

FDA Drugs

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 Select One		Tariff Number	
FDA Product Code <i>(if known)</i>		Customs Country of Origin**	FDA Country of Production**
Type of Product Select One		Product is for	Cargo Storage Status
Intended use			
Ingredient(s)		Percentage of Active Ingredient	Brand Name

* 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 of the food. 21 CFR 1.227(b)(2)

FDA Actual Manufacturer

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

Drug Listing Number *(Provide for all applicable)*

DA: New Drug Application Number (formerly NDA, ANDA & BLA)	
REG: Drug Registration Number (DUNS Number)	IND: Investigative New Drug Number
DLS: Drug Listing Number (formerly NDC 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.

DRUGS INTENDED USE

- 080.000 - For Human Medical Use as a Non-Food Product under Controlled Distribution - PRE Prescription
- 130.000 - For Consumer Use as a Non-food Product - OTC Over the Counter
- 150.007 - Active Pharmaceutical Ingredient/ bulk drug substance for processing into a pharmaceutical product
- 180.009 - Chemical for research and development in a pharmaceutical product - investigational new drugs, clinical trials or other human/animal ingestion
- 180.017 - Chemical for research and development in a pharmaceutical product - laboratory testing only-- no human/animal ingestion
- 970.000 - Import for Export - program
- 100.000 - Importation for personal use
- 155.009 - Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g. for use in a PMA/510(k) drug-device combination product
- 150.017 - Importation of a drug component (API) for use in a medical product regulated under device (CDRH) -combination product
- 150.018 - Active Pharmaceutical ingredient/ bulk drug substance to be used for pharmacy compounding
- UNK - Unknown