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

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

MEDICAL DEVICES

- 081.001 - For Human Medical use as a medical device (standard import of a medical device, accessories, or components) regulated as finished devices, import of refurbished device, import of a reprocessed device
- 081.002 - Refurbishing
- 081.003 - Domestically manufactured device that is part of a medical device convenience kit
- 081.004 - Foreign manufactured device that is part of a medical device convenience kit
- 081.005 - Device for use in a drug/device combination product
- 081.006 - Import of a medical device under enforcement discretion, applies to the following product codes: 80O--UG, 86N--FF, 86N--FG, 80N--XQ, 90L--MB, 90L--MD only
- 100.000 - Personal Use
- 110.000 - Public exhibition or taking orders (includes trade shows)
- 140.000 - Charitable organization use
- 081.007 - Component for further manufacturing into a finished medical device
- 081.008 - Device for use in a NDA/ANDA/BLA drug device combination product
- 170.000 - Repair
- 180.010 - Research & development as a medical device
- 180.014 - Research & development for bench testing or non-clinical research
- 180.015 - Research & development - clinical investigation use
- 920.001 - US manufactured medical device returned as over-stock, refund
- 920.002 - US manufactured device sale to a third party
- 940.000 - Compassionate use, emergency use device
- 950.001* - Single use device for domestic reprocessing
- 950.002* - Multi-use device for domestic reprocessing
- 970.000 - Import for export (must be further manufactured or processed, and then exported)- device or accessory
- 970.002 - Import for export (must be further manufactured or processed, and then exported)-component

NOTE: Conditional affirmations are required if applicable to the product being declared, for example, if the product requires premarket clearance 510k, then PM# must be provided.

* annotates that additional information may be needed at the time of entry in order for FDA to make a final admissibility decision.

- UNK - Unknown

ELECTRONICS

- 085.000 - For Veterinary Medical Use as a Non-Food Product under Controlled Distribution
- 090.000 - For Military Use as a Non- Food Product
- 100.000 - For Personal Use as a Non- Food Product
- 110.000 - For Public Exhibition or Display as a Non-Food Product
- 120.000 - For Public Safety Use as a Non-Food Product
- 130.000 - For Consumer Use as a Non- Food Product
- 140.000 - For Charitable Organization Use as Non-Food Product
- 150.000 - For Commercial Processing as a Non-Food Product
- 155.000 - For Commercial Assembly as a Non-Food Product
- 170.000 - For Repair of a Non-Food Product
- 180.000 - For Research and Development as a Non-Food Product
- 970.000 - For import for export
- 980.000 - For other use