Tips for Importing FDA-Regulated Products in ACE

Diagram depicts mandatory data elements by commodity type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further instruction. For more information email: ACE_Support@fda.hhs.gov .

January 2017
Effective:
February 9, 2017

Drugs:

Intended Use Code*

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

Name and Address of Device Initial Importer (medical devices only)

Affirmations of Compliance*

Required Data Elements for all FDA Products:

Commodity & Subtype

Product Code

Country of Production or Source

Product Description

Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party

Contact Information

Estimated Arrival Date & Time

Biologics:

Intended Use Code

Brand or Proper Name
(except for cells and tissues)

Affirmations of Compliance*

Animal Drugs & Devices:

Intended Use Code
(Animal Drugs only)

Affirmations of Compliance*

Food Products requiring Prior Notice:

Country of Shipment; Place of Growth (if applicable)

Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee (in lieu of DP); Grower or Consolidator if Applicable

Container Number

Quantity, Packaging

Affirmations of Compliance*

Anticipated Port of Arrival

Tobacco:

Brand Name
(for consumer-use products only)

Note: The following data elements are optional, but may expedite processing if transmitted: DUNS or FEI, Quantity and Value, and Filer Contact Information (PK).

*Indicates data elements are mandatory in some instances but not required for all scenarios. Cosmetics and Food Contact Items do not require any additional data elements other than what is listed in the center of the diagram.