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

FDA Industry Systems

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 1-800-218-7331 to confirm that the caller is acting on behalf of FDA.
Creating an ITACS Account

**Step 1: Select Applicable Center for Account Creation**

- Center for Biological Evaluation & Research (Export Certification Application and Tracking)
- Center for Devices & Radiological Health (Device Registration and Listing / Export Certification Application and Tracking / Laboratory Developed Tests Notification)
- Center for Drug Evaluation & Research (Export Certification Application and Tracking)
- Center for Food Safety & Applied Nutrition (FFRM, FSMA, LACF, SEPRM, SFCN, NDIN, PNSI / Systems Recognition Program / Certification Application Program (Includes Landfood, Seafood, Cosmetics, Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods, and Foods for Special Dietary Use), etc.)
- Center for Tobacco Products (Tobacco Registration and Product Listing)

Choose Other Systems

Choose ITACS

**Select the systems you will need to access**

- Import Trade Auxiliary Communication System (ITACS)

Indicate the type of firm. One or all types may be chosen.
Creating an ITACS Account

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.

Your account has been created but is currently inactive. An email has been sent to you with further details.
Your account ID is abc57768

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

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 Administrator 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 itaessupport@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

Acknowledging 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.

Welcome to the FDA Industry Systems. You are logged in as abc57768 for ABC Filers and Importers.

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.

Other Systems

Click to launch the Application(s)

- Import Trade Auxiliary Communication System (ITACS)
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.

Account Management

Welcome to the FDA Industry Systems. You are logged in as abc57768 for ABC Filers and Importers.

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.

Other Systems

Click to launch the Application(s)

- Import Trade Auxiliary Communication System (ITACS)
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

Click ‘Create a Subaccount’
Managing your ITACS Account
Firm Administrator
Creating Subaccounts

Create a Subaccount
Company Name is ABC Filers and Importers
Enter information for the subaccount holder:

<table>
<thead>
<tr>
<th>Point of Contact Information</th>
<th>Physical Address (Business) of Account Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Country/Area</td>
</tr>
<tr>
<td>Test</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Middle Initial (Optional)</td>
<td></td>
</tr>
<tr>
<td>User 1</td>
<td></td>
</tr>
<tr>
<td>Last Name / Surname</td>
<td>Address Line 1</td>
</tr>
<tr>
<td>Associate</td>
<td>123 Main Street</td>
</tr>
<tr>
<td>Job Title</td>
<td>Address Line 2 (Optional)</td>
</tr>
<tr>
<td>Subaccount Company Name (Optional)</td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td>City</td>
</tr>
<tr>
<td>123</td>
<td>4567890</td>
</tr>
<tr>
<td>Country Area</td>
<td>Phone Number</td>
</tr>
<tr>
<td>123</td>
<td>4567890</td>
</tr>
<tr>
<td>Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.</td>
<td></td>
</tr>
<tr>
<td>FAX Number</td>
<td>State / Province / Territory</td>
</tr>
<tr>
<td>E-mail Address</td>
<td>Washington</td>
</tr>
<tr>
<td><a href="mailto:test.user@abc.com">test.user@abc.com</a></td>
<td>Zip Code (Postal Code)</td>
</tr>
<tr>
<td>Confirm E-mail Address</td>
<td>98148</td>
</tr>
<tr>
<td><a href="mailto:test.user@abc.com">test.user@abc.com</a></td>
<td>Do you have preferred mailing address other than the physical address mentioned above?</td>
</tr>
</tbody>
</table>

Fill out the required information and click ‘Continue’
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

Click Deactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as abc57768 for ABC Filers and Importers.

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.

Other Systems

Click to launch the Application(s)

- Import Trade Auxiliary Communication System (ITACS)
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’.

DEACTIVATE SUBACCOUNT

You are about to deactivate:

| abc37130 | Test User 1  
|          | ABC Filers and Importers  
|          | Seattle, Washington 98148  
|          | UNITED STATES |

Submit
Managing your ITACS Account
Firm Administrator

Reactivating a Deactivated Subaccount

Click Reactivate a Subaccount
Managing your ITACS Account
Firm Administrator

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

Reactivate a Subaccount
Select the accounts you want to reactivate:

- Subaccount
  - abc37130
  - Test User 1
    - ABC Filers and Importers
    - Seattle, Washington 98148
    - UNITED STATES

- [Continue]
Managing your ITACS Account

Firm Administrator

Reactivating a Deactivated Subaccount

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

Account Management

Home  Reactivate Subaccount

REACTIVATE SUBACCOUNT

You are about to reactivate:

| abc37130 | Test User 1  
|          | ABC Filers and Importers  
|          | Seattle, Washington 98148  
|          | UNITED STATES |

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

### Manage Groups

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

<table>
<thead>
<tr>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Name</td>
</tr>
<tr>
<td>No data to display.</td>
</tr>
</tbody>
</table>

- Click Create New Group

---

Clicking ‘Manage Users’ on the home page will open Manage Users and Manage Groups functionalities.
Managing your ITACS Account
Firm Administrator
Creating Groups

Create Group

Name the Group

Select the applicable ports (Filers only)

Send Notices to all member emails or to group email

Click Save
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

### 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

<table>
<thead>
<tr>
<th>Group Admin?</th>
<th>Group Name</th>
<th>Name</th>
<th>Email Address</th>
<th>Phone</th>
<th>Job Title</th>
<th>Date Added</th>
<th>Get Email?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Group Leader 1</td>
<td></td>
<td>1-234567890</td>
<td></td>
<td>Group Lead</td>
<td>2/17/2016</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>Test User 1</td>
<td>1-0000000000</td>
<td>1-1234567890</td>
<td>President</td>
<td>2/10/2016</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Highlight the user to be added to the group and click ‘Modify User’.
Managing your ITACS Account
Firm Administrator
Creating Groups

Choose the Group

Note: when the Group is chosen that person will be associated with that Group’s ports and email preferences.
Managing your Account
Firm Administrator
Creating Groups

As a Firm Establishment Administrator, you are able to create, modify, or deactivate ITACS user accounts and manage groups. After a user is associated with a Group they can be converted to Group Admin. To do so click Manage Groups.
Managing your Account
Firm Administrator
Creating Groups

Highlight the Group Name and highlight the User Name for whom you would like to make Group Admin. Then click Convert to Group Admin.
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

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

**Manage Users**

<table>
<thead>
<tr>
<th>Group Admin?</th>
<th>Group Name</th>
<th>Name</th>
<th>Email Address</th>
<th>Phone</th>
<th>Job Title</th>
<th>Date Added</th>
<th>Get Email?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Group Leader 1</td>
<td></td>
<td></td>
<td>1-1234567890</td>
<td>Group Lead</td>
<td>2/17/2016</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>[Redacted]</td>
<td></td>
<td>1-00000000000</td>
<td>President</td>
<td>2/10/2016</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>Test User 1</td>
<td></td>
<td></td>
<td>1-1234567890</td>
<td>Associate</td>
<td>2/17/2016</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note from this screen you can also Create, Modify and Deactivate Subaccount Users. You can also convert another user to be the Firm Admin.
Managing your Account
Firm Administrator

If you convert another user to Firm Admin you will lose your Firm Administrator privileges and be converted to a Firm User.
Managing your Account
Firm Administrator
Updating email to receive Notices of FDA Action

In Manage Users, highlight the user name for whom you would like to provide an alternate email address and click ‘Modify User’.
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

After logging into your account, scroll down to Other FDA Systems and click the link to ITACS.
Retrieving Notices of FDA Action from ITACS

Indicates that you are logged in and the User Name for the account. Also provides links to modify your account and manage users if a Firm or Group Admin.

No CAPTCHA Code required when logged into your account.
Retrieving Notices of FDA Action from ITACS

To retrieve Notices choose ‘Retrieve Notices of FDA Action’ radio button and click TAKE ACTION.
Retrieving Notices of FDA Action from ITACS

Available Notices of FDA Action will be listed at the bottom of the page. Click on the PDF icons to open and view the Notices.
Emailed Notices of FDA Action

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

From: itacs@fda.hhs.gov
To: [redacted]
Cc: [redacted]
Subject: Notice of FDA Action Number 1 for Entry Number [redacted]

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

### Status and Actions

### Results

<table>
<thead>
<tr>
<th>Select</th>
<th>Entry/CBP-FDA [Summit]</th>
<th>Product</th>
<th>Product Code</th>
<th>Quantity</th>
<th>Country Name</th>
<th>FDA Line Status</th>
<th>FDA Line Status Date</th>
<th>ITACS Status</th>
<th>ITACS Status Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TUNA CHUNK IN WATER WITH VEGETABLE BROTH</td>
<td>16AEE45</td>
<td>Total: 2240.0 Case (2240.0 Case, 48.0 Can, Cylindrical, 5.0 Ounces, weight (avdp))</td>
<td>Thailand</td>
<td>Information Requested - See Notice of FDA Action for Details - Requested Information</td>
<td>06/24/2016</td>
<td>Document Submitted</td>
<td>03/24/2016</td>
</tr>
</tbody>
</table>

Click the link to show the information request.
Retrieving Information Requests from ITACS

The Information Request will be displayed in a pop up box.

Requests also available to download as pdf under Retrieve Notices of FDA Action.
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