

ITACS

Import Trade Auxiliary Communications System
Overview and Walkthrough of Functionality

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Food and Drug Administration
Division of Compliance Systems
Import Compliance Systems Branch

Topics

- Description of ITACS
- System Requirements
- Benefits to the Trade and FDA
- Walkthrough of Functionality

ITACS – Web Users

ITACS currently provides web users 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.

ITACS – Account Users

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.

ITACS – Account Users

To view the ITACS Account Management PP visit:

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

Details:

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

Trade System Requirements

- ITACS Internet access https://itacs.fda.gov
- Security Web User
 - Accounts Not Required
 - Only Entry Number/Line Number needed
 - Limited functionality available
- Security ITACS Account User
 - Approved ITACS Account required to receive Notices of FDA Action and Specific Information requests via email and/or to download them from within ITACS.
 - FURLS account access: https://www.access.fda.gov/oaa

FDA System Requirements

- File size limitation increased to 5 files of 50 MB each, for a total of 250 MB per submission
- Server storage capacity
- Variety of document types accepted including PDF, Word and Excel
- Receipt of conveyance arrival information from CBP for truck and air shipments
- Virus scanning of submitted documents

Benefits – Entry/Line Status

- Allows a quick way to check on the status of entries successfully transmitted to FDA
 - CBP/FDA Interface down
 - No time waiting for return phone calls
 - More specific information regarding a shipment during the admissibility process
 - Displays expected Laboratory Time Frames for sampled lines
 - Ability To Query Closed Entries
 - Enables FDA to focus resources on expediting review of entries and completion of designated shipment examinations

Benefits - Document Submission

Entry Document Submission

- No need to copy documents for FDA
- No need to fax or deliver documents to FDA
- No problems with lost document submissions
- Documented date and time of document upload
- No need to for FDA to retain paper copies of entry documentation
- Provides all FDA staff easy access to documents via FDA's Import systems (OASIS & ER)

Benefits – Availability Information

- Shipment Availability Information
 - No faxing
 - No phone calls
 - Less confusion between trade and FDA about date and location of availability
 - Documented date and time of submission of information

Benefits - ITACS Accounts

ITACS Accounts

 Faster receipt of Notices of FDA Action either via e-mail or via download within ITACS

No need to wait for hard copy mailed Notices

 Receipt of requests for specific information sent via email or via download within ITACS

Checking Entry/Line Statuses

Checking Statuses

 Enter a valid entry number (specific line numbers may be entered but are optional)

Enter the CAPTCHA letters

Click "Submit"

Checking Entry/Line Statuses

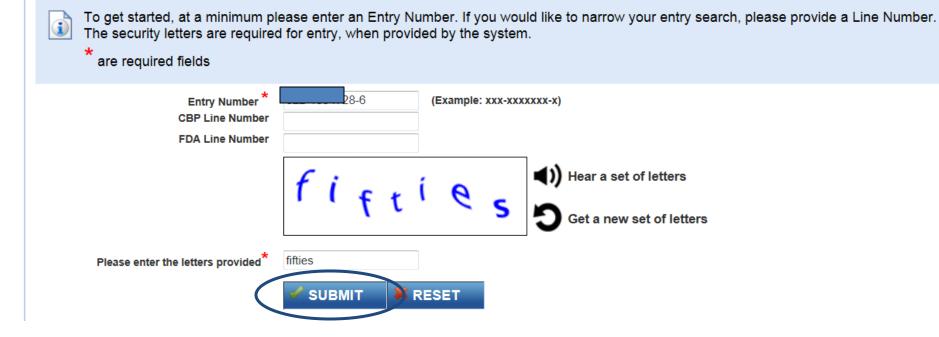


Import Trade Auxiliary Communications System

Welcome to Import Trade Auxiliary Communications System

ITACS allows the Import Trade Community to:

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

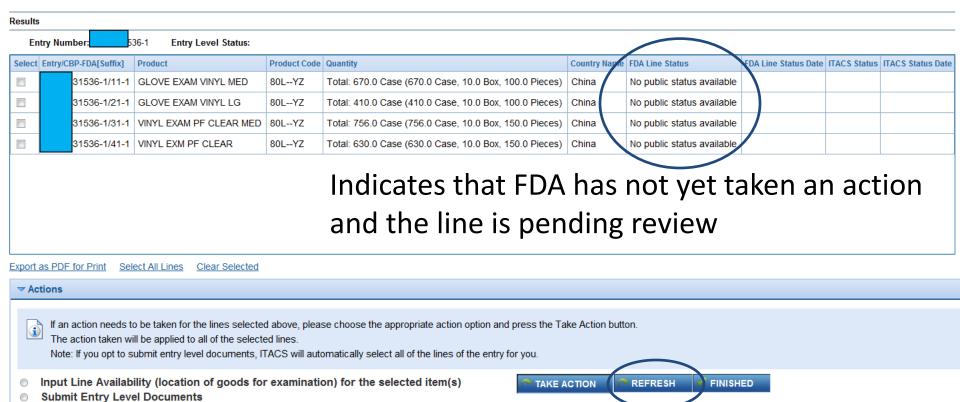


Status: Lines Still Under Review "No public status available"

Status and Actions

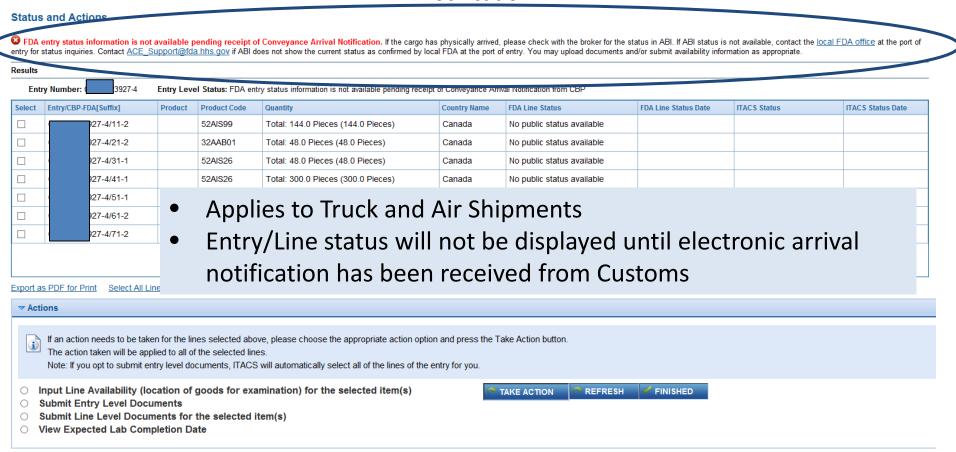
Submit Line Level Documents for the selected item(s)

View Expected Lab Completion Date



Status: CBP Conveyance Arrival Notification Not Received For Truck and Air Shipments

"FDA entry status information is not available pending receipt of Conveyance Arrival Notification"

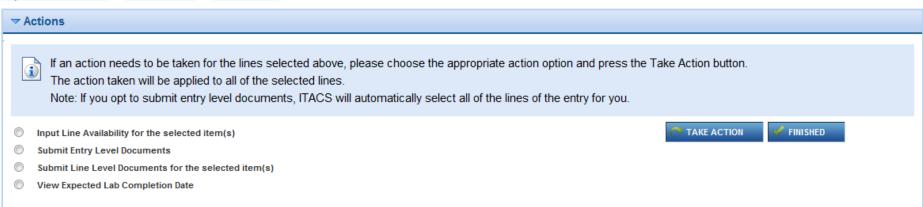


Status: Mixed for Multi-line Entry

Status and Actions

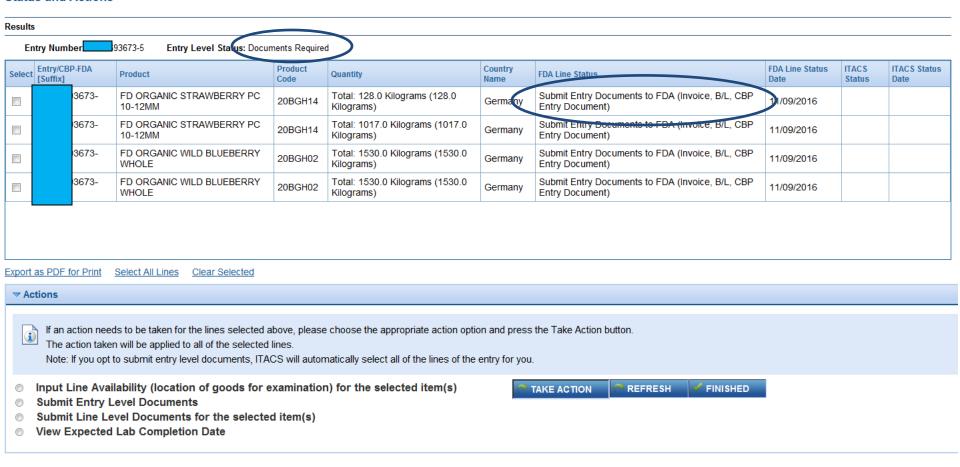
Results	6										
Entry Number: 1331-5 Entry Level Status: Hold Pending Further Written Notice from FDA											
	51	1331-	CUMIN POWDER	28BGH16	Total: 176 Kilograms (176 Kilograms)	India	(Released	06/10/2010		
	51	1331-	CORIANDER PROCESSED/DHANADAL	28BGH15	Total: 52 Kilograms (52 Kilograms)	India		Released	06/10/2010		
	5-	1331-	CORIANDER PROCESSED/DHANADAL	28BGH15	Total: 32 Kilograms (32 Kilograms)	India		Released	06/10/2010		
	5-	1331-	EX HOT CHILLI POWDER	28BGH08	Total: 215 Kilograms (215 Kilograms)	India	<	Submission Under Technical Review	11/09/2012	[
	51	1331-	EX HOT CHILLI POWDER	28BGH08	Total: 259 Kilograms (259 Kilograms)	India		Refused Inform FDA Before Export	11/09/2012		
	51	1331-	EX HOT CHILLI POWDER	28BGH08	Total: 134 Kilograms (134 Kilograms)	India	(Refused Inform FDA Before Export	11/09/2012		
	51	1331-	EX HOT CHILLI POWDER	28BGH08	Total: 96 Kilograms (96 Kilograms)	India		Refused Inform FDA Before Export	11/09/2012		

Export as PDF for Print Select All Lines Clear Selected

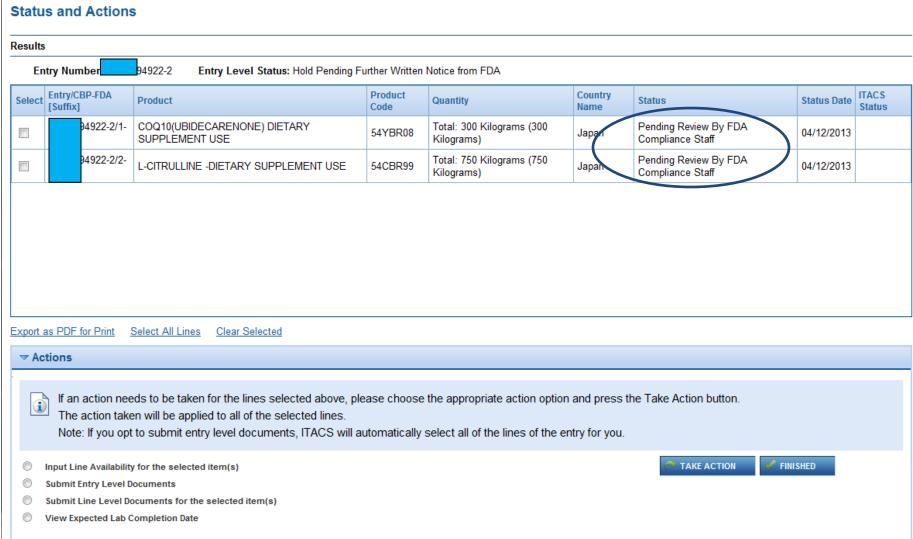


Status: Documents Required "Documents Required"

Status and Actions

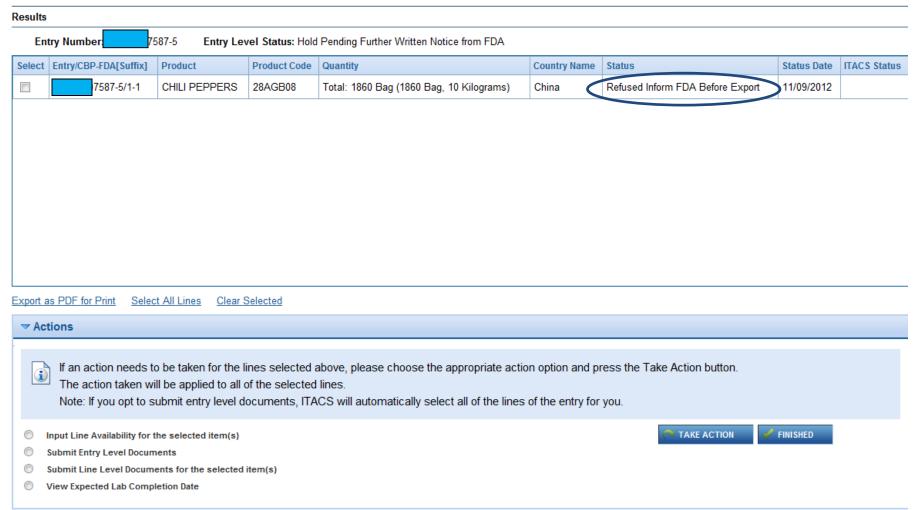


Status: Pending Compliance Review "Pending Review By FDA Compliance Staff"



Status: Refused Line "Refused Inform FDA Before Export"

Status and Actions



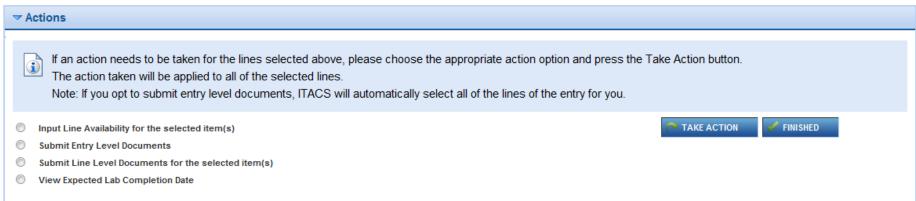
Status: Sample Collected by FDA

"FDA Sample Collected"

Status and Actions

esults	;									
Entry Number: 778142-6 Entry Level Status: Hold Designated Lines - Notify FDA of Location for FDA Examination										
Select	Entry/C [Suffix]	BP-FDA	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status	
		78142-	TINNED BAMBOO SHOOT STRIP IN WATER	24TEE03	Total: 400 Carton (400 Carton, 1 Tin, 20 Kilograms)	Thailand	May Proceed Without FDA Examination	02/07/2013		
		78142-	SWEET CHILLI SAUCE FOR CHICKEN	37JGT03	Total: 200 Carton (200 Carton, 24 Bottle, Non- Protected, Cyl, 10 Ounces, fluid)	Thailand	May Proceed Without FDA Examination	04/02/2013		
		78142-	SWEET CHILLI SAUCE FOR SPRING ROLL	37JGT03	Total: 200 Carton (200 Carton, 24 Bottle, Non- Protected, Cyl, 10 Ounces, fluid)	Thailand	FDA Sample Collected	04/12/2013		
		78142-	SWEET CHILLI SAUCE FOR CHICKEN	37JGT03	Total: 180 Carton (180 Carton, 12 Bottle, Non- Protected, Cyl, 25 Ounces, fluid)	Thailand	FDA Sample Collected	04/12/2013		
		78142-	SWEET CHILLI SAUCE FOR SPRING ROLL	37JGT03	Total: 200 Carton (200 Carton, 12 Bottle, Non- Protected, Cyl, 24 Ounces, fluid)	Thailand	FDA Sample Collected	04/12/2013		
		78142-	CANNED JACKFRUIT IN SYRUP-STRIP	21WET10	Total: 40 Carton (40 Carton, 24 Can, Cylindrical, 20 Ounces, weight (avdp))	Thailand	May Proceed Without FDA Examination	02/27/2012		

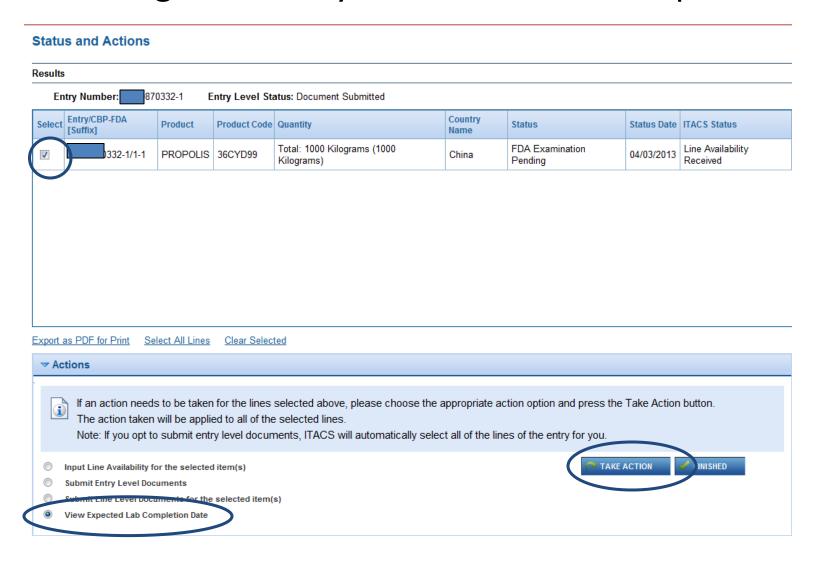
Export as PDF for Print Select All Lines Clear Selected



Status: Sample Collected by FDA Viewing Laboratory Timeframes for Sampled Lines

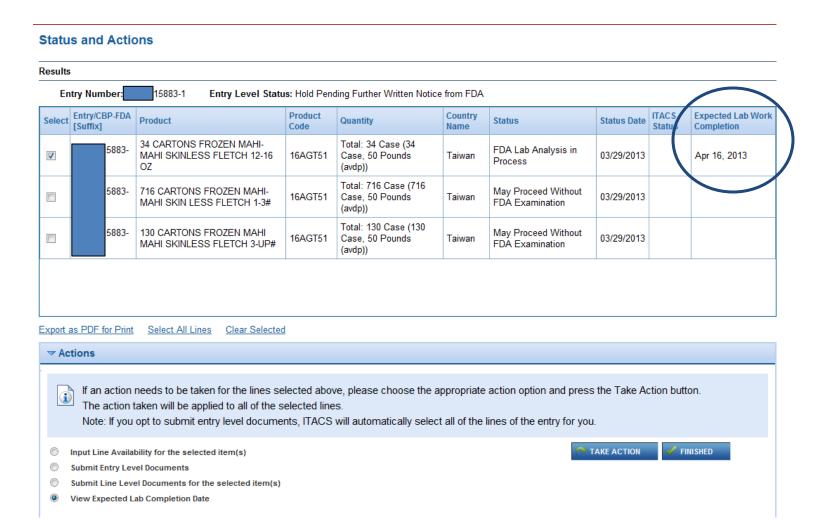
- •When a sample has been collected and the analysis is in progress, an estimated completion date may be viewed.
- Select a line using the checkbox, then select "View Expected Lab Completion Date" and click "Take Action"

Status: Sample Collected by FDA Viewing Laboratory Timeframes for Sampled Lines



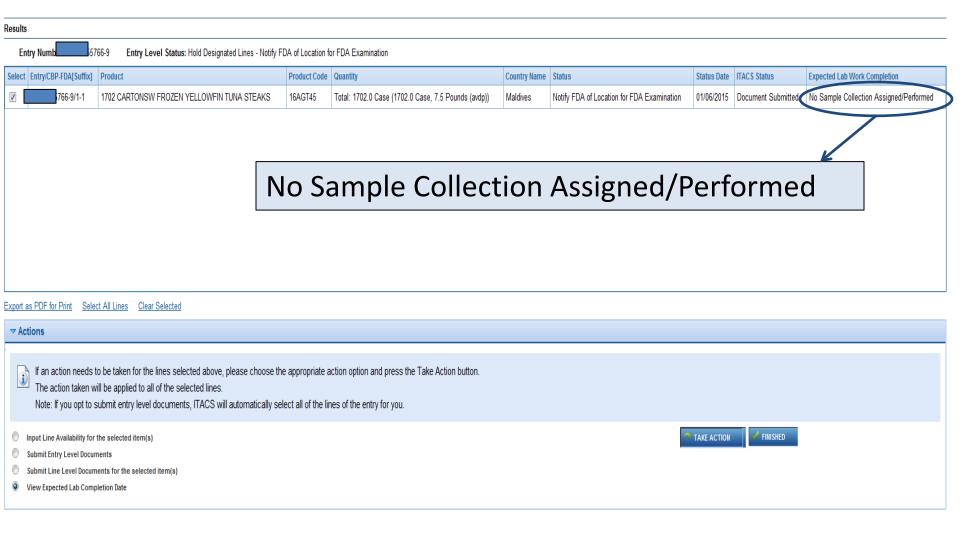
Status: Sample Collected by FDA

Viewing Laboratory Timeframes for Sampled Lines Example of Expected Lab Work Completion Date



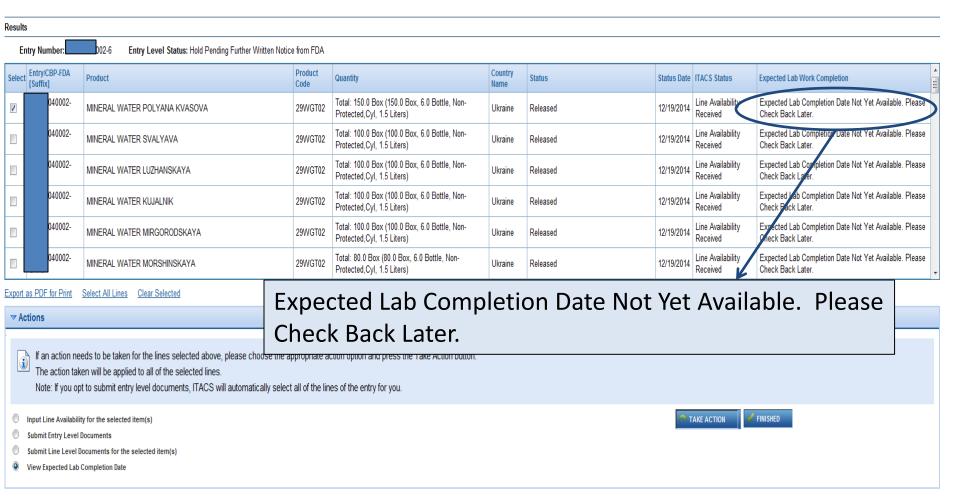
Status: Sample Collected by FDA Viewing Laboratory Timeframes for Sampled Lines No Sample Collected

Status and Actions



Status: Sample Collected by FDA Viewing Laboratory Timeframes for Sampled Lines Lab Completion Date Not Yet Available

Status and Actions



Checking Entry/Line Statuses

Status and Actions

Results Entry Number: 15649-5 Entry Level Status: Documents Required Entry/CBP-Product Country FDA Line ITACS **ITACS Status** Product FDA Line Status Select Quantity FDA[Suffix] Status Date Code Name Status Date Submit Entry FROZEN COHO FILLETS Total: 20.0 Package United Documents to FDA Document COMING BACK FOR 16YMD99 (20.0 Package, 07/19/2016 07/18/2016 Submitted States (Invoice, B/L, CBP Entry RELABELLIING & EXPOR 8301.0 Kilograms) Document)

Status results can be exported to a PDF file for printing or record keeping.

Click on the "Export as PDF for print" link

Export as PDF for Print

Select All Lines

Clear Selected

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



Checking Entry/Line Statuses Printer Friendly Results Example PDF

FDA Status for Entry 515649-5

Tue Jul 26, 2016 12:11:30 PM EDT

Entry/CBP- FDA[Suffix]	Product	Product Code	,	Country Name	Status	Status Date	ITACS Status
	FROZEN COHO FILLETS COMING BACK FOR RELABELLIING & EXPOR	16YMD99	Total: 20.0 Package (20.0 Package, 8301.0 Kilograms)		Submit Entry Documents to FDA (Invoice, B/L, CBP Entry Document)		Document Submitted

Checking Entry/Line Statuses

 Note: ITACS will display the status for closed entries. However; if the entry has been closed by FDA you will not be able to upload documents or submit availability information.

Submitting Documents

Submitting Documents

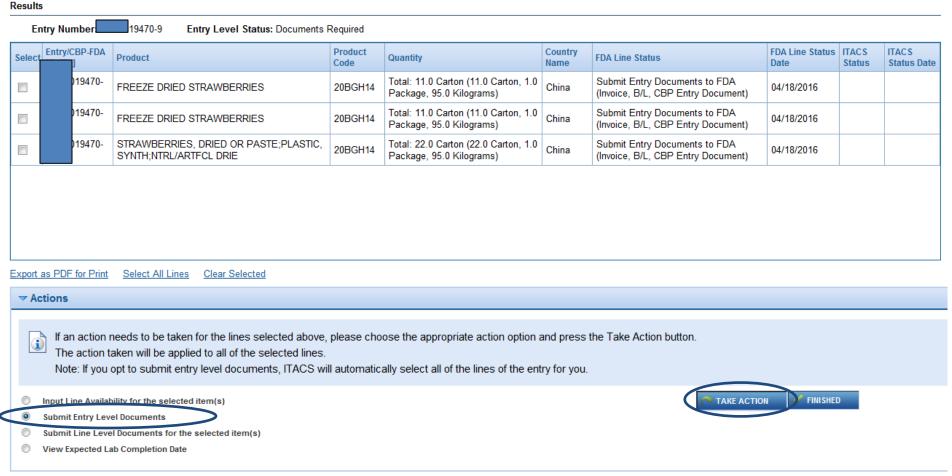
- Input an Entry Number
- Select the radio button next to:
 - "Submit Entry Level Documents" OR
 - "Submit Line Level Documents for the selected item(s)"

Note: If submitting line-level documents, select the checkbox next to the lines related to the document being submitted. Standard Entry Documentation (3461, invoice, bill of lading, packing lists) should be submitted at the Entry Level.

Click "Take Action"

Submitting Entry Level Documents

Status and Actions



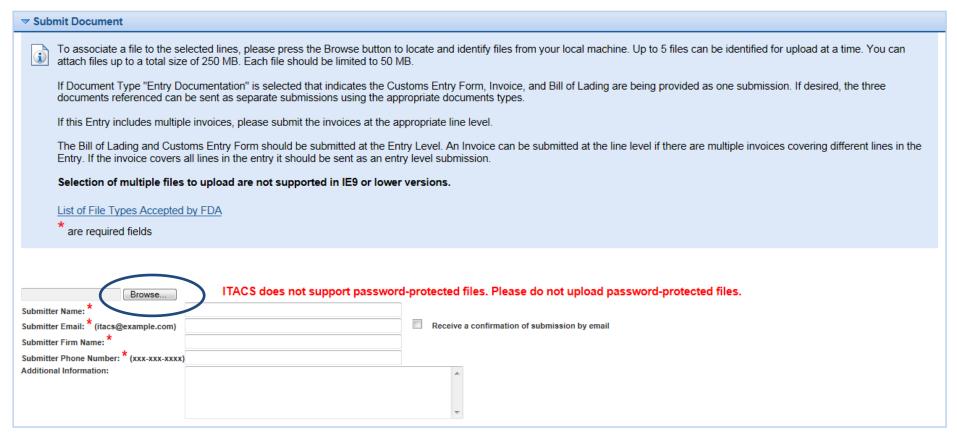
Submitting Documents (cont)

- Click the "Browse" button and locate the file you want to attach
- A document may be deleted from the list prior to submission if it has been attached in error
- Select the Document Type from the drop-down list
- Enter the required Submitter Information (marked with an asterisk)
- When done, click either "Submit and Finished" or "Submit and Return to Entry" button
- Repeat as needed
- You may attach up to 5 files of 50 MB each, for a total of 250 MB per submission

Finding Documents to Submit

Document Submission

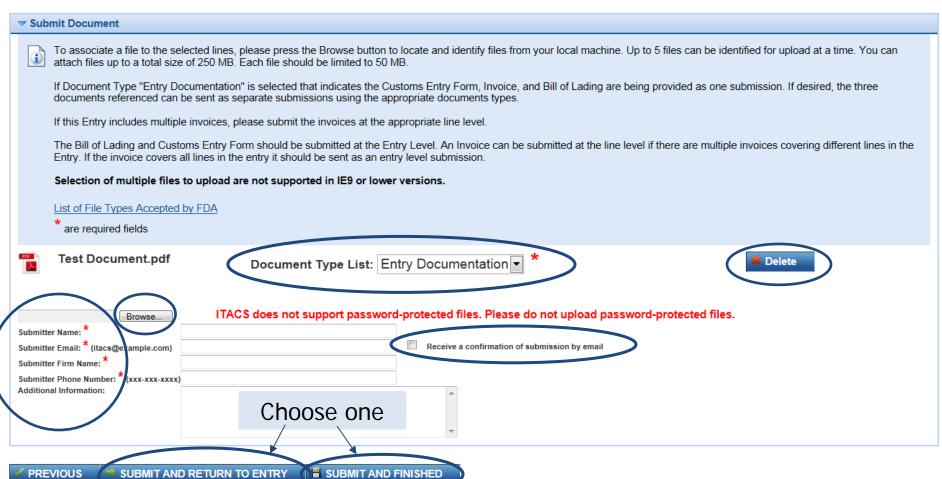
Entry/Doc-L	ine[Suffix]	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status
	3433-7/1-1	ALASKA FRZN SALMON	16AGT32	Total: 960.0 Carton (960.0 Carton, 49.5 Pounds (avdp))	China	FDA Examination Pending	11/21/2016	



Finding Documents to Submit

Document Submission

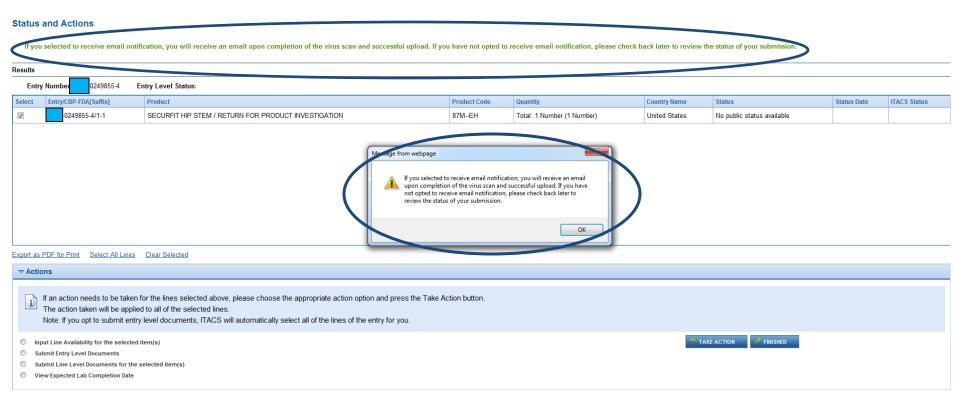
Entry/Doc-Line[St	uffix]	Product	Product Code	Quantity	Country Name	Status	Status Date	ITACS Status
433-	-7/1-1	ALASKA FRZN SALMON	16AGT32	Total: 960.0 Carton (960.0 Carton, 49.5 Pounds (avdp))	China	FDA Examination Pending	11/21/2016	



After Document Submission

 Immediately after submitting the documents, a message will be displayed at the top of the screen "If you selected to receive email notification you will receive an email upon completion of the virus scan and successful upload. If you have not opted to receive email notification please check back later to review the status of your submission"

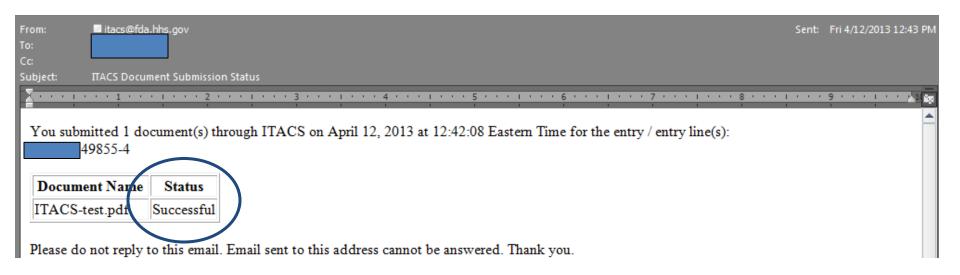
After Document Submission



After Document Submission

- With the implementation of virus scanning, document uploads may take up to fifteen minutes to complete.
- Users may select the checkbox "Receive a confirmation of submission by email". This email will notify the user whether the document(s) passed or failed the virus scan.
- If the virus scan is successful, the ITACS status will update to "Document Submitted" and the ITACS Status date will reflect the date of submission.

Successful Document Submission Example Email



Successful Document Submission "Document Submitted" Status

Status and Actions

Results												
Entry Number 0864-1 Entry Level Status: Document Submitted												
Select	Entry/CBP-FDA [Suffix]	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date			
	00864-	'ENERGY' TEA (HERBAL BLEND)	54ECT99	Total: 84.0 Carton (84.0 Carton, 1.0 Kilograms)	Sri Lanka	Submit Entry Documents to FDA (Invoice, B/L, CBP Entry Document)	04/25/2016	Document Submitted	04/25/2016			
						·						

Document Review by FDA

 When documents have been successfully submitted, FDA's Entry Review staff will see an icon which indicates documents are available for review and they can access and review those documents on-line.

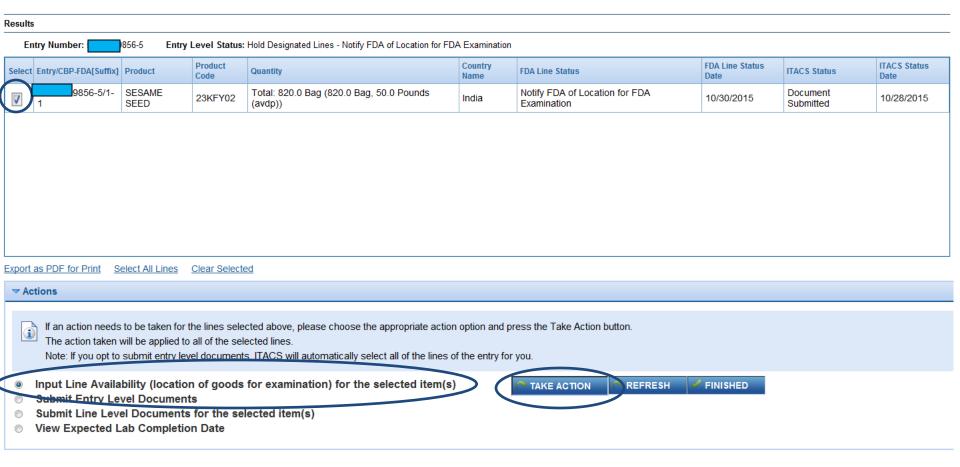
Submitting Availability

Submitting Availability Information for FDA Examination

- Query the entry number
- Click the checkbox next to the line(s) for which you wish to submit availability
- Select the radio button next to "Input Line Availability for the selected item(s)"
- Click on the "Take Action" button

Submitting Availability Information (All lines or Selected lines)

Status and Actions



Submitting Availability – Three Options

- 1. Goods for the selected lines are available at the Consignee address as filed
- 2. Goods for the selected lines are available at the Consignee address as filed with extra information as provided below
- Provide an updated location for the selected lines

Note: If there is any question about the validity of the consignee firm information as stored in FDA's Import system, do not use option 1 or option 2.

Required and Optional Information

- For all options, submitter information is required
- Required information is marked with an asterisk
- Information required varies depending on the option chosen
- Do not submit availability location in advance of the product being available for examination by FDA

Note: DO NOT SUBMIT AVAILABILITY INFORMATION IN ADVANCE OF THE PRODUCT BEING AVAILABLE FOR EXAMINATION BY FDA

Submitting Availability – Option 1

Only Submitter information is required

 The consignee as filed in the entry will be indicated as the location of goods

No additional information may be entered

Submitting Availability — Option 2

Submitter information is required

- The consignee as filed in the entry will be indicated as the location of goods
- Contact Name, Contact Phone Number,
 Warehouse/Pier Lot Number, Hours of
 Operation and Additional Information may all be entered optionally

Submitting Availability – Option 3

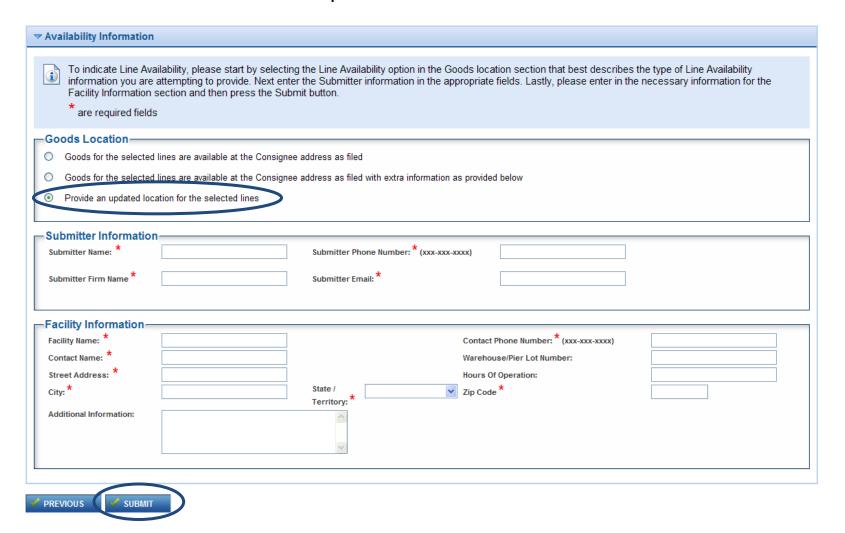
Submitter information is required

 Facility Name, Contact Name, Contact Phone Number, Street Address, City, State and Zip Code are required

 Warehouse/Pier Lot Number, Hours of Operation and Additional Information may all be entered optionally

Provide a Location of Goods (Not at Consignee)

"Provide an updated location for the selected lines"



Submitting Availability

 After filling out all required information and clicking "Submit", the Confirm Input Line Availability screen is presented.

 Verify all information is correct then click either "Submit and Return to Entry" or "Submit and Finished".

Verify Availability Information Before Submitting

Confirm Input Line Availability

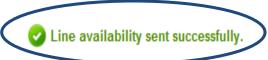
SUBMIT AND RETURN TO ENTRY

SUBMIT AND FINISHED

Entry/Doc-Line Product Country Product Quantity Status Status Date ITACS Status [Suffix] Name GOURAMY FISH Total: 50 Carton (50 Carton, 24 Bottle, Non-Protected, Cyl, 16 Notify FDA of Location for FDA Mar 13. 16YCP09 SAUCE Ounces, weight (avdp)) Examination 2013 7265 Jan 16. Document CRISPY COOKY 03HGT99 Total: 50 Carton (50 Carton, 24 Bag, 7 Ounces, weight (avdp)) Thailand Document Submitted 2013 Submitted Availability Information Please review the information below. If the information provided is correct and you would like to submit the information and query another entry or exit the system, press the Submit and Finished button. If the information displayed is correct and you would like to submit it and perform another action for this entry, press the Submit and Return to Entry button. If the information displayed is incorrect and you would like to change it, press the Previous button to return to the previous screen and edit your Line Availability. —Goods Location-Provide an updated location for the selected lines —Submitter Information Submitter Name: * Submitter Phone Number: * (xxx-xxx-xxxx) Joe Sample 888-463-6332 Submitter Email: * Submitter Firm Name: joe.sample@fda.hhs.gov Facility Information-Contact Phone Number: * (xxx-xxx-xxxx) Facility Name: * FDA 888-463-6332 Contact Name: * Joe Sample Warehouse/Pier Lot Number: Street Address: * 10903 New Hampshire Avenue Hours Of Operation: Maryland City: 7 ✓ Zip Code: Silver Spring 20993 Territory: Additional Information: Choose one

After Availability Information is Submitted

Status and Actions



Results

Entry Number: 8543-6 Entry Level Status: Document Submitted

Selec	Entry/CBP-FDA [Suffix]	Product	Product Code	Quantity	Country Name	FDA Line Status	FDA Line Status Date	ITACS Status	ITACS Status Date
V	543- 6/1-1	SORBITOL LIQUID OR DRY	45VY-99	Total: 72.0 Drum (72.0 Drum, 270.0 Kilograms)	Indonesia	FDA Examination Pending	04/26/2016	Updated Line Availability	04/26/2016

Line(s) Not Eligible for Availability Submission

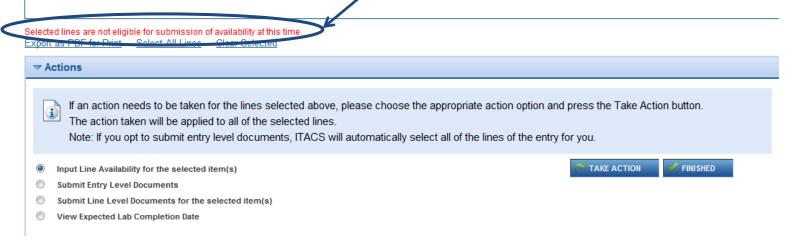
 Availability Information may only be submitted for entries where at least one line has been designated for physical exam/sample by FDA.

 If no lines have been designated, the message "Selected lines are not eligible for submission of availability at this time" will be displayed.

Line(s) Not Eligible for Availability Submission

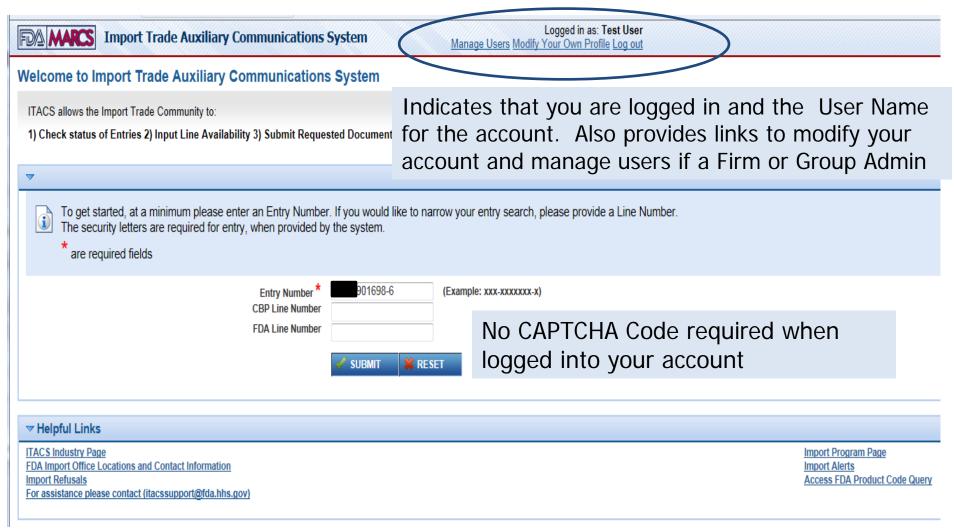
Status and Actions Results 249855-4 **Entry Number** Entry Level Status: Document Submitted Entry/CBP-FDA Product Country Select Product Status Status Date ITACS Status Quantity [Suffix] Code Name SECURFIT HIP STEM / RETURN FOR PRODUCT Total: 1 Number (1 United Document Document 87M--EH INVESTIGATION Number) States Submitted Submitted

Selected lines are not eligible for submission of availability at this time.



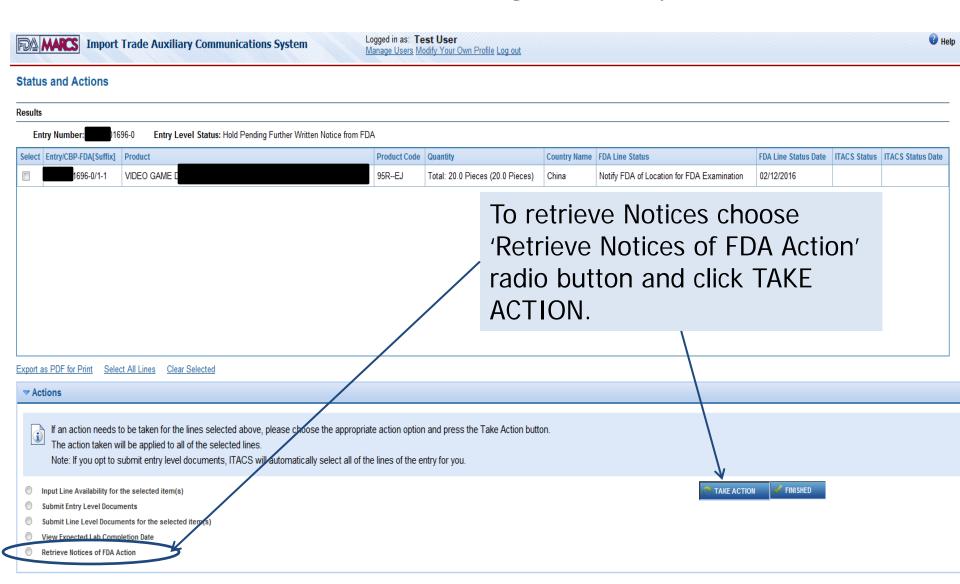
Retrieving Notices of FDA Action from ITACS

*ITACS Account Management Required



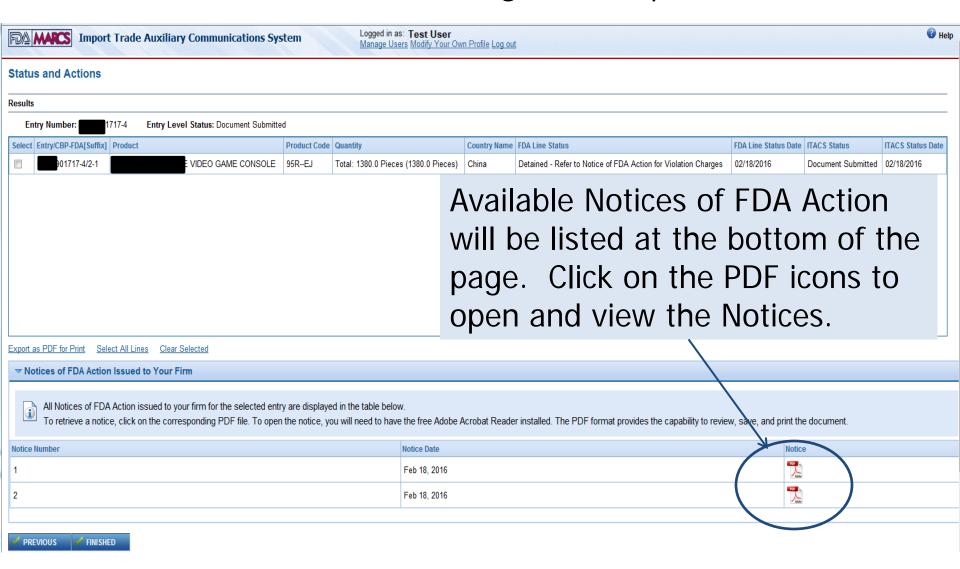
Retrieving Notices of FDA Action from ITACS

*ITACS Account Management Required



Retrieving Notices of FDA Action from ITACS

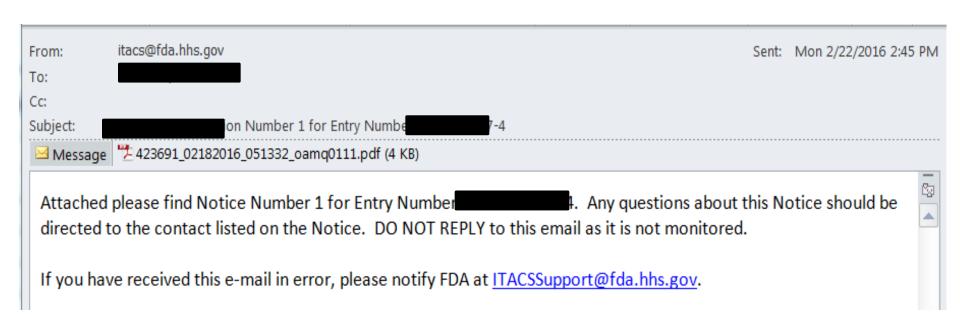
*ITACS Account Management Required



Emailed Notices of FDA Action

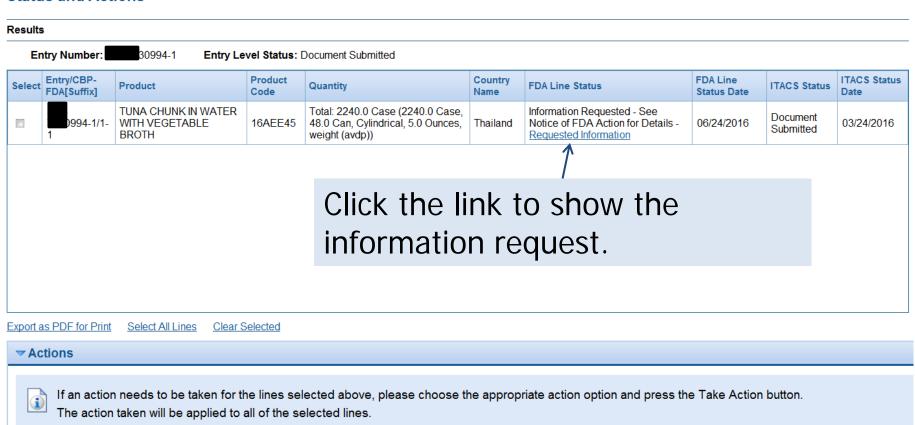
Example Email

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



Retrieving Information Requests from ITACS

Status and Actions



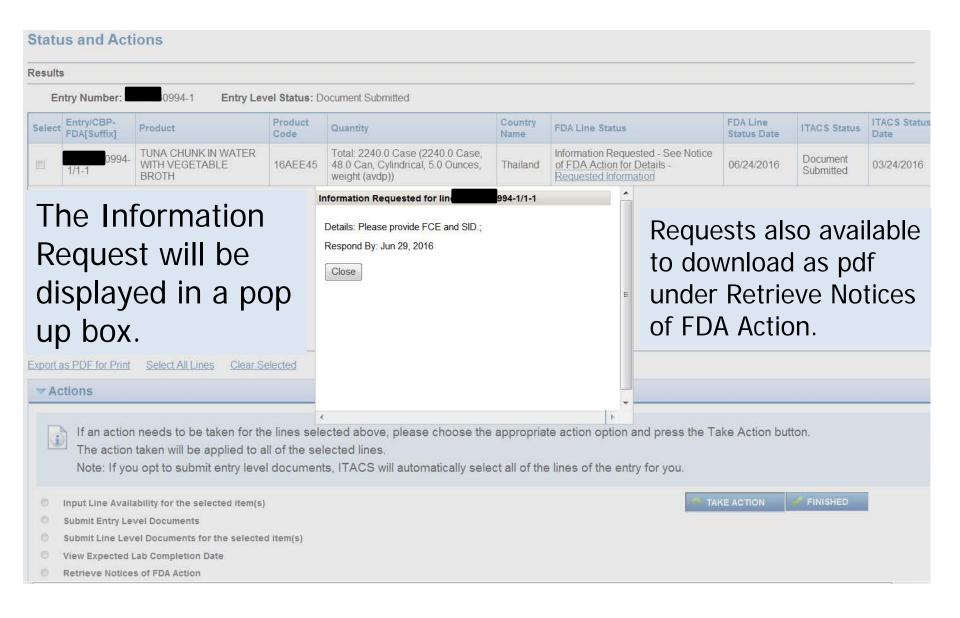
FINISHED

TAKE ACTION

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
- Retrieve Notices of FDA Action

Retrieving Information Requests from ITACS



Helpful Links

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

ITACS Industry Page

FDA Import Office Locations and Contact Information

Import Refusals

For technical assistance please contact (itacssupport@fda.hhs.gov)

Import Program Page
Import Alerts

Access FDA Product Code Query

ITACS Banner

 Can be placed on any ITACS page in red, bold font to notify users of issues or updates.

Status and Actions

FDA is experiencing temporary server issues. Documents cannot be uploaded via ITACS at this time.

Results

ITACS Link

Access ITACS directly at:

https://itacs.fda.gov

To view the ITACS for Industry page visit:

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

FDA Contacts

 Do NOT contact the field Divisions directly for ITACS technical assistance.

 To report problems, ask questions, or to suggest additional functionality please send emails to itacssupport@fda.hhs.gov.

