

FDA Automates ACE Rescind Messaging

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Office of Enforcement and Import Operations
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Objective

To inform filers of a future ACE enhancement to automate FDA rescind messaging

Background

What is 'Rescind Messaging'?

Periodically there are some scenarios when FDA may rescind one of the final admissibility decision statuses below:

- **May Proceed**
- **Release**
- **Refusal**

Current Process

- Once FDA takes a final action (i.e., May Proceed, Refusal, etc.) no additional messaging is sent to CBP.
- All subsequent actions are communicated outside of ACE and the ABI system (hard copy notice of action, email, etc.).

What is Changing?

New electronic ACE messaging to inform filer(s) that an FDA line has rescinded and FDA final admissibility.

Rescind Messaging Codes

If FDA Sends	Later FDA Could Send
Status Code: '07' = May proceed Reason Code: '22' = GENERAL	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 198 ** May Proceed Rescinded - Hold for Further Information from PGA
Status Code: '07' = May proceed Reason Code: '23' = Released	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 199 ** Release Rescinded - Hold for Further Information from PGA
Status Code: '07' = May proceed Reason Code: '24' = Released with Comment	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 199 ** Release Rescinded - Hold for Further Information from PGA
Status Code : '02' - Hold Intact Reason Code: '11' = General or '40' Refused SubReason Code : '102' = Refused	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained
Status Code : '02' - Hold Intact Reason Code: '11' = General '40' Refused SubReason Code : '103' = Partial Release and Refuse	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained
Status Code : '02' - Hold Intact Reason Code: '40' = Refused SubReason Code : '182' = Refused-Inform Before Export or Destruction	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained
Status Code : '02' - Hold Intact Reason Code: '40' = Refused SubReason Code : '192' = Refused-Inform After Export or Destruction	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained
Status Code : '02' - Hold Intact Reason Code: '40' = Refused SubReason Code : '184' = Partial Refusal-Inform Before Export or Destruction	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained
Status Code : '02' - Hold Intact Reason Code: '40' = Refused SubReason Code : '185' = Partial Refusal-Inform After Export or Destruction	Status Code : '02' - Hold Intact Reason Code: ** 37 ** PGA Decision Rescinded- Do Not Distribute Product SubReason Code : ** 200 ** Refusal Rescinded - Product Still Detained

What this means for you?

- ✓ Electronic Communication
- ✓ Notice of FDA Action
- ✓ 1USG Release Message
- ✓ Eliminates contradictions between ACE, the Notice of Action, and FDA's import systems



Reference

- [CSMS #50412777](#) - FDA to Automate Electronic Messaging for Rescind Activities on 01/22/2022

