the left to manage you To obtain access to available FDA systems, choose t	r account or select an FDA system below. he Update System Access option to add the FDA system to your account.	
Update System Access			
Create a Subaccount	Registration and Listing Programs		
Deactivate a Subaccount	Food Food Facility Registration	Export Listing Module	
Reactivate a Subaccount	, ,		
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	

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

Account Management		0	₽
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logge	d in as abc27781 for ABC Filers.	
Change My Password	You may choose an option on the left to manage your To obtain access to available FDA systems, choose th	account or select an FDA system below. e Update System Access option to add the FDA system to your account.	
Update System Access	Dovistation and Listing Drogeneo		
Create a Subaccount			
Deactivate a Subaccount	Food Facility Registration	Export Listing Module	
Reactivate a Subaccount			
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	



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

Account Management			0 🖶
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logge	d in as abc27781 for ABC Filers.	
Change My Password	You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.		nt.
Update System Access	Desistration and Listing Programs		
Create a Subaccount	Registration and Listing Programs		
Deactivate a Subaccount	Food		
Reactivate a Subaccount		Export Listing Module	
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	



Creating Subaccounts

Account Management

Account Management Welcome to the FDA Industry Systems. You are logged in as abc27781 for ABC Filers. 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 Export Listing Module Reactivate a Subaccount Acidified/Low-Acid Canned Foods Registration Qualified Facility Attestation Manage Users and Process Filing **Click Create Subaccount**

FDA

Clear

Ontinue

Creating Subaccounts

Create a Subaccount

Company Name is ABC Filers

Enter information for the subaccount holder.

Irst Name John Aiddle Initial (Optional) Optional .ast Name / Surname Doe	Country / Area UNITED STATES Address Line 1 123 Main Street Address Line 2 (Optional)
John Aiddle Initial (Optional) Optional	UNITED STATES ~ Address Line 1 123 Main Street Address Line 2 (Optional)
Aiddle Initial (Optional) Optional .ast Name / Surname Doe	Address Line 1 123 Main Street Address Line 2 (Optional)
Optional	123 Main Street Address Line 2 (Optional)
.ast Name / Surname Doe	Address Line 2 (Optional)
Doe	
	Optional
lob Title	City
Associate	Anytown
Subaccount Company Name (Optional)	State / Province / Territory
Optional	Washington ~
Phone Number	Zip Code (Postal Code)
Country 123 4568790 Ext	98123
Country Area Phone Number Extension 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)	Do you have preferred mailing address other than the physical address mentioned above?
Country Area Fax Number	
Country Area Fax Number	Fill out the required information
-mail Address	
john.doe@abc.com	and click 'Continue'
Confirm E-mail Address	
john.doe@abc.com	



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 username and temporary password.



Managing your Account

Deactivating Subaccounts

Account Management			0 🖶
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged in as abc27	781 for ABC Filers.	
Change My Password	You may choose an option on the left to manage your account or se To obtain access to available FDA systems, choose the Update Sys	elect an FDA system below. stem Access option to add the FDA system to your account.	
Update System Access	, , , , ,		
Create a Subaccount	Registration and Listing Programs		
Deactivate a Subaccount	Food Facility Registration	Export Listing Module	
Reactivate a Subaccount Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	
Click Deactivate a Subaccount			



Deactivating Subaccounts

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





Deactivating Subaccounts

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

Account Management			0 🖨
Home O Deactivate Subaccount			
Edit Account Profile		COUNT	
Change My Password	Tou are about to deactivate.		
Update System Access	abc94286	John Doe ABC Filers Bellingham, Washington 98225 UNITED STATES	
Create a Subaccount			
Deactivate a Subaccount			
Reactivate a Subaccount			
Manage Users	Cancel Cancel	I	O Submit





Reactivating a Deactivated Subaccount

Account Management			0 🔒			
Account Management						
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged in as ab	c27781 for ABC Filers.				
Change My Password	You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.					
Update System Access						
Create a Subaccount	Registration and Listing Programs					
Deactivate a Subaccount	Food Facility Registration	Export Listing Module				
Reactivate a Subaccount Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation				

Click Reactivate a Subaccount



Managing your ITACS Account Reactivating Subaccounts

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





Managing your Account

Reactivating Subaccounts

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

Account Management			0 🖨
Home			
Edit Account Profile	REACTIVATE SUBAC	COUNT	
Change My Password Update System Access	abc94286	John Doe ABC Filers Bellingham, Washington 98225 UNITED STATES	
Create a Subaccount			
Reactivate a Subaccount			
Manage Users	Cancel Cancel Previous		Submit



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

Account Management		6)			
Account Management						
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged	d in as abc27781 for ABC Filers.				
Change My Password	You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.					
Update System Access						
Create a Subaccount	Registration and Listing Programs					
Deactivate a Subaccount	Food Food Facility Registration	Export Listing Module				
Reactivate a Subaccount						
Manage Users	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation				



Creating Groups



Firm Name: ABC Filers

Firm Address: 123 Any Street, Bellingham, WA, 98225

ITACS account management functionality is no longer supported on Internet Explorer. Please use a modern browser such as Edge, Chrome, Firefox or Safari to access ITACS account management functionality.

Manage Users

Manage Groups



To create or manage groups click Manage Groups.

Search For User

iroup Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
No		John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes



Creating Groups

IDA U.S. FOOD & DRUG FDA/C	ORA Account Manageme	nt Logged in as	Jane Smith	ITACS Login	Modify Account Information	logout	Help
Firm Name: ABC Filers							
Firm Address: 123 Any St	treet,Bellingham,WA,98225						
Manage Groups							
As a Firm Administrator, you are a	able to create new groups or modify grou	ıp information.					
Manage Users							
Groups							
Group Name 个	Date Created	Created By	Administrator				
No data to display.							
Create New Group	Modify Group Delete Grou	up					
Group Details	To create a	a new grou	up click	Create	New Group.		
Name Email Addr	ess Account ID	Phone Job Title	Date Adde	ed			
No data to display.							
Convert to Group Admi	n						

Managing your ITACS Account Firm Administrator Creating Groups

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Create Group





- 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 Managing Groups

Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Manage Groups

Search For User

			F 11		0	1.1.70	D	o . o . m
Group Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
lo		John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes
		\						
		1						
	T	<u> </u>	To add or	romov		forag	roup	
			Fo add or	remove	e users t	for a g	roup,	

FD)

Modify Users





Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Search For User they can be converted to Group Admin. To do so click Manage Groups										
lsers	10 (CIICK IVIANA	age Gro	ups.					
iroup Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?		
lo		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes		
19			iohn doo@ahs.com	abc04286	1-1234568700	Associate	10/15/2024	Ver		

Managing your Account Firm Administrator Managing Groups



Manage Groups

As a Firm Administrator, you are able to create new groups or modify group information.

Manage Users

Groups Group Name Created By Administrator Date Created Jane A Smith Group 1 10/15/2024 Create New Group Modify Group Delete Group Highlight the group, then highlight the user, then click Group Details Convert to Group Admin. Group Name: Group Name Email Address Account ID Phone Date Added Job Title john.doe@abc.com abc94286 1-1234568790 10/15/2024 John Doe Associate Convert to Group Admin



Managing your Account

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.



FDA U.S. FOOD & DRUG FDA/ORA Account Management	Logged in as: Jane Smith	ITACS Login	Modify Account Information	logout	Help
Firm Name: ABC Filers					

Firm Address: 123 Any Street, Bellingham, WA, 98225

ITACS account management functionality is no longer supported on Internet Explorer. Please use a modern browser such as Edge, Chrome, Firefox or Safari to access ITACS account management functionality.

Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Manage	Groups

.....

Search For User

From the Manage Users screen you can also create or deactivate subaccount users, modify user preferences, and convert another user to be the ITACS Firm Administrator.

Group Admin:	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
No	Group 1	John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes

Managing your Account Firm Administrator Converting another user to Firm Administrator

FDA U.S. FOOD & DRUG ADMINISTRATION FDA/ORA Account Management	Logged in as: Jane Smith	ITACS Login	Modify Account Information	logout	Help
Firm Name: ABC Filers					
Firm Address: 123 Any Street Bellingham WA 98225					

ITACS account management functionality is no longer supported on Internet Explorer. Please use a modern browser such as Edge, Chrome, Firefox or Safari to access ITACS account management functionality.

Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Manage Groups	If you convert another user to Firm Administrator,	
✓ Search For User	you will lose your Firm Administrator privileges	
	and be converted to a Firm User.	
Users		

Group Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
No	Group 1	John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes
Create User Account	Modify User	Deactivate Us	ser Convert to Firm A	dmin				



Updating email to receive Notices of FDA Action

Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Manage Groups
 Email preferences for individual users can be updated by
 Search For User
 highlighting the username and clicking Modify User.

Users								
Group Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
No		John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes
No John Doe john.doe@abc.com abc94286 1-1234568790 Associate 10/15/2024 Yes Create User Account Modify User Deactivate User Convert to Firm Admin								



Updating email to receive Notices of FDA Action

Modify Users





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

Manage Users

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups.

Manage Groups

✓ Search For User

Firm Admins can update the firm's email preferences by highlighting their username and clicking Modify User.

Users								
Group Admin?	Group Name	Name	Email	Account ID	Phone	Job Title	Date Added	Get Email?
No		Jane A Smith	jane.smith@abc.com	abc27781	1-1231237890	Team Lead	10/15/2024	Yes
No		John Doe	john.doe@abc.com	abc94286	1-1234568790	Associate	10/15/2024	Yes
Create User Account Modify User Deactivate User Convert to Firm Admin								



Updating email to receive Notices of FDA Action

Viodity Users	
Name : Jane A Smith Contact Email Address * : jane.smith@abc.com Job Title : Team Lead 1 123123789 Contact Phone * : Bounte: Code Phone Mon The Firm Administrator has chosen the following method to receive FDA Notices of Action :	On this page Firm Admins can select the method for receiving Notices. Select Electronic to receive Notices via email when they are generated by FDA.
Alternate Email(s) for Receiving Notices : Same As Contact Email :	
Available Ports : Applicable only to Filers. This user will receive Notices of FDA Action only for selected Ports :	Firm Admins can also select Same As Contact Email or enter an alternate email(s) or distribution lists for receiving Notices.
	0106-Houlton 0107-Fort Fairfield
Click Save Save	Cancel



Account Management

Account Management					
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged in as abc277	781 for ABC Filers.			
Change My Password	You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.				
Update System Access					
Create a Subaccount	Other FDA Systems				
Deactivate a Subaccount	Prior Notice System Interface	Systems Recognition Program			
Reactivate a Subaccount	Import Trade Auxiliary Communication System (ITACS)	CBER Biological Product Deviation Reporting (CBER eBPDR)			
Manage Users	CDER Office of Manufacturing Quality (CDER OMQ e-Portal)				
		Observations and Corrective Action Report (OCAR)			

After logging into your FURLS account, scroll to the bottom and click the link to ITACS under Other FDA Systems.

Industry Portal



U.S. FOOD & DRUG Import Trade Auxiliary Communications System

Logged in as: Jane Smith Manage Users Modify Your Own Profile Log out

Help

Welcome to Import Trade Auxiliary Communications System

WARNING: This warning banner provides privacy and securit Government system, which includes all devices/storage mec improper use of this system is prohibited and may result in c government may monitor, record, and audit your system usa you have no reasonable expectation of privacy. Any commur purpose.

The system indicates that you are logged in and displays your username. It also provides links to back to FURLS to modify your account and manage users if you are a Firm Admin or Group Admin.

ITACS is no longer supported on Internet Explorer. Please use a modern browser such as Edge, Chrome, Firefox or Safari to access ITACS.

ITACS allows the Import Trade Community to:

1) Check status of Entries 2) Input Line Availability 3) Submit Requested Documents

-	
	To get started, at a minimum please enter an Entry Number. If you would like to narrow your entry search, please provide a Line Number. The reCAPTCHA verification is required for entry, when provided by the system. * are required fields
	Entry Number * (Example: xxx-xxxxxxxx) Enter the entry number and click Submit
	FDA Line Number No CAPTCHA Code required when logged into your account

FDA



FD)





Emailed Notices of FDA Action

Example Email

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



Attached please find Notice Number 1 for Entry Number **Example**. 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

Status and Actions

Result	S								
E	ntry Number:	Ent	t <mark>ry Level Status</mark> : [Ocument Submitted					
Select	Entry/CBP- FDA[Suffix]	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
			16AEE45	Total: 2240.0 Case (2240.0 Case, 48.0 Can, Cylindrical, 5.0 Ounces, weight (avdp))	Thailand	Information Requested - See Notice of FDA Action for Details - Requested Information	06/24/2016	Document Submitted	03/24/2016
	1	1			1	1			1
				Click the	link	to show the			
				information request.					
Export	as PDF for Print	Select All Lines C	lear Selected						
~ A	ctions								
If an action needs to be taken for the lines selected above, please choose the appropriate action option and press the Take Action button. The action taken will be applied to all of the selected lines. Note: If you opt to submit entry level documents, ITACS will automatically select all of the lines of the entry for you.									
\bigcirc	Input Line Availability for the selected item(s)								
Submit Entry Level Documents									
0	Submit Line Level Documents for the selected item(s) View Expected Lab Completion Date								

Retrieve Notices of FDA Action



Retrieving Information Requests from ITACS

Status and Actions									
Results									
Entry Number Entr	y Level Status: D	ocument Submitted							
Select Entry/CBP- FDA[Suffix] Product	Product Code	Quantity	Country Name	FDA Line Status		FDA Line Status Date	ITACS Status	ITACS Status Date	
	16AEE45	Total: 2240.0 Case (2240.0 Case, 48.0 Can, Cylindrical, 5.0 Ounces, weight (avdp))	Thailand	Information Requeste of FDA Action for De Requested Information	d - See Notice tails - m	06/24/2016	Document Submitted	03/24/2016	
The Information Request will be displayed in a pop- up box.		nformation Requested for line Details: Please provide FCE and SID.; Respond By: Jun 29, 2016 Close		н н	Requests are also available to download as PDF under Retrieve Notices of FDA Action.				
▼Actions				*					
 If an action needs to be taken for the lines selected above, please choose the appropriate action option and press the Take Action button. The action taken will be applied to all of the selected lines. Note: If you opt to submit entry level documents, ITACS will automatically select all of the lines of the entry for you. Input Line Availability for the selected item(s) Submit Entry Level Documents Submit Line Level Documents for the selected item(s) View Expected Lab Completion Date 									



Viewing Status History Report

DA U.S. FOO	M U.S. FORD & DRUG Import Trade Auxiliary Communications System Logged in as: Jane Smith Manage Users, Modify Your Own Profile Log out									Help
Status	tatus and Actions									
Results										
Entry N	umber:	Entry Level Status: H	old Designated	d Lines						
Select	Entry/CBP- FDA[Suffix]	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date	
	-1	(16YCI13	Total: 30.0 Carton (30.0 Carton, 24.0 Bottle, Non- Protected,Cyl, 5.0 Ounces, weight (avdp))	Thailand	FDA Examination Pending	04/19/2024	Line Availability Received	05/21/2024	
	-2		16YCI13	Total: 6000.0 Ounces, weight (avdp) (50.0 Carton, 10.0 Bottle, Non-Protected,Cyl, 12.0 Ounces, weight (avdp))	Thailand	FDA Examination Completed	09/04/2024	Line Availability Received	05/21/2024	
	-1	·	35AEE99	Total: 50.0 Carton (50.0 Carton, 24.0 Can, Rectangular, 14.0 Ounces, weight (avdp))	Thailand	May Proceed Without FDA Examination	04/04/2024	Line Availability Received	05/21/2024	
	-1		30ACE99	Total: 30.0 Carton (30.0 Carton, 12.0 Bottle, Non- Protected,Cyl, 24.65 Ounces, weight (avdp))	Thailand	May Proceed Without FDA Examination	08/13/2024	Line Availability Received	05/21/2024	
	-1 30ACE99 Total: 70.0 Carton (70.0 Carton, 12.0 Bottle, Non- Protected, Cyl, 26.0 Ounces, fluid) Thailand May Proceed Without FDA Examination 04/04/2024 Line Availability Received 05/21/2024									
Export as	s PDF for Print Export (Current Status History PDF for Print	>							
Action	ns									

A line-by-line status history report can be generated by selecting the line(s) and clicking Export Current Status History PDF for Print.

Viewing Status History Report Example PDF



	FDA Status History for Entry # Thu Oct 17 2024 08:46:55 GMT-0700 (Pacific Daylight Time)
Entry/CBP-FDA[Suffix]	1-1
Product	
Product Code	54YBS99
Quantity	Total: 740.0 Drum (740.0 Drum, 25.0 Kilograms)
Country Name	China

FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
Detained - Refer to Notice of FDA Action for Violation Charges	10/17/2024	Line Availability Received	10/17/2024
FDA Examination Completed	10/17/2024	Document Submitted	10/16/2024
FDA Examination Pending	10/16/2024		
Notify FDA of Location for Examination	10/16/2024	A report is gene	erated with a pag
Second and final request for information. Submit Entry Documents to FDA (Invoice, B/L, CBP Entry Document)	10/16/2024	full status histo or storage.	ry as PDF for prin
Entry Documents Required	10/12/2024		



Helpful Links

Found at the bottom of every ITACS page and provides links to helpful information.

✓ Helpful Links	
ITACS Industry Page Import Program Page FDA Import Office Locations and Contact Information Import Alerts Import Refusals	Access FDA Product Code Query For technical assistance please contact (itacssupport@fda.hhs.gov) Log In or Request an ITACS Account Vulnerability Disclosure Policy



ITACS Links

Access ITACS directly at: <u>https://itacs.fda.gov</u>

ITACS Support – for technical assistance regarding ITACS: ITACSSupport@fda.hhs.gov

To view the ITACS Presentation to Industry and this ITACS Account Management presentation visit FDA's ITACS for Industry web page:

<u>https://www.fda.gov/industry/import-</u> <u>systems/itacs</u>

