Industry Quick Reference Guide to the FDA ACE Supplemental Guide
INTRODUCTION

What is the Industry Quick Reference Guide to the FDA ACE SG?

The Industry Quick Reference Guide to the FDA ACE SG is a resource to help importers and filers understand the information reported to FDA for FDA-regulated products offered for import into the United States. This document highlights information that is mandatory, as well as the information that is helpful to the FDA’s review process.

This Industry Quick Reference Guide is a high-level document; it does not replace or provide all of the details included in the FDA Supplemental Guide for the Automated Commercial Environment/International Trade Data System (FDA Supplemental Guide for ACE). This document does not include:

- technical specifications for transmitting data;
- information for determining if FDA regulates a product;
- information on the Harmonized Tariff Schedule; or
- information on disclaiming a product.

Full details on the information collected for each commodity are available in the respective “Commodity Data Elements and Values” section of the FDA Supplemental Guide for ACE. Note that the FDA Partner Government Agency (PGA) message set, excluding Standalone Prior Notice, must be submitted with an ACE Cargo Release or ACE Entry Summary certified for cargo release transaction.


CBP’s ACE CATAIR Entry Summary Create/Update document is available at: https://www.cbp.gov/document/technical-documentation/entry-summary-createupdate.

How do I use the Industry Quick Reference Guide to the FDA ACE SG?

This document is divided into ten commodity chapters, following the structure of the FDA ACE SG, and four appendices. Fully consider each question below, while working through the appropriate commodity chapter and referencing the appropriate appendices and links. This will help importers and filers collect the information to report to FDA for FDA-regulated products offered for import into the United States.

- WHAT? What is being offered for import (commodity, product code, description, quantity and packaging, and value)?
- WHY? Why is the product being imported or offered for import (intended use)?
- HOW? How can commodity-specific requirements be verified (Affirmations of Compliance)?
- WHO? Who are the entities involved with each entry line?
- WHEN? When is the anticipated arrival (date and time) of the entry line?
- WHERE? Where is the product origin? Where is the port of arrival?
Each product category or commodity is a chapter in this document. Click on a commodity page number to go to detailed information on the data FDA collects.

<table>
<thead>
<tr>
<th>Commodities</th>
<th>Page Number</th>
<th>Description and Link to FDA Webpage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>Page 4</td>
<td>Biologic products such as human blood, blood donor screening tests, human tissue, embryos, human plasma, and medical devices for use in blood banking operations</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>Page 8</td>
<td>Cosmetic products such as shampoo and make-up</td>
</tr>
<tr>
<td>Human Drugs</td>
<td>Page 9</td>
<td>Active pharmaceutical ingredients, finished dosage drugs, and pharmaceutical necessities. Drugs include both prescription and over-the-counter medications.</td>
</tr>
<tr>
<td>Human and Animal Foods – Combined Entry (801(a) and Prior Notice)</td>
<td>Page 15</td>
<td>Foods for human and animal consumption, including dietary supplements, and color additives. Combined Prior Notice and 801(a) data requirements</td>
</tr>
<tr>
<td>Human and Animal Foods - Non- Prior Notice and Prior Notice Previously Met</td>
<td>Page 18</td>
<td>Foods for human and animal consumption, including dietary supplements, and color additives. Products that do not require Prior Notice data as ceramicware/food contact substance (CCW) or PN requirements previously met</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>Page 20</td>
<td>Medical devices such as first aid kits, pacemakers, surgical instruments, and sunglasses for human use</td>
</tr>
<tr>
<td>Tobacco Products</td>
<td>Page 23</td>
<td>Tobacco products such as cigarettes and its component parts, smokeless tobacco, and e-cigarettes</td>
</tr>
<tr>
<td>Radiation-Emitting Products</td>
<td>Page 25</td>
<td>Radiation-emitting products such as x-ray machines, microwave ovens, CD-ROMs, and laser pointers</td>
</tr>
<tr>
<td>Animal Drugs and Devices</td>
<td>Page 27</td>
<td>Animal drugs and medical devices for veterinary use</td>
</tr>
<tr>
<td>Appendices</td>
<td>Page 29</td>
<td>Information on: Entities; Food Processing Codes; Program, Processing, and Product Codes; “UNK” in Lieu of an Intended Use Code; Helpful Links and Contacts</td>
</tr>
</tbody>
</table>
1. BIOLOGICS

See the [FDA Supplemental Guide for ACE](https://www.fda.gov/) for full Biologics requirements.

Biologics program information is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIO - Biologic</td>
<td>ALG - Allergenics</td>
<td>57</td>
<td>One Processing Code</td>
</tr>
<tr>
<td></td>
<td>BBA - Blood Bag with Anti-coagulant</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BDP - Blood Derivatives</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BLD - Licensed Devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BLO - Blood and Blood Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CGT - Cell and Gene Therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCT - Human Cells and Tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PVE - Plasma Volume Expanders</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VAC - Vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>XEN - Xenotransplants</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA [Product Code Builder](https://www.fda.gov/).

Biologics product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Trade Name/Brand Name</td>
<td>Optional for processing code HCT; Conditional for all other processing codes</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td></td>
</tr>
</tbody>
</table>

Valid FDA Units of Measure (UOM) for Biologics Packaging Containers and UOM for the Base Unit (Last Quantity Transmitted) for Biologics are noted below.

<table>
<thead>
<tr>
<th>UOM Code</th>
<th>Description</th>
<th>Base UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>Aerosol</td>
<td>AU</td>
<td>Allergy Units (ml or tablet)</td>
</tr>
<tr>
<td>AM</td>
<td>Ampoule, Non-protected</td>
<td>BAU</td>
<td>Bioequivalent Allergy Units (ml or tablet)</td>
</tr>
<tr>
<td>AP</td>
<td>Ampoule, Protected</td>
<td>CAP</td>
<td>Capsule</td>
</tr>
<tr>
<td>AT</td>
<td>Atomizer</td>
<td>CG</td>
<td>Centigrams</td>
</tr>
<tr>
<td>BA</td>
<td>Barrel</td>
<td>FOZ</td>
<td>Ounces, fluid</td>
</tr>
<tr>
<td>BC</td>
<td>Bottle crate, Bottle rack</td>
<td>G</td>
<td>Grams</td>
</tr>
<tr>
<td>BG</td>
<td>Bag</td>
<td>GAL</td>
<td>Gallons (US)</td>
</tr>
<tr>
<td>BO</td>
<td>Bottle, Non-Protected, Cyl</td>
<td>KG</td>
<td>Kilograms</td>
</tr>
<tr>
<td>BQ</td>
<td>Bottle, Protected, Cylindrical</td>
<td>L</td>
<td>Liters</td>
</tr>
</tbody>
</table>
### Intended Use Codes (IUCs) and Affirmations of Compliance (AofCs) for each Biologics

Intended Use Code import scenario are noted in the table below. Refer to the FDA ACE AofCs document for more information and examples of AofCs. See Appendix D for information about “UNK”.

<table>
<thead>
<tr>
<th>Import Scenario</th>
<th>Processing Codes</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use</td>
<td>ALG, BBA, BDP, BLD CGT, PVE, VAC, BLD, XEN</td>
<td>180.009</td>
<td>Mandatory: IND</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Optional: REG</td>
</tr>
<tr>
<td>CBER-regulated Final product; ready for use. Importation of a licensed biological product. The Biologics License number (BLN) is the U.S. License Number. The Submission Tracking Number (STN) is associated with the manufacturer and a specific product and the first six digits represent the original submission tracking number.</td>
<td>ALG, BDP, BLD, BLO, CGT, VAC, or XEN</td>
<td>080.000</td>
<td>Mandatory: BLN or STN or both</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Optional: DLS, REG</td>
</tr>
<tr>
<td>CBER-regulated Final product; ready for use. Importation of drug regulated by CBER.</td>
<td>BBA, PVE</td>
<td>080.000</td>
<td>Mandatory: DA, REG, (DA includes NDA &amp; ANDA only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Optional: DLS</td>
</tr>
<tr>
<td>Import Scenario</td>
<td>Processing Codes</td>
<td>IUC</td>
<td>AofCs</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>-------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being imported or offered for import are in compliance with all applicable requirements of 21 CFR 1271.</td>
<td>HCT</td>
<td>082.000</td>
<td>Mandatory: HCT (No Qualifier Needed for HCT)</td>
</tr>
<tr>
<td>Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HRN Affirmation should be used for Importation of human cells, tissues and cellular and tissue-based product where the establishment is registered with the FDA.</td>
<td>HCT</td>
<td>082.000</td>
<td>Mandatory: HRN</td>
</tr>
<tr>
<td></td>
<td>ALG, BDP, BLD, BLO, CGT, VAC, or XEN</td>
<td>180.016</td>
<td>Optional: DLS, REG</td>
</tr>
<tr>
<td>CBER Product sample for testing or lot release</td>
<td>ALG, BDP, BLD, BLO, CGT, VAC, or XEN</td>
<td>155.000</td>
<td>Mandatory: BLN or STN or both</td>
</tr>
<tr>
<td>CBER product for further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)</td>
<td>ALG, BDP, BLD, BLO, CGT, VAC, or XEN</td>
<td></td>
<td>Optional: DLS, REG</td>
</tr>
<tr>
<td>Importation for personal use</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN</td>
<td>100.000</td>
<td>N/A</td>
</tr>
<tr>
<td>Bulk biological drug substance for processing into a pharmaceutical product</td>
<td>ALG, BDP, BLD, BLO, CGT, VAC, or XEN</td>
<td>150.007</td>
<td>Mandatory: BLN or STN or both</td>
</tr>
<tr>
<td></td>
<td>Optional: DLS, IND, REG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulk drug substance for processing into a pharmaceutical product</td>
<td>BBA or PVE</td>
<td>150.007</td>
<td>Mandatory: DA</td>
</tr>
<tr>
<td>Standard import of a biological drug or device for non-commercial distribution in government and non-government support program.</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN</td>
<td>140.000</td>
<td>Optional: BLN, DA, IND, STN</td>
</tr>
<tr>
<td>Import of a biological drug or device for trade show</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN</td>
<td>110.000</td>
<td>Optional: BLN, DA, IND, STN</td>
</tr>
<tr>
<td>For reconditioning or repair of a non-food product</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN</td>
<td>170.000</td>
<td>Optional: BLN, DA, HCT, HRN, IND, STN</td>
</tr>
<tr>
<td>Importation of non-compliant articles (including blood, blood components, Source plasma and source leukocytes) under the import for export</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN</td>
<td>970.000</td>
<td>Mandatory: IFE</td>
</tr>
</tbody>
</table>
**Import Scenario**

<table>
<thead>
<tr>
<th>Processing Codes</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>provisions 801(d) (3), &amp; 801(d) (4) of the FD&amp;C Act.</td>
<td></td>
<td>(No qualifier required)</td>
</tr>
<tr>
<td>Import of a biologic for non-clinical research use only, bench testing, etc.</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN</td>
<td>180.000</td>
</tr>
<tr>
<td>Importation of a drug (including a biological product) or device for compassionate use/emergency use</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN</td>
<td>940.000</td>
</tr>
<tr>
<td>Import of US Goods Returned</td>
<td>ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE VAC, or XEN</td>
<td>920.000</td>
</tr>
</tbody>
</table>

An additional optional Biologics AofC is Entry Review Requested (ERR).

Biologics **entity information** is noted in the table below. Refer to **Appendix A: Entity Glossary** for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process. FDA CBER prefers FEIs for biologics. See the Blood Establishment Registration (BER) Database and Human Cell and Tissue Establishment Registration Public Query for public FEIs and information.

Biologics **arrival** and **product origin information** are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
2. COSMETICS

See the [FDA Supplemental Guide for ACE](https://www.fda.gov/) for full Cosmetics requirements.

Cosmetics **program information** is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>COS - Cosmetics</td>
<td>N/A</td>
<td>50 or 53</td>
<td>Program Code + Product Code are Mandatory</td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA [Product Code Builder](https://www.fda.gov/).*

Cosmetics **product information** is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Optional, but encouraged; Refer to Appendix D of the FDA Supplemental Guide for ACE.</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Optional Cosmetics **Affirmation of Compliance (AofCs)** data requirements are noted below.

- Cosmetic Registration Number (COS)
- Entry Review Requested (ERR)

Cosmetics **entity information** is noted in the table below. Refer to [Appendix A: Entity Glossary](https://www.fda.gov/) for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process.

Cosmetics **arrival** and **product origin information** are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
3. HUMAN DRUGS

See the FDA Supplemental Guide for ACE for full Human Drugs requirements.

Human Drugs **program information** is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRU – Drug</td>
<td>INV - Investigational</td>
<td>54, 56, 58**, 60, 61, 62, 63, 64, 65, or 66</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>OTC - Over the Counter</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRE - Prescription</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RND - Research and Development</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PHN - Pharmaceutical Necessities</td>
<td>55, various codes could apply</td>
<td></td>
</tr>
<tr>
<td></td>
<td>804 – Section 804 Importation Program</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder. **Industry Code 58 will not be utilized/accepted until notification via a CSMS message.

Human Drugs **product information** is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td></td>
</tr>
<tr>
<td>PGA Line Value</td>
<td></td>
</tr>
<tr>
<td>Product Constituent Element</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Product Trade Name</td>
<td></td>
</tr>
<tr>
<td>Production Condition</td>
<td></td>
</tr>
</tbody>
</table>

Valid FDA **UOM for the Base Unit** (Last Quantity Transmitted) for Human Drugs are noted below. Refer to Appendix D of the FDA Supplemental Guide for ACE for valid units of measure for drugs packaging containers.

<table>
<thead>
<tr>
<th>Base UOM Code</th>
<th>Description</th>
<th>Base UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBL</td>
<td>Barrel (42 Gallons Ea)</td>
<td>LNM</td>
<td>Linear Meter</td>
</tr>
<tr>
<td>BOL</td>
<td>Boluses</td>
<td>M</td>
<td>Meter</td>
</tr>
<tr>
<td>CAP</td>
<td>Capsules (Dosage)</td>
<td>M2</td>
<td>Square Meter</td>
</tr>
<tr>
<td>CFT</td>
<td>Cubic Feet</td>
<td>M3</td>
<td>Cubic Meter</td>
</tr>
<tr>
<td>CG</td>
<td>Centigrams</td>
<td>MG</td>
<td>Milligrams</td>
</tr>
<tr>
<td>CM</td>
<td>Centimeters</td>
<td>MCG</td>
<td>Micrograms</td>
</tr>
<tr>
<td>CM3</td>
<td>Cubic Centimeters</td>
<td>ML</td>
<td>Milliliters</td>
</tr>
<tr>
<td>CYD</td>
<td>Cubic Yard</td>
<td>OZ</td>
<td>Ounces</td>
</tr>
<tr>
<td>FOZ</td>
<td>Ounces, fluid (Volume)</td>
<td>PCS</td>
<td>Pieces</td>
</tr>
<tr>
<td>Base UOM Code</td>
<td>Description</td>
<td>Base UOM Code</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------</td>
<td>---------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>FT</td>
<td>Feet</td>
<td>PTL</td>
<td>Pints</td>
</tr>
<tr>
<td>G</td>
<td>Grams</td>
<td>QTL</td>
<td>Quarts</td>
</tr>
<tr>
<td>GAL</td>
<td>Gallons</td>
<td>STN</td>
<td>Short Ton</td>
</tr>
<tr>
<td>KG</td>
<td>Kilograms (Weight)</td>
<td>SUP</td>
<td>Suppositories</td>
</tr>
<tr>
<td>KM</td>
<td>Kilometer</td>
<td>T</td>
<td>Metric Ton</td>
</tr>
<tr>
<td>KM2</td>
<td>1000 Square Meters</td>
<td>TAB</td>
<td>Tablets</td>
</tr>
<tr>
<td>KM3</td>
<td>1000 Cubic Meters</td>
<td>TON</td>
<td>Long Ton</td>
</tr>
<tr>
<td>L</td>
<td>Liter</td>
<td>TOZ</td>
<td>Ounces, Troy</td>
</tr>
<tr>
<td>LB</td>
<td>Pounds (avdp) (Weight)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The only **Intended Use Codes (IUCs)** and **Affirmations of Compliance (AofCs)** to be used for Human Drugs are noted in the table below. Refer to the [FDA ACE AofCs](#) document for more information and examples of AofCs. See Appendix D for information about “UNK”.

<table>
<thead>
<tr>
<th>Human Drug Import Scenarios</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription health or medical product for human use that is the subject of an approved</td>
<td>080.012</td>
<td>Mandatory: DA, DLS Conditional: REG, FSR, PRN Optional: PLR (not</td>
</tr>
<tr>
<td>new drug application, abbreviated new drug application, or biologics license application</td>
<td></td>
<td>available for Processing Code 804)</td>
</tr>
<tr>
<td>Importation for Personal Use</td>
<td>100.000</td>
<td>N/A</td>
</tr>
<tr>
<td>For Consumer Use as a Non-Food Product – Over the Counter (OTC)</td>
<td>130.000</td>
<td>Mandatory: DLS, REG Optional: DA</td>
</tr>
<tr>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical</td>
<td>150.007</td>
<td>Mandatory: REG, DLS Conditional: DA</td>
</tr>
<tr>
<td>product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding</td>
<td>150.013</td>
<td>Mandatory: DLS, REG</td>
</tr>
<tr>
<td>Importation of a drug component (API) for use in a medical product regulated under a device</td>
<td>150.017</td>
<td>Mandatory: DLS, REG Optional: DA, IDE, LST, PM#</td>
</tr>
<tr>
<td>(CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importation of a drug constituent part (drug product) for use in a medical product</td>
<td>155.009</td>
<td>Mandatory: REG, DLS Optional: DA, IDE, LST, PM#</td>
</tr>
<tr>
<td>regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>device combination product).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical for research and development of a pharmaceutical product – subject of an</td>
<td>180.009</td>
<td>Mandatory: IND</td>
</tr>
<tr>
<td>Investigational New Drug application (IND), including Placebos</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical for research and development of a pharmaceutical product – laboratory testing</td>
<td>180.017</td>
<td>N/A</td>
</tr>
<tr>
<td>only, no human/animal use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Human Drug Import Scenarios

<table>
<thead>
<tr>
<th>Human Drug Import Scenarios</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical for research and development; investigational use in animals</td>
<td>180.018</td>
<td>N/A</td>
</tr>
<tr>
<td>Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements.</td>
<td>180.026</td>
<td>N/A</td>
</tr>
<tr>
<td>US Goods Returned</td>
<td>920.000</td>
<td>Optional: DA, DLS, IND, REG,</td>
</tr>
<tr>
<td>Import for Export</td>
<td>970.000</td>
<td>N/A</td>
</tr>
<tr>
<td>For Other Use (APIs or Finished Drugs not elsewhere classified)</td>
<td>980.000</td>
<td>Mandatory: DLS, REG</td>
</tr>
</tbody>
</table>

**Human Drugs entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td></td>
<td>Mandatory</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td></td>
<td>Mandatory</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td>Optional, but encouraged</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Sponsor of IND - If different than MF or FD1 (SPO)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Producer (Producer of API) (GD)</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process, particularly submission of Sponsor and Producer information. See the Drug Establishments Current Registration Site for public DUNS and FEI numbers and information.

**Human Drugs arrival and product origin information** are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
4. HUMAN AND ANIMAL FOODS – STAND ALONE PRIOR NOTICE

See the FDA Supplemental Guide for ACE for full “Stand Alone” PN requirements.

Human and Animal Foods – Stand Alone PN program information is noted below. Refer to Appendix B: Food Processing Codes for additional program information.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOO – Food</td>
<td>ADD - Additives and Colors</td>
<td>02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52**, 54**, 69, 70, 71 or 72</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>DSU - Dietary Supplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEE - Animal Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NSF - Natural State Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRO - Processed Food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

**See the FDA Supplemental Guide for ACE for more information on class rules for Industry Code 52 and subclass rules for Industry Code 54.

Human and Animal Foods – Stand Alone PN product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Mandatory; Refer to Standalone section of the FDA Supplemental Guide for ACE for valid units</td>
</tr>
<tr>
<td>License Information</td>
<td>Conditional for Carriers that are Privately Owned Vehicles (POV)</td>
</tr>
<tr>
<td>Shipping Container Information</td>
<td>Conditional for containerized cargo arriving by water, air, rail or land</td>
</tr>
<tr>
<td>Express Courier Information</td>
<td>Conditional</td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) are optional for Prior Notice. See Appendix D for information about “UNK”.

Conditional and optional Human and Animal Foods – Stand Alone PN Affirmation of Compliance (AofCs) information is noted below. Refer to the FDA ACE AofCs document for detailed information and examples of AofCs.

<table>
<thead>
<tr>
<th>AofC Codes</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAN, FME, PFR, RNO, VFT, VES</td>
<td>Conditional</td>
</tr>
<tr>
<td>CFR, GFR, IFR, LFR, ORN, SFR, SRN, TFR, UFR</td>
<td>Optional</td>
</tr>
</tbody>
</table>
Human and Animal Foods – Stand Alone PN entity information is noted below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name</th>
<th>Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PN Submitter (PNS)</td>
<td>Mandatory</td>
<td>Mandatory, except if the PN Submitter’s ‘SRN’ is transmitted, then the address line 1 is optional.</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>PNT Transmitter (PNT)</td>
<td>Mandatory</td>
<td>Mandatory, except if the PN Transmitter’s ‘TFR’ is transmitted, then the address line 1 is optional.</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Choose one:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Manufacturer (MF) or FDA Consolidator (FDC) or 2. Grower (DFI)</td>
<td>Mandatory</td>
<td>Mandatory, except if the manufacturer’s (MF) ‘PFR’ is transmitted, then the address line 1 is optional.</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Location of Goods (Secure Holding Facility for PN Purposes) (LG)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (Importer of Record) (FD1)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>Optional, but encouraged</td>
<td></td>
</tr>
<tr>
<td>Ultimate Consignee* (Delivered to Party) (UC)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Owners (DFP)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Ultimate Consignee (Deliver To Party), Importer and Owner info is not required IF the product is imported for the transportation and exportation (T&E) entry type. Refer to the FDA Supplemental Guide for ACE additional information.

“Optional, but encouraged” information assists in matching firms in the FDA database.
Human and Animal Foods – Stand Alone PN **arrival** and **product origin information** are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date at Port of Arrival</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Arrival Time at Port of Arrival</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Port of Arrival</td>
<td>Mandatory</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of Shipment</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Choose one:</td>
<td>Mandatory</td>
</tr>
<tr>
<td>1. Place of Growth or</td>
<td></td>
</tr>
<tr>
<td>2. Country of Production</td>
<td></td>
</tr>
<tr>
<td>Country of Prior Refusal</td>
<td>Conditional</td>
</tr>
</tbody>
</table>
5. HUMAN AND ANIMAL FOODS – COMBINED ENTRY (801(A) AND PRIOR NOTICE)

See the FDA Supplemental Guide for ACE for full “Combined Entry” requirements.

The Human and Animal Foods – Combined Entry program information is noted in the table below. Refer to Appendix B: Food Processing Codes for additional program information.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOO – Food</td>
<td>ADD - Additives and Colors</td>
<td>02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52**, 54**, 69, 70, 71 or 72</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>DSU - Dietary Supplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEE - Animal Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NSF - Natural State Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRO - Processed Food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

**See the FDA Supplemental Guide for ACE for more information on class rules for Industry Code 52 and subclass rules for Industry Code 54.

Human and Animal Foods – Combined Entry product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Mandatory; Refer to Combined Entry section of the FDA Supplemental Guide for ACE for valid units.</td>
</tr>
<tr>
<td>License Information</td>
<td>Conditional for Carriers that are Privately Owned Vehicles (POV).</td>
</tr>
<tr>
<td>Shipping Container Information</td>
<td>Conditional for containerized cargo arriving by water, air, rail or land</td>
</tr>
<tr>
<td>Express Courier Information</td>
<td>Conditional</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) are optional for Human and Animal Foods – Combined 801(a) and Prior Notice. See Appendix D for information about “UNK”.

Conditional and optional Human and Animal Foods – Combined Entry Affirmation of Compliance (AofCs) information is noted below. Refer to the FDA ACE AofCs document for detailed information and examples of AofCs.
### AofC Codes

<table>
<thead>
<tr>
<th>AofC Codes</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAN, FCE, FME, FSX, PFR, RNE, RNO, SID, VES, VFT, VOL</td>
<td>Conditional</td>
</tr>
<tr>
<td>AIN, CFR, CIN, ERR, FAP, FCC, GFR, IBP, IFE, IFR, JIF, LFR, ORN, PKC, REG, SFR, SIF, SRN, TFR, UFR, VFD, VFL, VQI</td>
<td>Optional</td>
</tr>
</tbody>
</table>

### Human and Animal Foods – Combined Entry entity information

Human and Animal Foods – Combined Entry entity information is noted below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name</th>
<th>Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PNT Submitter (PNS)</td>
<td>Mandatory</td>
<td>Mandatory, except if the PN Submitter’s ‘SRN’ is transmitted, then the address line 1 is optional.</td>
<td>Mandatory</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>PNT Transmitter (PNT)</td>
<td>Mandatory</td>
<td>Mandatory, except if the PN Transmitter’s ‘TFR’ is transmitted, then the address line 1 is optional.</td>
<td>Mandatory</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Choose one: 1. Manufacturer (MF) or 2. FDA Consolidator (FDC) or 3. Grower (DFI)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>FDA Importer (Importer of Record) (FD1)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Optional, but encouraged</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Owners (DFP)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Ultimate Consignee (Delivered to Party) (UC)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Location of Goods (Secure Holding Facility for PN Purposes) (LG)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Entity Role (Code)</td>
<td>Entity Name</td>
<td>Entity Address</td>
<td>Individual Name, Tel# and Email</td>
<td>Entity ID Code and Number: DUNS or FEI</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------</td>
<td>----------------</td>
<td>---------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Foreign Supplier Verification Program Importer (FSV)</td>
<td>Conditional*</td>
<td>Conditional*</td>
<td>Email is Mandatory if FSV is provided Individual Name and Telephone Number are Optional, but encouraged</td>
<td>DUNS is Mandatory if FSV is provided</td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td></td>
<td></td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

*Mandatory, unless Industry Codes 16 or 32 are present in PG02 or an exemption is declared in the AoC using either codes FSX (FSVP Exempt) or RNE (Research and Evaluation).

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process.

Human and Animal Foods – Combined Entry **arrival** and **product origin information** are noted below.

### Arrival Information

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date at Port of Arrival</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Arrival Time at Port of Arrival</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Port of Arrival</td>
<td>Mandatory</td>
</tr>
</tbody>
</table>

### Product Origin Information

<table>
<thead>
<tr>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of Shipment</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Choose one:</td>
<td></td>
</tr>
<tr>
<td>1. Place of Growth or</td>
<td></td>
</tr>
<tr>
<td>2. Country of Production</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Country of Prior Refusal</td>
<td>Conditional</td>
</tr>
</tbody>
</table>
6. HUMAN AND ANIMAL FOODS - NON-PRIOR NOTICE AND PRIOR NOTICE PREVIOUSLY MET

See the FDA Supplemental Guide for ACE for full Non-PN and PN Previously Met requirements.

Human and Animal Foods – Non-PN and PN Previously Met program information is noted below. Refer to Appendix B: Food Processing Codes for additional program information.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOO – Food</td>
<td>ADD - Additives and Colors</td>
<td>02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52, 54, 69, 70, 71 or 72</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>DSU - Dietary Supplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEE - Animal Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NSF - Natural State Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRO - Processed Food</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CCW - Ceramicware and Food Contact Substances</td>
<td>52</td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Human and Animal Foods – Non-PN and PN Previously Met product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Prior Notice Confirmation Number</td>
<td>Mandatory for foods with a previously submitted Prior Notice</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Optional, but encouraged; Refer to Non-PN and PN Previously Met section of the FDA Supplemental Guide for ACE for valid units.</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) are optional for Human and Animal Foods - Non-Prior Notice and Prior Notice previously met. See Appendix D for information about “UNK”.

Conditional and optional Human and Animal Foods – Non-PN and PN Previously Met Affirmation of Compliance (AofCs) information is noted below. Refer to the FDA ACE AofCs document for more information.

<table>
<thead>
<tr>
<th>AofC Codes</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCE, FSX, RNE, SID, VOL</td>
<td>Conditional</td>
</tr>
<tr>
<td>CCC, CIN, ERR, FAP, FCC, AIN, VQI, JIF, SIF, IBP, IFE, PKC, REG, VFD, VFL</td>
<td>Optional</td>
</tr>
</tbody>
</table>
Human and Animal Foods – Non-PN and PN Previously Met entity information is noted below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name</th>
<th>Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (Importer of Record) (FD1)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Optional, unless filing a CCW for food contact service, Mandatory.</td>
<td>DUNS is Mandatory if FSV is provided</td>
</tr>
<tr>
<td>Delivered To Party (DP)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Foreign Supplier Verification Program Importer (FSV)</td>
<td>Conditional</td>
<td>Conditional</td>
<td>Email is Mandatory if FSV is provided Individual Name and Telephone Number are Optional, but encouraged</td>
<td></td>
</tr>
<tr>
<td>Filer's/Broker's Point of Contact (PK)</td>
<td></td>
<td></td>
<td>Optional, but encouraged</td>
<td></td>
</tr>
</tbody>
</table>

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Human and Animal Foods – Non-PN and PN Previously Met arrival and product origin information are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Place of Growth OR Country of Production</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
7. MEDICAL DEVICES

See the FDA Supplemental Guide for ACE for full Medical Devices requirements.

The Medical Devices program information is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEV - Medical Device</td>
<td>NED - Non-Radiation Emitting Device</td>
<td>73-92</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>RED - Radiation-Emitting Device</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Medical Devices product information are noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Radiation-Emitting Device</th>
<th>Non-Radiation Emitting Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Mandatory if the product requires FDA Form 2877, otherwise optional, but encouraged</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Valid FDA Units of Measure (UOM) and UOM for the Base Unit (Last Quantity Transmitted) for Medical Devices are noted below.

<table>
<thead>
<tr>
<th>UOM Code</th>
<th>Description</th>
<th>Base UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS</td>
<td>Case</td>
<td>PCS</td>
<td>Pieces (Count)</td>
</tr>
<tr>
<td>CT</td>
<td>Carton</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BX</td>
<td>Box</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PK</td>
<td>Package</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) and Affirmations of Compliance (AofCs) for each Medical Device import scenario are noted in the table below. The conditional AofCs are mandatory if the associated regulatory requirements apply to the product being offered for import. For example, if the product requires premarket clearance (e.g. submission of a 510(k) as notification to FDA), then PM# must be provided. See FDA ACE AofCs for more information. See Appendix D for information about “UNK”.
<table>
<thead>
<tr>
<th>Medical Device Import Scenarios</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standard import of a foreign manufactured device, accessories, or components regulated as a finished device</td>
<td>081.001</td>
<td>Mandatory: DEV, DFE, LST</td>
</tr>
<tr>
<td>• Import of refurbished device</td>
<td></td>
<td>Conditional: IRC, LWC, PM#</td>
</tr>
<tr>
<td>• Import of a reprocessed device</td>
<td></td>
<td>Optional: DI</td>
</tr>
<tr>
<td>Import of a foreign manufactured device for domestic refurbishing</td>
<td>081.002</td>
<td>Mandatory: DEV, DFE, LST</td>
</tr>
<tr>
<td>Domestic manufactured device that is part of a medical device convenience kit</td>
<td>081.003</td>
<td>Mandatory: DDM, DFE, KIT, LST</td>
</tr>
<tr>
<td>A foreign manufactured device that is part of a medical device convenience kit</td>
<td>081.004</td>
<td>Mandatory: DEV, DFE, KIT, LST</td>
</tr>
<tr>
<td>Device constituent part for drug-device combination product</td>
<td>081.005</td>
<td>Mandatory: DA, DEV, DFE, IND, LST</td>
</tr>
<tr>
<td>Import under enforcement discretion provisions per final guidance</td>
<td>081.006</td>
<td>N/A</td>
</tr>
<tr>
<td>Import of a General Wellness Product per final guidance:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Component for further manufacturing into a finished medical device</td>
<td>081.007</td>
<td>Mandatory: CPT</td>
</tr>
<tr>
<td>Device component for use in a drug-device combination product</td>
<td>081.008</td>
<td>Mandatory: CPT</td>
</tr>
<tr>
<td>Device for Personal Use</td>
<td>100.000</td>
<td>N/A</td>
</tr>
<tr>
<td>Public Exhibition/Trade Show</td>
<td>110.000</td>
<td>N/A</td>
</tr>
<tr>
<td>Import of a device for charity</td>
<td>140.000</td>
<td>Mandatory: DEV, DFE, LST</td>
</tr>
<tr>
<td>Repair of medical device and re-exportation</td>
<td>170.000</td>
<td>Mandatory: IFE</td>
</tr>
<tr>
<td>Import of research or investigational use in vitro diagnostic device</td>
<td>180.010</td>
<td>N/A</td>
</tr>
<tr>
<td>• Import of a device for non-clinical use/bench testing</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>• Import of device sample for customer evaluation</td>
<td>180.014</td>
<td>N/A</td>
</tr>
<tr>
<td>Import of a medical device for clinical investigational use</td>
<td>180.015</td>
<td>Mandatory: IDE</td>
</tr>
<tr>
<td>Import of a device that is US goods returned for refund/overstock (to manufacturer)</td>
<td>920.001</td>
<td>Mandatory: DDM, LST</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conditional: DFE, IRC, LWC, PM#</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Optional: DI</td>
</tr>
</tbody>
</table>
### Medical Device Import Scenarios

<table>
<thead>
<tr>
<th>Scenario</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
</table>
| Import of device that is US goods returned for sale to a third party     | 920.002 | Mandatory: DDM, DFE, LST  
Conditional: IRC, LWC, PM#  
Optional: DI |
| Compassionate Use/Emergency Device                                       | 940.000 | N/A                                                                |
| Import of a single-use device for domestic reprocessing                  | 950.001 | Mandatory: DDM, LST  
Conditional: DFE, IRC, LWC, PM#  
Optional: DI |
| Import of a multi-use device for domestic reprocessing                   | 950.002 | Conditional: DDM, DFE, IRC, LST, LWC, PM#  
Optional: DI |
| Import for Export:                                                       |       | Optional, but encouraged                                               |
| - Import of a medical device for further processing and re-exportation   |       | Mandatory: DEV, DFE, IFE, LST                                        |
| - Importation of a medical device or accessory for further manufacturing into an export-only medical device |       | Mandatory: IFE, CPT, DDM, LST                                        |

Additional optional Medical Devices AofCs are: Device Identifier (DI) and Entry Review Requested (ERR).

Medical Device **entity information** is noted in the table. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>N/A</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>N/A</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Device Initial Importer (DII)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td></td>
<td>Optional, but encouraged</td>
<td></td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process. FDA CDRH prefers FEIs for devices. See Establishment Registration & Device Listing for public FEIs and information.

Medical Devices **arrival** and **product origin information** noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
8. TOBACCO PRODUCTS

See the FDA Supplemental Guide for ACE for full Tobacco Products requirements.

Tobacco program information is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOB - Tobacco</td>
<td>CSU - Consumer Use</td>
<td>98</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>FFM - For Further Manufacturing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>INV - Investigational</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Tobacco product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Trade Name/Brand Name</td>
<td>Mandatory for processing code CSU</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Valid FDA Units of Measure (UOM) for Packaging Containers and UOM for the Base Unit (Last Quantity Transmitted) for Tobacco Products are noted below.

<table>
<thead>
<tr>
<th>UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
<td>Atomizer</td>
</tr>
<tr>
<td>BL</td>
<td>Bale, Compressed</td>
</tr>
<tr>
<td>BN</td>
<td>Bale, Non-Compressed</td>
</tr>
<tr>
<td>BX</td>
<td>Box</td>
</tr>
<tr>
<td>CON</td>
<td>Container</td>
</tr>
<tr>
<td>CS</td>
<td>Case</td>
</tr>
<tr>
<td>CT</td>
<td>Carton</td>
</tr>
<tr>
<td>CTR</td>
<td>Cartridge</td>
</tr>
<tr>
<td>DR</td>
<td>Drum</td>
</tr>
<tr>
<td>KIT</td>
<td>Kit</td>
</tr>
<tr>
<td>PK</td>
<td>Package</td>
</tr>
<tr>
<td>VI</td>
<td>Vial</td>
</tr>
<tr>
<td>VL</td>
<td>Bulk Liquid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Base UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBL</td>
<td>Barrels (42 Gallons Ea)</td>
</tr>
<tr>
<td>DOZ</td>
<td>Dozen</td>
</tr>
<tr>
<td>DPC</td>
<td>Dozen Pieces</td>
</tr>
<tr>
<td>FOZ</td>
<td>Ounces, fluid</td>
</tr>
<tr>
<td>GAL</td>
<td>Gallons (US)</td>
</tr>
<tr>
<td>L</td>
<td>Liters</td>
</tr>
<tr>
<td>ML</td>
<td>Milliliters</td>
</tr>
<tr>
<td>NO</td>
<td>Number</td>
</tr>
<tr>
<td>PCS</td>
<td>Pieces</td>
</tr>
<tr>
<td>PTL</td>
<td>Pints, liquid (US)</td>
</tr>
<tr>
<td>QTL</td>
<td>Quarts, liquid (US)</td>
</tr>
<tr>
<td>G</td>
<td>Grams</td>
</tr>
<tr>
<td>KG</td>
<td>Kilograms</td>
</tr>
<tr>
<td>LB</td>
<td>Pounds (avdp)</td>
</tr>
</tbody>
</table>

Conditional Intended Use Codes (IUCs) for Tobacco Products are noted below. See Appendix D for information about “UNK”.
### Intended Use Description

<table>
<thead>
<tr>
<th>IUC</th>
<th>Intended Use Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>150.000</td>
<td>For commercial process as Non-Food</td>
</tr>
<tr>
<td>155.000</td>
<td>For Commercial Assembly as a Non-Food Product to be consumed</td>
</tr>
<tr>
<td>180.001</td>
<td>For Research and Development as a non-Food Product - Animal or plant for biomedical research</td>
</tr>
<tr>
<td>180.000</td>
<td>For Research and Development as a non-Food Product – All other Uses</td>
</tr>
<tr>
<td>110.000</td>
<td>For Public Exhibition or Display as a Non-Food Product</td>
</tr>
<tr>
<td>130.000</td>
<td>For Consumer Use as a Non-Food Product</td>
</tr>
<tr>
<td>140.000</td>
<td>For Charitable Organization Use as Non-Food Product</td>
</tr>
<tr>
<td>130.037</td>
<td>For re-packaging and re-labelling</td>
</tr>
</tbody>
</table>

Optional Tobacco Products **Affirmations of Compliance (AofC)** are noted below. Refer to the [FDA ACE AofCs](#) document for detailed information and examples of AofCs.

<table>
<thead>
<tr>
<th>Tobacco Products AofCs</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ILS, CMT, ERR, EXE, HPC, PMT, SE, TST</td>
<td>Optional</td>
</tr>
</tbody>
</table>

Tobacco Products **entity information** is noted in the table below. Refer to [Appendix A: Entity Glossary](#) for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Independent Third Party Laboratory (ITL)</td>
<td>Conditional</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Laboratory or Clinical Site (LAB)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Retailer/Distributor (RD)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Submitter (TB)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process.

Tobacco Products **arrival** and **product origin information** are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Place of Growth OR Harvested OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
9. RADIATION-EMITTING PRODUCTS

See the FDA Supplemental Guide for ACE for full Radiation-Emitting Products requirements. Some Radiation-Emitting Products are Medical Devices. If the product is also a Medical Device, then all Medical Device data elements noted in the Medical Device chapter of the FDA Supplemental Guide for ACE are also required.

Radiation-Emitting program information is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAD - Radiation-Emitting Products</td>
<td>REP - Non-Medical Radiation-Emitting Product</td>
<td>94-97</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Radiation-Emitting product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Trade Name/Brand Name</td>
<td>Conditional: mandatory for articles required to submit form FDA 2877</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td></td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Valid FDA Units of Measure (UOM) and UOM for the Base Unit (Last Quantity Transmitted) for Radiation-Emitting Products are noted below.

<table>
<thead>
<tr>
<th>UOM Code</th>
<th>Description</th>
<th>Base UOM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS</td>
<td>Case</td>
<td>PCS</td>
<td>Pieces (Count)</td>
</tr>
<tr>
<td>CT</td>
<td>Carton</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BX</td>
<td>Box</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PK</td>
<td>Package</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) for Radiation Emitting Products are noted below. See Appendix D for information about “UNK”.

<table>
<thead>
<tr>
<th>IUC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>085.000</td>
<td>Veterinary Medical Use as a Non-Food Product under Controlled Distribution</td>
</tr>
<tr>
<td>090.000</td>
<td>Military Use as a Non-Food Product</td>
</tr>
<tr>
<td>100.000</td>
<td>Personal Use as a Non-Food Product</td>
</tr>
<tr>
<td>110.000</td>
<td>Public Exhibition or Display as a Non-Food Product</td>
</tr>
<tr>
<td>120.000</td>
<td>Public Safety Use as a Non-Food Product</td>
</tr>
<tr>
<td>130.000</td>
<td>Consumer Use as a Non-Food Product</td>
</tr>
<tr>
<td>140.000</td>
<td>Charitable Organization Use as Non-Food Product</td>
</tr>
<tr>
<td>150.000</td>
<td>Commercial Processing as a Non-Food Product</td>
</tr>
<tr>
<td>155.000</td>
<td>Commercial Assembly as a Non-Food Product</td>
</tr>
<tr>
<td>170.000</td>
<td>Repair of a Non-Food Product</td>
</tr>
</tbody>
</table>
Below are Affirmations of Compliance (AofC) that may be used if Form FDA 2877 is Mandatory. Refer to the FDA ACE AofCs document for detailed information and examples.

<table>
<thead>
<tr>
<th>AofC</th>
<th>Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA1, RA2, RA3, RA4, RA5, RA6 and RA7</td>
<td>EPRC Radiation - emitting Products. Use if FDA compliance is non-applicable. Refer to Form FDA 2877</td>
<td>Conditional</td>
</tr>
<tr>
<td>RB1, RB2</td>
<td>EPRC Radiation – emitting Products. Use if product is FDA compliant. Refer to Form FDA 2877</td>
<td></td>
</tr>
<tr>
<td>RC1, RC2</td>
<td>EPRC Product Declaration Form FDA 2877</td>
<td></td>
</tr>
<tr>
<td>RD1, RD2, RD3</td>
<td>EPRC Radiation products. Use if product is non-compliant but will be re-conditioned under bond and Form FDA766. Refer to Form FDA 2877</td>
<td></td>
</tr>
<tr>
<td>ACC</td>
<td>EPRC (Electronic Product Radiation Control) Accession Number</td>
<td></td>
</tr>
<tr>
<td>ANC</td>
<td>PRC Radiation - emitting Products Annual Report Accession Number</td>
<td>Optional</td>
</tr>
<tr>
<td>MDL</td>
<td>Model Number of the Product</td>
<td></td>
</tr>
<tr>
<td>ERR</td>
<td>Entry Review Requested</td>
<td></td>
</tr>
<tr>
<td>IFE</td>
<td>Import For Export</td>
<td></td>
</tr>
<tr>
<td>CCM</td>
<td>Name of the Certified Component Manufacturer</td>
<td></td>
</tr>
</tbody>
</table>

Radiation-Emitting Products entity information is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td></td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td>Optional, but encouraged</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Filer's/Broker’s Point of Contact (PK)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process.

Radiation-Emitting Products arrival and product origin information are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
10. ANIMAL DRUGS AND DEVICES

See the FDA Supplemental Guide for ACE for full Animal Drugs and Devices requirements.

The Animal Drugs and Devices program information is noted in the table below.

<table>
<thead>
<tr>
<th>Program Code and Commodity</th>
<th>Processing Code and Commodity Subtype</th>
<th>Product Industry Code*</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>VME - Animal Drug or Device</td>
<td>ADR - Animal Drug</td>
<td>54, 56, 60, 61, 62, 63, 64, 65, 66 or 67</td>
<td>Program Code + One Processing Code + Product Code are Mandatory</td>
</tr>
<tr>
<td></td>
<td>ADE - Animal Device</td>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Animal Drugs and Devices product information is noted in the table below.

<table>
<thead>
<tr>
<th>Product Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Quantity and Packaging</td>
<td>Optional, but encouraged; Refer to Appendix D of the FDA Supplemental Guide for ACE.</td>
</tr>
<tr>
<td>Product Constituent Element for ADR</td>
<td>Optional, but encouraged</td>
</tr>
</tbody>
</table>

Intended Use Codes (IUCs) and Affirmations of Compliance (AofCs) for each Animal Drug import scenario is noted in the table below. Refer to the FDA ACE AofCs document for more information and examples of AofCs. See Appendix D for information about “UNK”.

<table>
<thead>
<tr>
<th>Animal Drugs Import Scenarios</th>
<th>IUC</th>
<th>AofCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug subject of a new animal</td>
<td>085.003</td>
<td>Mandatory: NDC, REG, and either VAN or VNA Optional: VFD, VFL,</td>
</tr>
<tr>
<td>drug application, conditionally approved application, or Index listing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importation for Personal Use</td>
<td>100.000</td>
<td>N/A</td>
</tr>
<tr>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding</td>
<td>150.013</td>
<td>Mandatory: NDC, REG</td>
</tr>
<tr>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing</td>
<td>150.020</td>
<td>Mandatory: NDC, REG, and either VAN or VNA</td>
</tr>
<tr>
<td>For research and development in a pharmaceutical product – clinical investigations in animals (INAD)</td>
<td>180.009</td>
<td>Mandatory: VIN</td>
</tr>
</tbody>
</table>
Animal Drugs Import Scenarios | IUC | AofCs
--- | --- | ---
For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals. | 180.018 | Optional: VIN
US Goods Returned | 920.000 | N/A
Import for Export | 970.000 | N/A
For Other Use (APIs or Finished Drugs not elsewhere classified) | 980.000 | Mandatory: NDC, REG, Optional: VAN, VFD, VFL, VNA

Animal Drugs and Devices entity information is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name and Entity Address</th>
<th>Individual Name, Tel# and Email</th>
<th>Entity ID Code and Number: DUNS or FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Mandatory</td>
<td>N/A</td>
<td>Optional, but encouraged</td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td></td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Producer of API (GD)</td>
<td>Optional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Filer's/Broker's Point of Contact (PK)</td>
<td>Optional, but encouraged</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

“Optional, but encouraged” information assists in matching firms in the FDA database and/or facilitates the entry review process.

Animal Drugs and Devices arrival and product origin information are noted below.

<table>
<thead>
<tr>
<th>Arrival Information</th>
<th>Status</th>
<th>Product Origin Information</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated Arrival Date AND Time at Port of Entry</td>
<td>Mandatory</td>
<td>Country of Production OR Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>FTZ Information</td>
<td>Conditional</td>
<td>Country of Prior Refusal</td>
<td>Optional</td>
</tr>
</tbody>
</table>
### 11. Appendix A: Entity Glossary

For full definitions in FDA laws and regulations, see the [FDA Regulatory Information](https://www.fda.gov) webpage.

<table>
<thead>
<tr>
<th>Entity Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer of goods ('MF')</td>
<td>The FDA Manufacturer is the site-specific location where the product is manufactured, produced or grown.</td>
</tr>
<tr>
<td>Shipper ('DEQ')</td>
<td>The shipper is the firm or individual responsible for introducing merchandise into interstate commerce by way of transport and that does not act as a manufacturer, repacker, distributor.</td>
</tr>
<tr>
<td>FDA Importer of Record ('FD1')</td>
<td>The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry.</td>
</tr>
<tr>
<td>Device Initial Importer ('DII')</td>
<td>The initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. The initial importer must have a physical address in the United States staffed by individuals responsible for ensuring the compliance of imported devices with all applicable FDA laws and regulations.</td>
</tr>
<tr>
<td>Delivered to Party ('DP')</td>
<td>The site where the goods are to be delivered. It represents the facility to physically receive the goods after arrival in the US. 'UC' is applicable for Prior Notice data and is synonymous to 'DP'.</td>
</tr>
<tr>
<td>Ultimate Consignee ('UC')</td>
<td></td>
</tr>
<tr>
<td>Point of Contact ('PK')</td>
<td>The individual who can respond to FDA’s questions on a specific shipment, usually the broker or entry filer.</td>
</tr>
<tr>
<td>Prior Notice Submitter ('PNS')</td>
<td>The PNS is any person with knowledge of the required information may submit prior notice for an article of food. The person is the submitter.</td>
</tr>
<tr>
<td>Prior Notice Transmitter ('PNT')</td>
<td>The PN Submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278).</td>
</tr>
<tr>
<td>Owner ('DFP')</td>
<td>The term owner or consignee means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the &quot;importer of record.&quot;</td>
</tr>
<tr>
<td>Grower ('DFI')</td>
<td>Grower means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.</td>
</tr>
<tr>
<td>Consolidator ('FDC')</td>
<td>The firm that has consolidated the articles of food from different growers or different growing locations.</td>
</tr>
</tbody>
</table>
## 12. Appendix B: Food Processing Codes

For definitions in FDA laws and regulations, see the [FDA Regulatory Information](https://www.fda.gov) webpage.

<table>
<thead>
<tr>
<th>Processing Code</th>
<th>Description</th>
</tr>
</thead>
</table>
| Natural State Food (NSF) | 21 USC 321(r)-The term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.¹  
Note (1): This includes vegetables and grains, as well as whole fish headed, eviscerated or frozen attendant to harvest.  
Note (2): No longer in its natural state means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart. |
| Processed Food (PRO)     | 21 USC 321(gg)-The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.                                                                                                                     |
| Animal Food (FEE)        | 21 USC 321(w)-The term "animal feed", means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.                                                                                                           |
| (Food)Additives and Colors (ADD) | 21 USC 321(s) and 21 USC 321(t) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—  
(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or  
(2) a pesticide chemical; or  
(3) a color additive; or                                                |
<table>
<thead>
<tr>
<th>Processing Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(4)</td>
<td>any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];</td>
</tr>
<tr>
<td>(5)</td>
<td>a new animal drug; or</td>
</tr>
<tr>
<td>(6)</td>
<td>an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.</td>
</tr>
<tr>
<td>(t)(1) The term &quot;color additive&quot; means a material which—</td>
<td></td>
</tr>
<tr>
<td>(A)</td>
<td>is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and</td>
</tr>
<tr>
<td>(B)</td>
<td>when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.</td>
</tr>
<tr>
<td>Dietary Supplement (DSU)</td>
<td>21 USC 321(ff)-The term &quot;dietary supplement&quot;—</td>
</tr>
<tr>
<td>(1)</td>
<td>means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:</td>
</tr>
<tr>
<td>(A)</td>
<td>a vitamin;</td>
</tr>
<tr>
<td>(B)</td>
<td>a mineral;</td>
</tr>
<tr>
<td>(C)</td>
<td>an herb or other botanical;</td>
</tr>
<tr>
<td>(D)</td>
<td>an amino acid;</td>
</tr>
<tr>
<td>(E)</td>
<td>a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or</td>
</tr>
<tr>
<td>(F)</td>
<td>a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);</td>
</tr>
<tr>
<td>Ceramicware and other Food Contact Substances (CCW)</td>
<td>21 USC 348(h)(6)-The term &quot;food contact substance&quot; means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.</td>
</tr>
</tbody>
</table>
### 13. Appendix C: Program, Processing, and Industry Codes by Commodity

The table below identifies commodities, their subtypes, and the industry for their product codes.

<table>
<thead>
<tr>
<th>Program Code or Commodity</th>
<th>Processing Code or Commodity Subtype</th>
<th>Product Industry Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIO - Biologic</td>
<td>ALG - Allergens</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>BBA - Blood Bag with anti-coagulant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BDP - Blood Derivatives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BLD - Licensed Devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BLO - Blood and Blood Products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CGT - Cell and Gene Therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCT - Human Cells and Tissue</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PVE - Plasma Volume Expanders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VAC - Vaccines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>XEN - Xenotransplants</td>
<td></td>
</tr>
<tr>
<td>COS - Cosmetic</td>
<td>N/A</td>
<td>50 or 53</td>
</tr>
<tr>
<td>DRU – Drug</td>
<td>INV - Investigational</td>
<td>54, 56, 58*, 60, 61, 62, 63, 64, 65, or 66</td>
</tr>
<tr>
<td></td>
<td>OTC - Over the Counter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRE - Prescription</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RND - Research and Development</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PHN - Pharmaceutical Necessities</td>
<td>55, various codes could apply</td>
</tr>
<tr>
<td></td>
<td>804 – Section 804 Importation Program</td>
<td>54, 56, 60, 61, 62, 63, 64, 65, or 66</td>
</tr>
<tr>
<td>VME - Animal Drug or Device</td>
<td>ADE - Animal Device</td>
<td>54, 56, 60, 61, 62, 63, 64, 65, 66 or 67</td>
</tr>
<tr>
<td></td>
<td>ADR - Animal Drug</td>
<td>68</td>
</tr>
<tr>
<td>FOO – Food</td>
<td>ADD - Additives and Colors</td>
<td>02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52, 54, 69, 70, 71 or 72</td>
</tr>
<tr>
<td></td>
<td>DSU - Dietary Supplement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEE - Animal Feed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NSF - Natural State Food</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PRO - Processed Food</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CCW - Ceramicware or Food Contact Substance</td>
<td>52</td>
</tr>
<tr>
<td>DEV - Medical Device</td>
<td>NED - Non-Radiation Emitting Device</td>
<td>73-92</td>
</tr>
<tr>
<td></td>
<td>RED - Radiation-Emitting Device</td>
<td></td>
</tr>
<tr>
<td>RAD - Radiation-Emitting Products</td>
<td>REP - Non-Medical Radiation-Emitting Product</td>
<td>94-97</td>
</tr>
<tr>
<td>TOB - Tobacco</td>
<td>CSU - Consumer Use</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>FFM - For further manufacturing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INV - Investigational</td>
<td></td>
</tr>
</tbody>
</table>

*Industry Code 58 will not be utilized/accepted until notification via a CSMS message.

If after consultation with the importer, who should know the intended use of the product, the filer still does not know the intended use of the product, “UNK” may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if “UNK” is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.
15. **Appendix E: Helpful Links and Contacts**

Below are helpful links and contact information for importers and filers.

<table>
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<th>Helpful Links and Contact Information</th>
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<td>FDA Supplemental Guide for ACE</td>
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<td>FDA ACE Quantity Data Instructions</td>
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<td>FDA Affirmations of Compliance for ACE</td>
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<td>Product Code Builder</td>
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<td>FDA ACE Error Guide</td>
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Contact Information:

- **FDA Import Contacts and Office Locations**
- **FDA Import Offices and Ports of Entry**
  - First-line support for product coding and entry-specific questions, including working through the FDA entry admissibility process, once the entry is successfully transmitted to FDA and accepted
- **ACE Support Desk**
  - ACE_Support@fda.hhs.gov
  - Contact for questions regarding this Industry Quick Reference Guide, technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.
- **Division of Import Operations (DIO)**
  - FDAImportsInquiry@fda.hhs.gov
  - 301-796-0356
  - Contact for general questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration