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, call 1-877-345-1101 or email ACE_Support@fda.hhs.gov.

Required Data Elements for all FDA Products:

- Commodity & Subtype
- Product Code
- Country Code identifying where the product was produced, sourced, grown, or harvested
- Product Description
- Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party
- Contact Information
- Estimated Arrival Date & Time

- Drugs:
  - Intended Use Code*
  - Country of Production or Source
  - Affirmations of Compliance*

- Medical Devices & Radiation-Emitting Products:
  - Intended Use Code
  - Country of Production or Source
  - Name and Address of Device Initial Importer (medical devices only)
  - Affirmations of Compliance*

- Biologics:
  - Intended Use Code
  - Country of Production or Source
  - Brand or Proper Name (except for cells and tissues)
  - Affirmations of Compliance*

- Animal Drugs & Devices:
  - Intended Use Code (animal drugs only)
  - Country of Production or Source
  - Affirmations of Compliance*

- Food Products requiring Prior Notice:
  - Country of Production or Place of Growth; Country of Shipment
  - Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee (in lieu of DP); if Applicable: Grower or Consolidator; FSV
  - Container Number
  - Quantity, Packaging
  - Affirmations of Compliance*
  - Anticipated Port of Arrival

- Tobacco:
  - Country of Production
  - Brand Name (for consumer-use products only)

*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. See FDA Supplemental Guide for conditions.