FDA ITACS Public Statuses

One of the features of FDA's Import Trade Auxiliary Communication System (ITACS) is the availability of what FDA has designated as statuses that can be displayed to the public. The following are statuses corresponding with many of the FDA admissibility decisions and activities used to record interim field and compliance actions which are recorded in FDA's Import system. They are meant to augment the 15 electronic statuses which are currently transmitted via the FDA/Customs Interface, as well as the larger set currently included in Notices of FDA Action. Some of the status text displayed as Public Statuses in ITACS have been modified to be more easily understood.

Audit Sample Received by FDA Lab
Compliance Response to Trade Communication - Please Refer to Notice of FDA Action
Detained - Refer to Notice of FDA Action for Violation Charges
Detained Without Physical Exam - Refer to Notice of FDA Action for Violation Charges
Detained May be Destroyed - Refer to Notice of FDA Action for Violation Charges
Detention Withdrawn - Pending Further FDA Compliance Review
Document Accepted
Document Rejected - Attempt to Resubmit
Document Submitted
Duplicate Entry has been closed
Duplicate Line has been closed
Entry Closed - No Further FDA Action
Entry Deficient - Please Refer to Notice of FDA Action for Details
Entry Documents Required
Entry Documents Required - Notify FDA of Location for FDA Examination
Extension Granted - Refer to Notice of FDA Action for Response Deadline
Extension Request Denied

Extension Request Received

FDA Audit Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.

FDA Audit Lab Analysis in Process

FDA Audit Sample Collected

FDA Examination Completed

FDA Examination Pending

FDA Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.

FDA Lab Analysis in Process

FDA Reconditioning Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.

FDA Reconditioning Lab Analysis in Process

FDA Reconditioning Sample Collected

FDA Sample Collected

Further Reconditioning Approved

Goods Were Not Available for FDA Examination - Notify FDA When Available

Held Pending Receipt of Requested Information - See Notice of FDA Action for Details

Hold All Designated Lines

Hold All Designated Lines - Do Not Devan

Hold All Designated Lines - Do Not Devan - Entry Documents Required

Hold All Designated Lines - Do Not Devan - Entry Documents Required - Notify FDA of Location for Examination

Hold All Designated Lines - Do Not Devan - Notify FDA of Location for Examination Hold All Designated Lines - Entry Documents Required Hold All Designated Lines – Entry Documents Required - Notify FDA of Location for Examination Hold All Designated Lines - Notify FDA of Location for FDA Examination **Hold Designated Lines** Hold Designated Lines -Entry Documents Required Hold Designated Lines -Entry Documents Required - Notify FDA of Location for FDA Examination Hold Designated Lines - Notify FDA of Location for FDA Examination Hold Line – Notify FDA of Location for FDA Examination Hold Pending Analysis Results of Sampled Line Information Requested - See Notice of FDA Action for Details Interface Error Contact FDA Line Availability Received Line Availability Received, FDA Examination Pending Line Closed Line has been cancelled by CBP Line Split Due to Multiple Products Identified - See Notice of FDA Action for Details. Review ITACS for Status of Split Lines. Mail/Baggage Entry Destroyed Mail/Baggage Entry Partially Released, Partially Destroyed Mail/Baggage Entry Partially Returned to Sender, Partially Destroyed Mail/Baggage Entry Released Mail/Baggage Entry Returned to Sender May Proceed Rescinded - Hold for Further Information from FDA May Proceed Without FDA Examination

Non-FDA Lab Rejected - Additional Private Lab Submission Not Allowed Non-FDA Analysis Rejected following Audit Sample - No Resubmission Allowed Non-FDA Analysis Rejected following Audit Sample - Resubmission Allowed Non-FDA Lab Rejected Non-FDA Lab Rejected - Resubmission Allowed Non-FDA Lab Report Received Non-FDA Lab Under Review Notify FDA of Location for FDA Examination Partial Refusal - Inform FDA After Export or Destruction of Refused Portion Partial Refusal - Inform FDA Before Export or Destruction of Refused Portion Pending Review by FDA Compliance Staff Private Laboratory Analysis Confirms Product is Violative Proof of Export or Destruction Received Reconditioned Materials Released Reconditioning Completion Notification Received by FDA Reconditioning Request (FDA-766) Denied Reconditioning Request (FDA-766) Under Review Reconditioning Request Approved - FDA Supervision Not Required Reconditioning Request Approved - Contact FDA to Arrange Supervision Reconditioning Request Conditionally Approved Reconditioning Request Conditionally Approved - Contact FDA to **Arrange Supervision** Reconditioning Request Conditionally Approved - Refer to Notice of FDA **Action for Conditions** Reconditioning Request Denied - Resubmission Allowed Reconditioning Request Incomplete - Resubmission Allowed

Reconditioning Supervision Waived - Contact FDA when Reconditioning is Complete

Reconditioning Unsatisfactory

Reconditioning Unsuccessful - Resubmission Allowed

Refusal Follow-up Completed

Refusal Rescinded - Product Still Detained

Refused Admission by FDA and Returned to Sender

Refused Inform FDA After Export or Destruction

Refused Inform FDA Before Export or Destruction

Release Rescinded - Hold for Further Information from FDA

Released

Released With Comment - Future Violative Shipments May Be Detained - Refer to Notice of FDA Action for More Information.

Sample Received by FDA Lab

Submission Under Technical Review

Submit Entry Documents to FDA (Invoice, B/L, CBP Entry Document)

Submit Proof of Export or Destruction to FDA (CBP Form and On-Board shipping records)