Automated Commercial Environment (ACE)

Information for FDA Entry Filings

September 14, 2023

U.S. Customs and Border Protection

ace

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1. Introduction

This document is being provided to assist importers and their authorized agents involved in filing entries with the U.S. Food and Drug Administration (FDA) through the Automated Commercial Environment (ACE). Parties shall continue to utilize the FDA Supplemental Guide for the Automated Commercial Environment/ International Trade Data System (FDA Supplemental Guide for ACE), the appropriate CBP and Trade Automated Interface Requirements (CATAIR) and supporting documents for entry filing requirements.

For technical questions about the content of this document, contact FDA's ACE Support, ACE_Support@fda.hhs.gov, Monday – Friday: 8AM-8PM ET (excluding Federal Holidays).

2. Port of Entry Changes for Entries* with FDA Message Set Data

To change the Port of Entry for entries with FDA data, including disclaims, use Update Action Code U. Refer to the ACE Cargo Release CATAIR for information on Update Action Code U. When an entry has been accepted and processed by FDA, additional versions of the entry with FDA data will be rejected with the exception of entry types 02, 06, 07, 12.

- If the Port of Entry must be changed, **do not change any data elements in the FDA message set.** Only the change in Port of Entry will be processed by FDA. Changes to the FDA message set will not be considered by FDA.
- If FDA has accepted an entry and a change(s) to the FDA message set is needed, contact the local FDA office for assistance. If the local office cannot assist, the entry will need to be canceled and re-filed.
- All decisions/previous status messages stand and remain applicable to the entry and its FDA lines.
- To acknowledge the change to the Port of Entry has been received one of the following reason codes will be sent, with an appropriate status code, for all lines with the full FDA message set.
    - Reason Code: 47
        - Description: Change to port of entry accepted. Amendments to other data elements not reviewed. If PGA data has changed, cancel, and refile the entry.
    - Reason Code: 48
        - Description: Change to port of entry accepted. Amendments to other data elements not reviewed. If PGA data has changed, cancel, and refile the entry. Previous status applies.

*Note: Changes to Port of Entry do not apply to standalone prior notice submissions.