# 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.

#### 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\*

Animal Drugs & Devices:

Intended Use Code

(animal drugs only)

Country of Production or Source

Affirmations of Compliance\*



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## Biologics:

Intended Use Code

Country of Production or Source

Brand or Proper Name (except for cells and tissues)

Affirmations of Compliance\*

### **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

**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)

The following data elements are optional, but may expedite processing if transmitted: Quantity and Value, Filer Contact Information (PK), DUNS or FEI. Please note DUNS is required for FSV.

\*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