ACE PGA Required Data Elements and Values for Biologics Program

- Will always be “BIO”

Process: Please indicate one of the following selections

- “ALG”- Allergens
- “VAC”- Vaccines
- “HCT”- Human Cells & Tissue
- “XEN”- Xenotransplant
- “CGT”- Cell & Gene Therapy
- “BLO”- Blood & Blood Products
- “BLD”- Licensed Devices
- “BDP”- Blood Derivatives
- “BBA”- Blood Bag with Anticoagulant
- “PVE”- Plasma Volume Expanders
- “BRD”- Biologics Regulated Devices (not subject to licensure)

Description

- Should be the description as per the Commercial Inv.
Intended Use: Must be populated with one of the below codes

<table>
<thead>
<tr>
<th>Sub-Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>080.000</td>
<td>For Human Medical Use as a Non-Food Product under Controlled Distribution</td>
</tr>
<tr>
<td>082.000</td>
<td>For Immediate use by authorized medical officials in the medical treatment of humans</td>
</tr>
<tr>
<td>150.000</td>
<td>For further processing into nonmedicinal and medicinal products</td>
</tr>
<tr>
<td>150.013</td>
<td>For processing into a medical device</td>
</tr>
<tr>
<td>150.007</td>
<td>For processing into a pharmaceutical product</td>
</tr>
<tr>
<td>180.016</td>
<td>For processing samples submitted to CBER for lot release testing.</td>
</tr>
<tr>
<td>100.000</td>
<td>For private non-commercial use under the FDA personal importation policy (PIP)</td>
</tr>
<tr>
<td>140.000</td>
<td>For improving living conditions during a natural disaster.</td>
</tr>
<tr>
<td>180.000</td>
<td>For Research and Development as a Non-Food Product</td>
</tr>
<tr>
<td>180.009</td>
<td>For Research and Development of a pharmaceutical product</td>
</tr>
<tr>
<td>180.010</td>
<td>For Research and Development of a medical device</td>
</tr>
<tr>
<td>110.000</td>
<td>For Public Exhibition or Display as a Non-Food Product</td>
</tr>
<tr>
<td>170.000</td>
<td>For reconditioning or repair of a Non-Food Product</td>
</tr>
</tbody>
</table>

Product Code
- Must enter FDA product code (Ex: 81O--IB)

Constituent Element (CE)
- Will remain blank

Qty of CE
- Will remain blank

UOM of CE
- Will remain blank

Percent of CE
- Will remains blank
Active
Will remain blank

ISO Produce (Manufacturer/Grower) (2 Digit Alphanumeric Code)
- ISO Country Code for the country the product was produced (Ex: JP for Japan)
  For a complete ISO Country Code list, click [here](#)

ISO Source (Shipping Country)
- ISO Country Code for the country the product exported from
  *Note: ISO Source should remain blank if you are entering the ISO Produce. Only enter the ISO Source if the ISO Produce is unknown.

Previously Refused ISO
- If the cargo was previously refused from another country, this field must be populated with an ISO Country code.

Trade/Brand Name
- If a product is licensed, Trade Name or Proper Name is mandatory. Vaccines (VAC), Blood Derivatives (BDP) and Licensed Devices (BLD) are required to include Trade/Brand Name if it exists.
- If no Trade Name is available then its Proper Name should be provided. Per 21CFR600.3 (k), Proper name is defined as the name designated in the product license, for use upon each package of the product. Tissues and cells only have product description (HCT).

Character Description
- Should be the description as per the Commercial Inv.
Full Quantity Breakdown

- Provide packaging and quantity for the item (Ex: 6 Cartons, each carton contains 4 Boxes, each box has 4 Pieces)

Can Dimensions

- Will remain blank

Anticipated Arrival Date

- Enter the arrival date and time (should default from file data)

Time

- System should default to 08:00

Location

- System should default port of entry

Product Line Value

- The value associated with the PGA community
  *Must be entered in whole dollars & be right-justified with preceding zeros

Lot Number

- Lot Number is Mandatory for Blood Derivatives; otherwise Optional

**Entities Required**

<table>
<thead>
<tr>
<th>Role Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MF</td>
<td>Manufacturer of Goods</td>
</tr>
<tr>
<td>DEQ</td>
<td>Shipper</td>
</tr>
<tr>
<td>FD1</td>
<td>FDA Importer (Importer of Record)</td>
</tr>
</tbody>
</table>
**List of Affirmation of Compliance Code**

If the commodity is “BBA”- Blood Bag with Anticoagulant or “PVE”- Plasma Volume Expanders, the below field is mandatory.

**DA**
- Biologics New Drug or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number

For more information on Application numbers, click [here](#)

If the commodity is “BRD”- Biologics Regulated Devices, the below fields are required.

**HDE**
- Humanitarian Device Exemption (if applicable)

For more information on HDE, click [here](#)

**PM#**
- Biologics PreMarket Approval Number

For more information on PM#, click [here](#)

**IDE**
- Biologics Investigational Device Exemption

For more information on IDE, click [here](#)

**DEV**
- Device Foreign Manufacturer Registration Number

For more information on DEV, click [here](#)
CPT
- Component Identifier
  *Note: This is an Indicator Only. No Value to be entered. Only enter if commodity is a component.

LST
- Device Listing Number
For more information on LST, click here

If the commodity is “HCT”- Human Cells & Tissue, the below field is mandatory.

HRN
- Biologics Human Cells, Tissues/Cellular and Tissue Based Product Establishment Registration Number (HCT/P Registration Numbers)
For more information on HRN, click here


IND
- Biologics Investigation New Drug Application Number
For more information on IND, click here

BLN
- Biologics License Number
For more information on BLN, click here

**STN**
- Biologics Submission Tracking Number

For more information on STN, click here

Required Affirmation of Compliance for all commodities except for “HCT”- Human Cells & Tissue & “BRD”- Biologics Regulated Devices

**REG**
- Drug Registration Number

For more information on REG, click here

*Note: Affirmation code requirements change based on Import Scenarios. See below examples of Required AOC’s based on specific scenarios

**Example Scenarios:**

- Importation of biological human drug- The qualifier requires BA or BN prefix followed by the abbreviated new drug application number or new drug application number. DA & REG are required AOC.

- Importation of Biological Device- The qualifier requires BP or BM prefix followed by Biologics Device Pre-Market Approval Number. PM#, DEV, & LST are required AOC.

- Importation of Human Cells, Tissues and Cellular and Tissue-Based Product where the establishment is registered with the FDA- HRN is a required AOC.

- Importation of a Biologics Investigational New Drug- The qualifier should be the Investigational New Drug Application Number. IND is a required AOC.
• Importation of Biologics Investigational Device and the qualifier should be the Investigational Device Exemption Number. IDE is a required AOC.

• Importation of a licensed biological product. The Biologics License Number is the U.S. license number (not the STN number). An STN number for the product can also be provided along with its qualifier. BLN is a required AOC.

• Importation of a licensed biological product using the submission tracking number. The Submission Tracking number is the biologics license application (BLA) number. The STN is associated with the manufacturer and a specific product, and the first six digits represent the original submission tracking number (“XXXXXX”). An applicant license number could also be provided. STN is a required AOC.

• Importation of a Biologics Device associated with a Pre-Market Notification Number 510(k)- PM#, DEV, & LST are required AOC.

• Import of Biologics Regulated Device (Not subject to licensure) (BIO/BRD)- HDE is a required AOC.

Should you have any question, concerns or simply wish to discuss this new requirement please feel free to email compliance@shipamerican.com with your inquiry. Otherwise please feel free to contact your Customer Service Representative, Sales Person or your usual contact party.