FDA ITACS Public Statuses

One of the features of FDA's Import Trade Auxiliary Communications 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
Detention Withdrawn - Pending Further FDA Compliance Review
Document Accepted
Document Rejected - Attempt to Resubmit
Document Submitted
Documents Required
Entry Closed - No Further FDA Action
Entry Deficient - Please Refer to Notice of FDA Action for Details
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

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

Field Exam Completed

Further Reconditioning Approved

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

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

Hold All Lines - Do Not Devan

Hold All Lines - Do Not Devan - Documents Required

Hold All Lines - Do Not Devan - Documents Required - Notify FDA of Availability for Examination

Hold All Lines - Do Not Devan - Notify FDA of Availability for Examination

Hold All Lines - Documents Required

Hold All Lines - Documents Required - Notify FDA of Availability for Examination

Hold All Lines - Notify FDA of Location for FDA Examination

Hold Designated Lines - Notify FDA of Location for FDA Examination

Hold Pending Further Written Notice from FDA

Information Requested - See Notice of FDA Action for Details

Interface Error Contact FDA

Line Availability Received

Line Availability Received, FDA Examination Pending

Line Split Due to Multiple Products Identified - See FDA Notice of Action for Details

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 - No Further FDA Action

Refused Inform FDA After Export

Refused Inform FDA After Export or Destruction

Refused Inform FDA Before Export

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

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)