

Sanofi U.S. Returned Goods Policy and Trade Terms: Lemtrada® (Alemtuzumab)

MS One to One Customer Support phone: 1-855-676-6326 / Fax: 855-557-2478
Order Processing & Return Inquiries email: Lemtradabuyandbillaccount@lashgroup.com
Credit & Claim Inquiries email: customercare.US@sanofi.com
Sanofi U.S. Trade Customer Support website: <https://www.sanofi.us/en/contact-us>

Sanofi U.S. Returned Goods Policy and Trade Terms: Lemtrada (“Terms”) govern the sale of Lemtrada (“Product” or “Products”) directly from Genzyme Corporation, a Sanofi Company (“Sanofi.”). These Terms take precedence over Customer’s additional or different terms, to which Sanofi hereby gives notice of objection. Sanofi’s acceptance of Customer’s order, commencement of performance, or delivery of Products will not constitute acceptance of Customer’s additional or different terms.

Part A: Returned Goods Policy

The FDA mandated Risk Evaluation and Mitigation Strategy (REMS) requires that all unused vials of Product in their original container and bearing their original label must be returned to Sanofi within 75 business days (no longer 50 days) from the original date of submission of the valid patient authorization and baseline lab form (as required by the Lemtrada REMS Program). Both Product eligible for Return and Credit and Product Not Eligible for Credit (as set forth in these trade terms) must be returned within 75 business days from the original date of submission of the valid patient authorization and baseline lab form.

PRODUCT DAMAGE AND SHORTAGE CLAIMS/OVERAGE CLAIMS

- If damage, shortage, or overage is visible at the time of unloading and receipt of Product, Customer must: (1) accept and physically receive all Product, (2) sign and notate Bill of Lading with description of visible damage, shortage, or overage, (3) take photos of any visible damage, (4) email the invoice number or order number in question and any applicable photos to customercare.US@sanofi.com. Photos of the damage must be submitted with the claim for credit.
- Visible damage must be reported within 10 business days of receipt and acceptance of Product.
- Concealed damage, overage, and shortage claims must be reported within 30 business days of receipt and acceptance of Product.
- Customer agrees to report and return to Sanofi any Product overage.
- Sanofi reserves the right to deny the credit if the claim is not reported directly to Customer Care team at customercare.US@sanofi.com.
- Where loss, shortage, breakage, leakage, or other damage has occurred in transit, Customer agrees to cooperate fully with Sanofi to establish a claim against the transportation company.
- Requests for credit submitted without appropriate documentation may be denied.
- As the Product is the property of Customer, Customer is responsible for paying Sanofi in accordance with the invoice regardless of when any eligible credit may be issued.
- Credits for damage and shortage claims will be issued at the original invoice price. Prompt pay discount or any other discounts, if applicable, will be deducted from the credit amount.

PROCESS FOR UNUSED VIAL RETURNS

- In the event that unused vials of Product must be returned, the Direct Customer must contact MS One to One at 1-855-676-6326.
- Direct Customer must submit all return requests through MS One to One and comply with all requirements for Product returns to be eligible for Return and Credit or destruction according to this Return Policy.

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PROCEDURE FOR EXPIRED PRODUCT RETURNS (FOR DISPENSING PHARMACIES ONLY)

- All expired returns must be sent to Sanofi's Third-Party Processor: Inmar, Inc., Before sending the returns, please request a Return Authorization on the website: <https://hrm.reskureturns.com/>
- All returns must be listed on a debit memo that complies with the following requirements:
- The debit memo must not include returned expired Product from multiple facilities on one debit memo. The debit memo must only include returns of expired Product from an individual facility.
- Sanofi requires the following detail from each returning entity that purchased Product and is returning the Product pursuant to the Sanofi Returned Goods Policy herein:
 - Customer through which to issue credit, if applicable; Debit Memo Number; Debit Memo Date.
 - In addition, for a returning facility (including for Customers not purchasing directly from Sanofi), the following details must be provided:
 - Name, DEA (on which the Product was purchased) or other pharmacy identifier, Address, City, State, Zip; Product; and
 - Details, including Product Description, NDC, and Expiration Date of the Product returned, Lot Number, Quantity.
- Product returns from 340B covered entities and federal government purchasers must be specified on the debit memo, including specific identifications such as 340B ID.
- For Customers returning through other third-party processors: Sanofi will not issue credit if the third-party processor does not provide the required information noted above to Inmar, Inc.
- In addition, Sanofi will not reimburse Customer for any transportation charges, processing fees or handling fees incurred by Customer when returning Product through other third-party returned goods processors.

RETURNED PRODUCTS ELIGIBLE FOR CREDIT

- Dispensed but unused vials of Product provided that Customer has completed Exhibit A, Lemtrada® Letter of Attestation.
- Indated Product if returned to, and received by, Sanofi's Third-Party Processor (Inmar) within 6 months prior to the expiration date (for Dispensing Pharmacies Only).
- Outdated Product if returned to, and received by, Sanofi's Third-Party Processor (Inmar) up to 6 months past the expiration date (for Dispensing Pharmacies Only).
- Full and unopened Product in the original packaging sold by Sanofi if returned to, and received by, Sanofi's Third-Party Processor (Inmar) within 6 months prior to the expiration date or 6 months past the expiration date (for Dispensing Pharmacies Only).
- Credit will be issued for any Product being returned by a Customer in any state or U.S. territory that requires credit. In-order-to receive credit under the corresponding state law, Customers must clearly segregate such returns on separate debit memos.
- Sanofi may accept other returns at its sole discretion with prior approval.
- Returns from 340B Customers must be included in separate debit memo.

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RETURNED PRODUCTS NOT ELIGIBLE FOR CREDIT

- Product received by Sanofi's Third-Party Processor (Inmar) more than 6 months prior to its expiration date (for Dispensing Pharmacies Only).
- Product received by Sanofi's Third-Party Processor (Inmar) more than 6 months past its expiration date (for Dispensing Pharmacies Only).
- Opened, partial, tampered, or broken seal packages or Product, unless mandated by state law.
- Product on batched or consolidated debit memos that include Product from multiple facilities on one debit memo.
- Product returned without adequate information regarding the returning entity (see Procedure section above).
- Product with original labels removed.
- Product not in original packaging.
- Repackaged Product.
- Product received in quantities exceeding original package size.
- Product purchased from a source other than a Customer of Sanofi unless agreed to in writing by Sanofi.
- Product purchased from sources outside of the United States.
- Product involved in a bankruptcy sale or natural disaster.
- Product deteriorated or damaged due to conditions beyond the control of Sanofi such as improper storage, heat, cold, water, smoke, etc.
- Product Sanofi has previously designated as "non-returnable".
- Product otherwise adulterated, misbranded, or counterfeit, as determined by Sanofi, at its sole discretion.
- Per the REMS, Product not eligible for credit must be returned for destruction as directed by Sanofi even though credit will not be provided.

CREDIT FOR ELIGIBLE PRODUCT RETURNS

- For returns from Sanofi Customers, credit will be issued in the form of a credit memo.
- For returns from Indirect Customers, credit will be issued through the Sanofi U.S. Customer that services the account.
- The below crediting policy applies as follows:
 - **Anyone returning unused vials within 75 business days:** Credit will be issued at invoice price
 - **For Expired Returns (Dispensing Pharmacies Only)**
 - **Anyone without a Sanofi U.S. contract price:** Credit will be issued at current WAC-9%\$.
 - **Anyone with a Sanofi U.S. contract price:** The average contracted price as determined by Sanofi during the time frame in which the Lot was sold by Sanofi.
 - **Anyone with a Sanofi U.S. 340B contract price:** The average 340B price as determined by Sanofi during the time frame in which the Lot was sold by Sanofi.
 - Prompt pay discount, if eligible, will be deducted from expired returns credit.

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These Terms govern the sale of Product to Customer. These Terms take precedence over Customer's additional or different terms, to which Sanofi hereby gives notice of objections. Sanofi's acceptance of Customer's order, commencement of performance, or delivery of Products will not constitute acceptance of Customer's additional or different terms.

Part B: Terms and Sales Conditions for Customers

PRICES AND ORDERS

- All orders are subject to acceptance by Sanofi and to the limitations and requirements of the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS).
- Orders will be invoiced at the price in effect on the date and time the order is accepted.
- Customer agrees that any orders made under prices other than those in effect on the date and time of Sanofi acceptance will be changed by Sanofi, without notice.
- All prices are subject to change without notice.
- It is Customer's sole responsibility to update all pricing schedules and Customer contracts administered by Customer, consistent with any price change made by Sanofi. Pricing must be included on order.
- All orders must meet the established minimum/multiple order quantities.
- Sanofi, at its sole discretion, reserves the right to reject orders, to limit or allocate order quantities, to defer orders or line items, to backorder orders or line items, or to cancel orders or line items.

TERMS OF SALE

- Payment terms are stated on Sanofi invoices.
- Late payment may result in a change of credit terms at Sanofi's sole discretion.
- The amount due must be paid pursuant to the terms herein and on the invoice, regardless of, if, or when Customer receives insurance reimbursement.
- Customer shall not deduct unauthorized amounts from payment due.

SHIPMENTS

- All orders shall be shipped prepaid, with title and risk of loss for the Product passing to Customer upon delivery of the Product to the Customer's facility by Sanofi's carrier.
- Sanofi will pay standard transportation charges and insurance on all orders. However, if Customer requests special transportation, carrier sorting, or routing, Sanofi may require Customer to bear the costs of such special handling.

BACKORDERS

- In the event Sanofi experiences a backorder on Product which is expected to persist for longer than 30 calendar days, Sanofi will reject all orders upon receipt and will require Customer to reorder Product when it becomes available. In the event a backorder has been in effect for 30 calendar days, Sanofi will cancel all orders it has outstanding and require the Customer to reorder the Product when supply becomes available.

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CUSTOMER DISPUTES (APPLIES TO DIRECT AND INDIRECT CUSTOMERS)

- Any disputes involving issues related to pricing, discounts, credits, returns, or accounts receivable must be reported to Sanofi and documented in writing within 90 calendar days from the date of issuance by Sanofi of the disputed invoice or credit. If the reported dispute is not resolved after one year, no credits or adjustments will be issued.

STORAGE AND HANDLING OF SANOFI PRODUCT (APPLIES TO DIRECT AND INDIRECT CUSTOMERS)

- Customers and Indirect Customers taking possession of Sanofi Product are fully responsible for complying with all applicable federal, state, and local laws and regulations related to storage, handling, and distribution of such Product. Customers and Indirect Customers are also fully responsible for complying with Sanofi's Product labeling and instructions as well as all storage, handling, and distribution requirements of Product. Customers and Indirect Customers shall provide Product only to healthcare professionals duly licensed and authorized prescribe, dispense, or administer Product.

WARRANTY

- Sanofi's warranty is limited to the identity and the quality of ingredients used in the Product at the time it is manufactured, and in the care and skill exercised in its manufacture. **SANOFI DOES NOT MAKE ANY WARRANTIES, EXPRESS OR IMPLIED, OF ANY KIND, INCLUDING WARRANTIES AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT, OR CONCERNING INDICATIONS AND CONTRAINDICATIONS, DOSAGES USED, METHOD OF ADMINISTRATION OR CONDITIONS OF USE.** A qualified healthcare professional should decide the indications or contraindications of Product, as well as the suggested dose, frequency, or method of administration, after proper diagnosis.

CUSTOMER SUPPORT

- Customer Support inquiries may be directed by mail, email, phone, or fax.

Mail:

MS One to One

PO Box 220790

Charlotte, NC 28222-0790

MS One to One Customer Support phone: 1-855-676-6326

Fax: 855-557-2478

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Lemtrada® Letter of Attestation

DATE: _____

Returns Shipping Instructions

***ALL RETURNS REQUIRE PRIOR AUTHORIZATION FROM SANOFI.** Each Return Authorization (RA) number is unique and may not be used for any subsequent returns.

Your RA # for this return is: _____

Patient REMS ID Number: _____

Number of vials being returned: _____

Lot/Batch Number: _____

Reason for return indicated below:

- ☐ Vial(s) unused
- ☐ Vial(s) received in error (only to be used for direct purchase customers)

Step 1. Please use the provided packaging materials (Returns box, packing envelope, etc.) to safely return the product.

Step 2. Please review ALL information on the provided Return Authorization Manifest form for accuracy. For discrepancies, please contact MS One to One at 1-855-676-6326.

Step 3. Please provide Returns Box to your Shipping/Receiving Department for pick up by FedEx, so pickup may be scheduled.

*Inquiries pertaining to this Return should reference the above RA number.

PER THE FDA, LEMTRADA® RETURNS MUST BE PROCESSED EXPEDIENTLY, PLEASE ENSURE THAT PICKUP OF YOUR LEMTRADA RETURN IS SCHEDULED AS SOON AS POSSIBLE.

ATTESTATION:

By signing below, I attest that my facility has received no payment for these unused vials of **LEMTRADA**, nor will my facility bill any individual, insurer, third party payer, or other entity for these unused vials of **LEMTRADA**.

Name: _____ Signature: _____

Questions? Contact MS One to One at 1-855-676-6326