



International Shipping Procedures:

Part I: Imports to the U.S.

Please review these procedures carefully. These procedures apply to all shipments from outside the U.S. which are intended for any Amgen site within the U.S. or the U.S. territories. This also includes all international shipments to any U.S. or U.S. territory vendor, supplier, contractor or partner who may be receiving shipments on behalf of Amgen; or where Amgen is responsible for clearance through U.S. Customs or is the ultimate consignee.

Amgen reserves the right to refuse and return at the shipper's expense any shipment for which complete and accurate information, as required by any government agency for import and clearance purposes, has not been provided within the stated time frame. Deviations from this procedure may be reported to Amgen's Global Strategic Sourcing and Law Departments, and others as deemed necessary.

Carrier Information:

Express Consignment (small package – except temperature-sensitive): Shippers will utilize Amgen's preferred carrier **UPS** for international shipments destined for the U.S. mainland and **FedEx** for international shipments destined for Puerto Rico if the shipping weight is less than 150 lbs (70 kgs). Account numbers are provided on the Purchase Order. Amgen company name, or the name of one of Amgen's affiliated, companies or designated representatives must show in the "ship to" or "consignee" fields on the airway bill. * *Please leave broker information of the AWB blank.**

Temperature-sensitive, heavy weight freight and ocean shipments: Shippers will forward temperature-sensitive shipments and shipments of more than 150 lbs (70kgs) via Amgen's freight forwarder **Unitrans International**. Contact at amgenimport@unitrans-us.com for transportation arrangements and to arrange for the Importer Security Filing (see pages 2-3 for more details) when shippers use their preferred ocean freight carrier.

Procedures:

Shipper must complete and provide shipping documents (see below for required documentation) to Amgen Global Trade Operations (GTO) at import-exportcompliance@amgen.com at least 2 business days prior to shipping.

GTO will validate documents, direct brokers on specific clearance instructions and communicate with Shipper if additional / clarification of information is required. Once approval to ship has been provided by GTO, shipment may proceed.

Documentation:

Shipping documentation must include as appropriate:

- Airway Bill
- Customs Invoice, including HTSUS and other detailed information (see below)
- TSCA Certification (see below for guidance on chemical shipments)
- USDA Statement (see below for guidance on chemically synthesized materials, animal/plant derived material shipments or shipments of animals/plants)
- Other Documentation as required per commodity (see below)



Customs Invoice: Per the U.S. Code of Federal Regulations, [19 CFR 141.86](#), the invoice MUST contain the following information supplied by the Shipper:

1. Shipper and Importer/Consignee name and address (Shipper must provide complete contact information for **AT LEAST** two individuals, including names, phone numbers and email addresses).
2. **Detailed** commodity description, quantity/weights, cost/value, proposed Harmonized Tariff Schedule number, and CAS number (if available) of **each** item. Chemical compounds that are proprietary in nature shall have sufficient description and chemical structure made available to enable proper tariff classification.

The complete HTSUS, as published by the United States International Trade Commission, can be found [here](#) .

3. Total cost/value of shipment with currency of sale indicated

Please note: Per the U.S. Code of Federal Regulations, [19 CFR 152 Subpart E](#) , U.S. Customs requires an accurate **value** be placed on imported goods for duties to be assessed. The transaction value serves as the primary basis of appraisal. Transaction value is the price actually paid or payable by the buyer to the seller for the goods imported. Other factors may also add to the dutiable value of merchandise, such as packing costs, selling commissions, royalty or licensing fees, etc. If the transactional value cannot be determined or the goods are being sent free of charge, then an accurate and defensible value must be assigned to the goods by the seller. This can be supplied on a separate invoice for Customs purposes only, or as a separate statement on the original invoice. The value of the goods can never reflect a \$0 dollar amount or an intentionally reduced amount.

4. Break down of itemized charges if included in the invoice value:

Freight (if prepaid by shipper)	Rebates, discounts, commissions
Insurance (if arranged by shipper)	Assists (tools or materials supplied by Amgen at no charge)
Packing (if not included in the price of goods)	

NOTE: Unless DDP term is used, and the shipper acts as a non-resident importer of record in the United States, Amgen is responsible for clearance and the associated charges; these charges should not be included in the cost of the merchandise.

5. Country of origin of the merchandise (not the origin of shipment) as defined in [19 CFR 134.1](#)
6. Shipping conditions (includes HazMat information and temperature requirements)
7. Terms of sale / delivery terms– Incoterms
8. Purchase Order, Agreement or Contract number **MUST** be provided.

Shipments accompanied by incomplete documentation or documentation that contains inaccurate information, may be rejected by Amgen and, at Amgen’s option, returned at the shipper’s sole expense.

Importer Security Filing: The Security Filing is a U.S. Customs and Border Protection (CBP) regulation that requires importers to provide additional trade data to CBP for shipments arriving into the United States Customs territory (including Puerto Rico) by vessel **no later than 24 hours** prior to loading. Unitrans International, as Amgen’s authorized freight forwarder, collects necessary data via their agents overseas. Shippers must provide Unitrans or its agents with the requested information in the timeframe and manner specified by Unitrans. When a freight forwarder other than Unitrans is utilized, the required information must be furnished to **Unitrans** (amgenimport@unitrans-us.com) **and Amgen GTO at least 48 hours prior to loading**. It is critical that requested data is supplied in a timely manner, because CBP may issue “Do Not Load” messages to carriers, and border holds and penalties to the importers for non-compliance. Penalties incurred by Amgen caused by Seller/Shipper’s non-compliance with this program will be passed back to the Seller unless the U.S.-based Seller acts as the Importer of Record and assumes the associated responsibilities and risks.



The following information must be supplied to Unitrans or promptly upon request and in no event less than 24 hours prior to loading, except in the case of shipments for which a freight forwarder other than Unitrans is utilized, in which case the following information must be supplied to Unitrans and Amgen GTO at least 48 hours prior to loading, regardless of whether specifically requested: the names and addresses of the seller, buyer, ship to party, manufacturer/supplier, importer of record; container stuffing location; country of origin; 6-digit HTS commodity code(s); consolidator (stuffer); and AMS Bill of Lading number. For more information please visit [Security Filing "10+2"](#)

Chemical Shipments: All Chemical shipments require a **signed** certification for the Environmental Protection Agency (EPA: [Importing Chemical Substances](#)) stating they comply with the regulations of the Toxic Substance Control Act (TSCA) or they are exempt from the TSCA requirements. **Shipments will not be released without this certification.** The shipper can make this certification on the Customs Invoice or provide a separate statement.

Chemically Synthesized Materials, Animal/Plant Derived Material Shipments or Shipments of Animals/Plants: Commodities of these types may require either a USDA import permit or USDA statement, depending on the commodity. Please review the [USDA Guidelines for Importation](#)

Please contact GTO in advance to determine if a permit is required (most permits take a minimum of 8 to 12 weeks to receive). If the commodity does not require a permit, a signed USDA statement, on letterhead, in accordance with the USDA Guidelines for Importation (above) must be provided for clearance through U.S. Customs. **Shipments will not be released without this certification.**

Other Documentation / Labeling

Chemicals/controlled substances/pharmaceuticals: Shipments may be subject to Drug Enforcement Administration (DEA) regulations and may require an import permit for clearance into the United States. Shippers must review commodities and apply for any necessary permits. Please utilize the following link [DEA Import Export of Controlled Substances](#) or contact Amgen GTO with questions.

Please note that any human use materials listed in the [FDA Import Alerts](#) will be detained without examination and subject to exportation or destruction. It is advisable to review the alerts prior to shipping the material.

Pharmaceutical Product Labeling: Shipments of pharmaceutical products must be specifically marked with an additional label/text statement per instructions below. This label may be placed on the drug product and/or on the drug product's outer packaging, where it is visible to inspectors at the port. This statement must also be documented on the shipping documentation. A photo of this label/text statement as it appears on the actual shipment is required as confirmation.

- Drugs for use in research not involving clinical use, or in chemical analysis, or physical testing must be labeled with the following or similar statement:
"Drug for use in non-clinical research, analysis or testing. Not for use in humans".
- Drug for nonclinical use that involves laboratory animals or for tests in vitro must be labeled with the following statement:
"Caution: Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans"
- Drugs/drug substance in bulk form intended for processing, repacking or use in the manufacture of another drug intended for human use must be labeled with one of the following statements:
Drugs subject to a marketing application: *"Caution: For manufacturing, processing, or repacking. Rx only"*
Drugs intended for investigational use: *"Caution: For manufacturing, processing, or repacking in the preparation of a new drug limited by United States law to investigational use"*

Biological specimens for lab testing or research: To avoid delays, FDA recommends that the labeling of each specimen container include the following information:

- An accurate description of the biological specimens. For example: human blood specimen, human tissue specimen, human DNA specimen.
- A statement regarding the intended use of the specimen. For example: "Human Blood For Testing in a Clinical Laboratory," or "Human DNA Specimen for Basic Scientific Research."



- If the biological specimen has been tested for infectious agents such as the hepatitis B surface antigen (HBsAg) and/or the antibody to human immunodeficiency virus (anti-HIV), a statement relative to the test results should be included.

Perishable Shipments: Perishable shipments should be shipped on Mondays or Tuesdays only. This will reduce the risk of being held over the weekend in the event of a clearance delay. Shipments packed with dry ice must use the appropriate air waybill per carrier requirements, and the package labeled accordingly. Failure to do so is a direct IATA (International Air Transport Association) violation.

Pathogens: Materials of non-human primate origin or materials which are known or suspected to contain a human pathogen, etiological agent, host or vector of human disease may require a Centers for Disease Control (CDC) permit to import. Contact GTO for more information. Infectious materials must be packaged to withstand breakage and leakage of contents, and labeled in accordance with the Dangerous Goods (Hazardous Materials) regulations. Please review [CDC Guidelines](#) for more information on import/shipping requirements for infectious materials.

For all other commodities which do not contain or are not suspected to contain a human pathogen, etiological agent, host or vector of human disease, and thus do not require a permit, the CDC (<http://www.cdc.gov>) requests the Shipper to include a signed statement on a company letterhead with the following information:

- 1) A description of the material;
- 2) A statement that this material meets one of the above criteria (e.g. this material is not known or suspected to contain a human pathogen, etiological agent, host or vector of human disease); and,
- 3) Verification that it has been packaged, labeled and transported in accordance with all applicable regulations.

Wildlife: Any live animal or animal product is subject to the U.S. Fish and Wildlife Service (FWS) permit, declaration and clearance. The information required for clearance includes the scientific and common name for each species and country of species origin. Refer to [FWS Form 3177](#) for more details. Endangered species and materials derived from them also require a CITES permit issued by the country of exportation.

Chinese Hamster Ovary (CHO) Cell Specimens: FWS considers CHO cells wildlife (see [The FWS notice](#) for details). Any applicable material which still contains CHO material, must be imported under a permit. If the material is derived from or has contained CHO material, but has been purified and/or filtered so the CHO is no longer present, the shipment documentation must include a signed statement on Shipper letterhead to that effect. The following is an example of that Statement.

This shipment contains _____ which are derived from Chinese hamster ovary cells.

These specimens have undergone _____ (describe process here)_____.

During this process, all restricted material such as antibodies or recombinant proteins, was extracted from CHO cells, cell cultures or cell lines and was purified to remove all cell material, DNA or animal material.

The materials described above are then not considered wildlife and FWS clearance is not required.

Medical Devices: Syringes, auto-injectors and the like Class II medical devices may require the manufacturer to provide the device listing number (Premarket submission number / 510(k) number), FDA product code, and device manufacturer and shipper establishment registration number(s) in order to facilitate FDA clearance. Shipments from Shippers who have not completed this electronic registration will be refused entry into the U.S. Current establishment registrations and device listings are available in the [FDA Establishment Registration & Device Listing Database](#) .

- Medical devices intended for research not involving clinical use, or in chemical analysis, or physical testing must be labeled with the following statement: *“For use in research, chemical analysis or physical testing. Not for use in humans”*.
- Medical devices intended for nonclinical research involving laboratory animals or in vitro tests must be labeled with the following statement: *“Caution: Device for investigational use in laboratory animals or other tests that do not involve human subjects”*.



- Medical devices for processing, repacking, or use in manufacture of another drug or device intended for human use must be labeled with the following statement: *“Caution: For manufacturing, processing, or repacking”*.

Products emitting radiation: Shipments of radiation-emitting products (X-ray equipment, electronic microscopes, ultraviolet or laser analyzers, ultrasonic equipment, etc.) will require submission of [FDA Form 2877](#). Some of these products may also be considered medical devices. For more information on medical devices and radiological please refer to the FDA regulations [21 CFR Subchapter H & J](#).

Communications/radio frequency devices: Shipments of communications/radio frequency devices capable of causing harmful interference (phones, computers, receivers, transmitters, etc...) will no longer require submission of [FCC Form 740](#). Please refer to the Federal Communications Commission Regulations on [Radio Frequency Devices](#) for further information.

Personal Gift/Food Shipments: Any miscellaneous commodities and/or food products and food contact materials (e.g. mugs) sent as personal shipments or sent as a gift are strictly prohibited. That may include certain personal office items for transferred employees. Shipments of this nature will be refused and returned to the Shipper.

Articles of Wood: Import of plant and plant products (including wooden frames, tableware of wood, wood statuettes and the like, wood furniture, tools and other articles of wood) manufactured after May 22, 2008 require reporting of the plant scientific name and the country of harvest. More information is available at the [Lacey Act Declaration](#) web-page.

Wood Packaging Materials (WPM) in cargo shipments must comply with International Standards for Phytosanitary Measures (ISPM 15) and must be appropriately treated and marked in the country of export. The approved treatments for wood packaging material are 1) heat treatment to a minimum wood core temperature of 56°C for a minimum of 30 minutes or 2) fumigation with methyl bromide. To certify treatment, the WPM must be marked with the following International Plant Protection Convention (IPPC) logo. Paper certificates are not accepted.



XX represents the ISO country code.
000 represents the unique number assigned by the national plant protection organization.
YY represents either HT for heat treatment or MB for methyl bromide fumigation.

Additional details can be found on the [USDA WPM](#) web-page.

Origin Marking

Every article of non-US origin, unless specifically exempt by law, is required to bear a country of origin marking per the U.S. Code of Federal Regulations [19 CFR 134.11](#).

IMPORTANT:

Amgen reserves the right to refuse and return at shipper's sole expense any shipment for which complete and accurate information, as required by any government agency for import and clearance purposes, has not been provided within the stated time frame. Deviations from this procedure may be reported to Amgen's Global Strategic Sourcing and Law Departments and others as deemed necessary.



Customs Trade Partnership Against Terrorism (CTPAT)

Amgen is a participant in U.S. Customs and Border Protection (CBP) initiative, Customs Trade Partnership Against Terrorism (CTPAT). CTPAT is a voluntary government-business initiative to build cooperative relationships that strengthen and improve overall international supply chain and U.S. border security. For further information regarding CTPAT and its requirements, please visit [C-TPAT Program Information](#)

In support of Amgen's commitment to CTPAT, suppliers are encouraged to incorporate and implement the [CTPAT Minimum Security Criteria and Guideline](#) outlined by CBP

Ocean Shipments: In conjunction with Amgen's participation in C-TPAT (Customs Trade Partnership Against Terrorism), any Shipper sending cargo via ocean must comply with all CBP mandated security requirements as follows:

- 1) Procedures to properly seal and maintain the integrity of the shipping containers at the point of loading.
- 2) A high security seal, which meets or exceeds the current PAS ISO 17712 standards for seals, must be affixed to every loaded container bound for the United States.
- 3) Prior to loading, the physical integrity of the container must be verified. This verification must include the reliability of all locks, and should also include the following seven-point inspection: front wall, left side, right side, ceiling/roof, inside/outside doors, interior floors, and outside/undercarriage.
- 4) Procedures instructing how seals are to be controlled and affixed to loaded containers, including procedures for recognizing and reporting compromised seals to US Customs or the appropriate foreign authority. Distribution of container seals should be limited to designated employees.
- 5) Containers must be stored in a secure area, with procedures in place to report and neutralize unauthorized entry into the storage areas or the containers themselves.

Shippers must be able to provide confirmation of procedural compliance upon request. Shipments not adhering to these requirements may be refused by Amgen and returned at the Shipper's sole expense.

Part II: 3rd Party Exports from the U.S.

All export and re-exports processed on behalf of Amgen and/or its subsidiaries must be in compliance with the U.S. Export Controls and Foreign Trade Regulations found in [15 CFR Subtitle B](#) - Chapters I and VII. This compliance obligation applies to shipments initiated by Amgen and shipped from non-Amgen U.S. sites (e.g. 'drop-shipments' to foreign destinations) and shipments from Amgen sites routed by foreign consignees ('routed exports').

Commercial or Customs invoices are required for all exports including shipments between the United States and Puerto Rico. Some commodities may require additional export clearance and/or import licenses/permits prior to export.

Global Trade Operations (GTO) reviews export documents and is available to assist with U.S. export requirements determination, assignment of Schedule B/HTS, ECCN numbers, export license applicability, country of origin certificates for Amgen products, import requirements, Incoterms responsibilities, import duty/tax rates and payment options.

Drop-shipments

When Amgen purchases goods from a U.S.-based Seller and instructs the Seller to drop-ship to a location outside of the U.S. or otherwise initiates an export that originates from a 3rd party, Amgen uses a preferred carrier and pays international freight charges (C or D-group incoterms). As the entity receiving the primary benefit from that export, Amgen is the United States Principal Party in Interest and the party responsible for export reporting, screening and fulfillment of the export license requirements.



The 3rd Party Seller/Shipper must complete and provide shipping invoice/packing list to Amgen GTO at import-exportcompliance@amgen.com at least 5 business days prior to an estimated shipping date.

Seller is responsible to provide Amgen GTO proposed ECCN and Schedule B/HTSUS numbers. GTO will validate documents, perform export screening, determine additional requirements, and provide approval to ship.

Routed Exports

Foreign consignee uses their preferred carrier and pays freight charges (EXW and F-group incoterms). When a foreign consignee appoints a freight forwarder as their U.S. agent to “route” or facilitate an export from the United States, Amgen requires a copy of the power of attorney or other written authorization issued by the foreign consignee (who is the Foreign Principal Party in Interest) to their U.S. agent and a Letter signed by the foreign consignee assuming the export responsibilities (see below template). Email copies of the both documents to GTO at import-exportcompliance@amgen.com along with the freight forwarder’s contact information. GTO will provide the data elements required for filing of the Electronic Export Information and the U.S. Export License determination. Please be prepared to provide a copy of the filing along with the carrier transportation bill (airway, truck or ocean bill of lading) or instruct your U.S. agent / freight forwarder to do so.

[Electronic Export Information](#)
[Export License Obligations in Routed Export Transactions](#)

[To be typed on the letterhead of Foreign Principal Party in Interest]

U.S. Census Bureau Foreign Trade Regulations 15 C.F.R. Part 30.3
U.S. Export Administration Regulations 15 C.F.R. Part 758.3

Amgen Inc.
Global Trade Operations
One Amgen Center Drive
Thousand Oaks, CA 91320

Re: Assumption of Export Responsibilities

We **[company name]**, acknowledge that we are the Foreign Principal Party in Interest (FPPI) in a routed export transaction in which we have authorized **[U.S. agent name]** as our U.S. agent and the exporter for the Export Administration Regulations (EAR) purposes.

We hereby expressly assume responsibility for determining export licensing requirements and obtaining any required export licenses, if applicable, export reporting and any other export compliance requirements in connection with routed export transactions in which Amgen Inc. or any of its U.S. subsidiaries is the United States Principal Party in Interest (USPPI).

Signature

Printed Name and Title

Date