

FDA Biologics

Account Number		Account Name	
DUNS Number <i>(if available)</i>		Client Part Number*	
Description of Product <i>(as complete as possible)</i>			
Government Agency Processing Code		Tariff Number	
FDA Product Code <i>(if known)</i>		Country of Origin**	FDA Country of Production**
Cargo Storage Status	Intended Use		
Name of active ingredient(s) in prescription, over the counter, animal, drugs or medicated animal feeds:			

* Part number as shown on Customs document to identify the product (item number, SKU, etc.)

** U.S. Customs considers the country of origin to be the country where the product last underwent a "substantial transformation" (resulting in an increase in value.) The FDA considers the country of origin to be that of the actual manufacturer. Actual manufacturer is defined as the last party involved in the production process.

FDA Actual Manufacturer

Company Name			
Address			City
State/Province	Zip/Postal Code	Country	DUNS Number <i>(if available)</i>

Manufacturer/Exporter Registration Numbers *Provide registration numbers for all applicable*

DA: New Drug, Abbreviated New Drug	PM#: Biologics Premarket Notification Number 501K
IND: Biologic Investigation New Drug Application Number	HRN: Biologic Cells, Tissues Product Establishment Registration
STN: Biological Submission Tracking Number	BLN: Biologic License Number
Other:	

FDA Shipper *(As shown on Customs document, BOL or airway bill)*

Company Name			
Address			City
State/Province	Zip/Postal Code	Country	DUNS Number <i>(if available)</i>

FDA INTENDED USE

ACE INFORMATION SHEET

GHY USA needs to know, as your customs broker, how the FDA-regulated products being imported are intended to be used and/or why the products are being imported.

In order for us, here at GHY USA, to enter the appropriate end use code, as an importer you should confirm that your invoices clearly show what the end use is going to be for the product. Please refer to the below intended use descriptions required, to ensure your own descriptions are complete.

BIOLOGICS INTENDED USE

- 080.000 - CBER-regulated final product ready for use
- 081.000 - CSER-regulated product for processing into a medical device
- 082.000 - Human cells, tissues, and cellular tissue based products for implant, transplant, infusion or transfer into human recipient
- 100.000 - Importation for personal use
- 110.000 - Import of biological drug or device for trade show
- 140.000 - Standard import of a biological drug or device for non-commercial distribution in organization support program
- 150.007 - Bulk drug substance for processing into a pharmaceutical product
- 155.000 - CBER product for further manufacturer of a licensed biological product under a short supply agreement (21CFR 601.22)*
- 170.000 - Import of biological product, drug, or device that is US goods returned to manufacturer
- 180.000 - Import of biologic for NON-clinical research use only.
- 180.009 - Import of biological or chemical for research and development into a pharmaceutical product
- 180.010 - Import of a biological or chemical for research and development into a medical device
- 180.016 - CBER product sample for testing or lot release
- 970.000 - CBER-Import for Export
- 940.000 - Compassionate use/emergency use
- UNK - Unknown