

# GENENTECH USA, Inc. RETURN GOODS POLICY

Effective Date: March 1, 2025



**Welcome to Genentech's Return Goods Policy. Our policy is rooted in patient safety. Genentech strives to ensure our products arrive safely, work as indicated, are administered correctly, and are used before their expiration date. Genentech USA, Inc. (e.g. "Genentech") has multiple product return programs for our customers and patients:**

This document is focused on expired returns. If your product is damaged, you have a quality issue, or your product is spoiled, please go [here](#) or read below to learn more.

## DAMAGE AND TEMPERATURE EXCURSION



Product purchased directly from Genentech that is damaged in transit from Genentech or for which a temperature tag has been triggered, signaling a compromise in temperature during shipment, shall be immediately reported to Genentech Customer Service by calling at 1-800-551-2231 Monday-Friday 6 am - 5 pm PST.

## PRODUCT QUALITY COMPLAINTS



Genentech will issue replacements for defective products and instances in which there is a product quality issue. Please contact Genentech's Quality Department at (800) 334-0290 for more information.

## SPOILAGE



For spoiled products, please visit [genentechdirect.com/returns](https://genentechdirect.com/returns) to fill out an online request form for product replacement.

## DSCSA REQUEST RETURNS



Any inquiries and returns requests related to the Drug Supply Chain Securities Act are out of scope for this policy.

Please contact [genentechdqa-d@gene.com](mailto:genentechdqa-d@gene.com) to inquire about DSCSA inquiries and returns.

## EXPIRED RETURNS



Expiration date is the last day of the month listed on the product's outer packaging.

Our Return Goods Policy complies with all laws and regulations, including the federal Anti-Kickback Statute. No incentives, such as rebates or discounts, will be offered for returned products. Returns must go through authorized channels with proper documentation. No Genentech employee can promise or provide compensation for returns. The expired return eligibility requirements set forth below are applicable to all products distributed by Genentech except as noted otherwise.

## EXPIRED PRODUCTS ELIGIBLE FOR RETURN CREDIT



- Product within (2) months of expiration or up to (6) months past the product's expiration date. The first qualifying day of expiration is the last day of the month listed on the product's outer packaging.
- Unless noted herein, and except for ampules and stickpacks, expired product is eligible for credit if it is in its original unopened packaging and bearing its original label.
- Where required by state law, product outside of its original packaging either as a partial pack or partial container, is eligible for credit; For clarification, individual vials separated from their original pack are returnable only where they remain sealed, unopened, and unused.
- FDA approved product purchased through Genentech's Commercial Clinical Trial Program for research or clinical trials within the USA.
- Partial containers or packs of ampules and/or stickpacks of Genentech products.
- Lucentis (Ranibizumab) Pre-filled Syringe (PFS):
  - Product can be returned without the original carton.
  - If product is returned without the original carton, it must be returned in a sealed Tyvek tray bearing the NDC # 50242008203 for Lucentis 0.3 PFS and 50242008003 for Lucentis 0.5 PFS, Lot#, and Expiration date.
- Components of SUSVIMO (ranibizumab injection) supplied for the Initial Fill and Implant Insertion procedure SUSVIMO Initial fill needle kit (NDC 50242-078-55) and Ocular Implant & Insertion Tool Assembly and the SUSVIMO Refill-Exchange Kit (NDC 50242-078-12) containing a single-dose vial designed to deliver 0.1 mL of 10 mg/ 0.1 mL ranibizumab solution and the SUSVIMO refill-exchange needle are eligible for early return for the following circumstances:

SUSVIMO that qualify for early returns include:

- SUSVIMO Initial fill needle kit (NDC 50242-078-55), which contains one SUSVIMO 100 mg/mL single-dose glass vial and one SUSVIMO initial fill needle (34-gauge needle with a 5 µm integrated filter) with a blue cap, and the Ocular Implant & Insertion Tool Assembly for use with SUSVIMO 100 mg/mL, which contains one carrier with implant and one insertion tool
- SUSVIMO Refill-Exchange Kit (NDC 50242-078-12) which contains one SUSVIMO 100 mg/mL carton containing a single-dose vial designed to deliver 0.1 mL of 10 mg/ 0.1 mL ranibizumab solution and one SUSVIMO refill-exchange needle (34-gauge needle with a 5 µm integrated filter)

In order to be eligible, the product must have been purchased by a healthcare provider as a backup for an individual procedure that is no longer needed for that patient and/or there are no other patients that can use the product.

The SUSVIMO Initial fill needle kit (NDC 50242-078-55) and the SUSVIMO Refill-Exchange kit (NDC 50242-078-12) may be returned early for credit through Genentech Direct Returns at [genentechdirect.com/returns](https://genentechdirect.com/returns).

- Components of expired SUSVIMO (ranibizumab injection) supplied for the Initial Fill and Implant Insertion procedure and the Refill-exchange procedure can be returned separately for credit:

For the SUSVIMO Initial fill kit (NDC 50242-078-55), which contains one SUSVIMO 100 mg/mL single-dose glass vial and one SUSVIMO initial fill needle (34-gauge needle with a 5 µm integrated filter) with a blue cap, and the Ocular Implant & Insertion Tool Assembly for use with SUSVIMO 100 mg/mL, which contains one carrier with implant and one insertion tool, can be returned separately according to the expiration date printed on their respective cartons.

For the SUSVIMO carton (NDC 50242-078-12) containing a single-dose vial designed to deliver 0.1 mL of 10 mg/ 0.1 mL ranibizumab solution, can be returned by itself for credit within the window in Product Eligible for Return

The SUSVIMO Refill Needle containing one SUSVIMO refill needle (34-gauge vented needle with a 5 µm integrated filter) with a clear cap, cannot be returned for credit.

- Product which Genentech has specified can be returned

## PRODUCTS NOT ELIGIBLE FOR RETURN CREDIT



- Product received by Genentech's designated returns vendor greater than two (2) months prior to or greater than six (6) months after the product's expiration date.
- Product where the lot number and/or expiration date is missing, illegible, or covered on the original unopened packaging, and/or with a prescription label attached, unless an exception is noted.
- Product, other than ampules or stickpacks as described in the Eligible for Return section of this Return Policy, not in their original unopened packaging and/or not bearing its original label unless required by law, in which case partial packs or containers are returnable. In no case will open vials be returnable under this policy.
- Product that has been damaged due to improper storage or handling, fire, flood, or catastrophe.
- Product that has been sold expressly on a non-returnable basis or is provided as free goods, samples, or labeled NFS (Not for Sale).
- Product sold in bulk package sizes (over 500 units per bottle).
- Partial blister packs
- Partial or open packs of vials unless required by State Law.
- Product purchased outside of the United States.
- Open or partially used vials
- Product billed for to any payer is not returnable.
- Product that Genentech determines, in its sole discretion, is otherwise adulterated, misbranded, counterfeit and/or obtained illegally or via diverted means.

- Unless otherwise specified by Genentech, Tamiflu and Xofluza product purchased for stockpiling in preparation of a flu pandemic, regardless of whether Tamiflu or Xofluza are purchased directly or from an authorized distributor. This provision applies to all sectors including federal, state, and local governments, public, private, not for profit companies and all other classes of trade.

## RETURN GOODS AGENT



Qualanex is the approved return goods vendor for Genentech. Customers returning eligible return goods product do not incur any processing fees or service charges and Genentech will be responsible for the associated costs for return goods processing and product destruction.

Qualanex will accept Genentech return good shipments from other third party return goods processors according to Genentech's return policy. Genentech will not be responsible for the associated cost to ship return goods from any customer or third party to Qualanex. Qualanex may refuse any return goods shipments sent COD (collect on delivery).

**To receive return credit, all eligible returns should be shipped pre-paid to Qualanex using a Genentech Return Authorization.**

Genentech Return Authorizations can be obtained through Genentech Direct Returns. To get a Genentech Return Authorization, visit [genentechdirect.com/returns](http://genentechdirect.com/returns).

## PROCESSING A RETURN - RETURN AUTHORIZATIONS



- To return a product, all return packages must include a Return Authorization from Genentech.
- Return Authorizations can be obtained by filling out the Expired Returns form on [Genentech Direct Returns](http://Genentech Direct Returns).
- If your facility is contracted with a Third Party Returns Vendor, Return Authorizations may also be obtained through Qualanex. Packages received without a Return Authorization will not be accepted. Please remember to closely follow the instructions on the Return Authorization and print two copies.
  - Place one copy of the Return Authorization in the box with the return and attach the other copy on the outside of the box separate from the shipping label.
- For return instructions please see below and/or visit Genentech Customer Service Online at ([www.gene.com/customerservice](http://www.gene.com/customerservice)) or call 1-800-551-2231.

Qualanex requires a printed Return Authorization for any product being returned to their facility. The return address will be on the Return Authorization. Requests for Return Authorizations can be made by accessing Genentech Direct Returns at [genentechdirect.com/returns](http://genentechdirect.com/returns). You will need to upload a Debit Memo document, which is a list of products you are returning, including the NDC, Quantity, and Expiration Date. Instructions on how to create a Return Authorization can be found on [the Genentech Direct Returns support webpage](http://the Genentech Direct Returns support webpage).

Genentech will only accept returns shipped to Qualanex, unless directed otherwise by Genentech. All eligible products shipped to Qualanex shall be shipped in a safe, secure, and reliable manner and in compliance with all applicable federal, state, and local laws, regulations, and statutes. It is the shipper's responsibility to securely package all return goods to prevent breakage during transit and otherwise comply with laws and regulations applicable to the packaging, shipping, and transport of return goods shipments. Genentech is not responsible for shipments lost and/or damaged in transit. Genentech recommends that all customers insure return goods shipments.

Please do **NOT** ship products in Biohazard bags, IV bags, or syringes, as they cannot be processed upon receipt at our return processing sites and vendor sites.

All of our approved return vendors will audit the quantities of return goods and final return credit will be based on our approved return vendors count. Return credit for bottles of tablets will be based on individual tablet count. Return credit will be issued for only the specified amount of the original packaged quantity. For example, if thirty-five (35) tablets are returned in a thirty (30)-count bottle, return credit will only be issued for a maximum of thirty (30) tablets. The quantity of tablets exceeding thirty (30) will be destroyed and no return credit will be issued for such quantity. All products will be issued return credit in an amount at or close to the original purchase price, using the lot number or serial number on the packaging.

Direct-purchasing customers' reimbursement will be issued in the form of a credit. Indirect-purchasing customers shall return product following the Genentech Return Goods Process and credit will be issued through their wholesaler. All credit assignments will be determined by the information provided on the Return Authorization request.

Product shipped for return that are deemed to be outside of this policy will not be returned to the customer or the third-party processor and no return credit will be issued by Genentech for said product unless state or local law requires otherwise.

**Genentech USA Inc. Return Goods Policy is subject to change at any time and without prior notice to other parties.**