



# BUREAU OF CUSTOMS

MAKABAGONG ADUANA, MATATAG NA EKONOMIYA



PROFESSIONALISM

INTEGRITY

ACCOUNTABILITY

AOCG Memo No. 182-2023


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BOC-09-41508

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## MEMORANDUM

TO : ALL DISTRICT COLLECTORS  
ALL SUB-PORT COLLECTORS  
ALL OTHERS CONCERNED

FROM :   
ATTY. VENER S. BAQUIRAN  
Deputy Commissioner  
Assessment and Operations Coordinating Group

SUBJECT : Food and Drug Administration (FDA) Recommendation for  
The Release of Donated Pharmaceutical Products from  
Direct Relief to UNIVERSITY OF THE PHILIPPINES-MANILA  
(Institute of Human Genetics)

DATE : 23 June 2023

Forwarding the herein attached letters dated 31 May 2023 from Jesusa Joyce N. Cirunay, Rph, Director IV, Center for Drug Regulation and Research, FDA, addressed to Maria Melanie Liberty B. Alcausin, Director, Institute of Human Genetics-University of the Philippines recommending clearance for the release of donated pharmaceutical products from Direct Relief to **UNIVERSITY OF THE PHILIPPINES MANILA** (Institute of Human Genetics)

Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Quantity
Idursulfase [Elaprase] 2mg/ml (6 mg/3ml) Concentrate Solution for IV Infusion <b>Packaging:</b> Type I Clear and Colorless Glass Vial (Box of 1's) <b>Manufactured by:</b> Genzyme Northborough Operations Center-11 Forbes Road Northborough, MA 01532 <b>Storage conditions:</b> Store at temperatures between 2-8°C. Protect from light.	CY0102	May 2024	728 vials



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<p>Agalsidase Beta [Fabryzyme] 35 mg Powder Concentrate Solution for IV Infusion  <b>Packaging:</b> Type I Clear and Colorless Glass Vial (Box of 1's)  <b>Manufactured by:</b> Genzyme Northborough Operations Center-11 Forbes Road Northborough, MA 01532  <b>Storage conditions:</b> Store at temperatures between 2-8°C. Do not freeze/shake.</p>	BY0490	30 April 2024	108 vials
<p>Imiglucerase [Cerezyme] 400 U Powder for Intravenous Infusion  <b>Packaging:</b> 10 ml Clear, Colorless Type I Glass Vial per box. For single use only.  <b>Manufactured by:</b> Genzyme Northborough Operations Center-11 Forbes Road Northborough, MA 01532  <b>Storage conditions:</b> Store at temperatures not exceeding 2-8°C.</p>	CY008  CY0205	31 August 2024  31 December 2024	600 vials  480 vials
<p>Alglucosidase Alfa [Lumizyme] 50 mg Lyophilized Powder for Concentrate for Solution for IV Infusion  <b>Packaging:</b> Type I Clear and Colorless Glass Vial (Box of 1's)  <b>Manufactured by:</b> Genzyme Northborough Operations Center-11 Forbes Road Northborough, MA 01532  <b>Storage conditions:</b> Store at temperatures between 2-8°C.</p>	CW1889  CW2749	31 January 2025  31 May 2025	700 vials  29 vials

The release of the donated pharmaceutical products, intended for patients with lysosomal storage disorders, is on the condition that the products shall have:

1. a shelf-life of not less than 12 months at the time of arrival;
2. the labels (primary, secondary, and product information) shall be in the English language; and
3. the clearance is without prejudice to tariff rules and customs regulations.

For information and appropriate action



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**

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**FDA**  
Food and Drug Administration  
PHILIPPINES

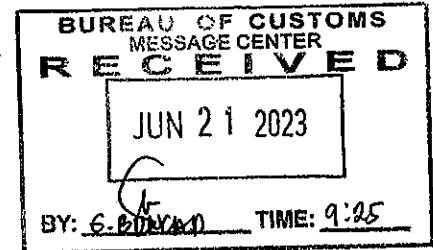
**CLEARANCE LETTER**

31 May 2023

**MARIA MELANIE LIBERTY B. ALCAUSIN, MD, FPPS**

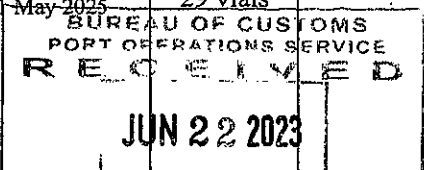
Director

Institute of Human Genetics-University of the Philippines Manila  
625 Pedro Gil St., Ermita, Manila Philippines

**Subject: Clearance of Foreign Drug Donations**Dear **Dr. Alcausin**:

Please be informed that this Office recommends clearance for the release of the following products donated by *Direct Relief*- 6100 Wallace Becknell Road, Santa Barbara, CA 93117, United States to *Institute of Human Genetics-University of the Philippines Manila* located at the abovementioned address:

Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Quantity
Agalsidase Beta [Fabrazyme] 35 mg Powder Concentrate Solution for IV Infusion <b>Packaging</b> : Type I Clear and Colorless Glass Vial (Box of 1's) <b>Manufactured by:</b> Genzyme Northborough Operations Center -11 Forbes Road Northborough, MA 01532 <b>Storage conditions:</b> Store at temperatures between 2-8°C. Do not freeze/shake.	BY0490	30 April 2024	108 vials
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-----NOTHING FOLLOWS-----

BY: Noriel E. Angalla TIME: 10/3  
FOS/ACG

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines  
Trunk Line +63 2 857 1900 Fax +63 2 807 0751  
Website: www.fda.gov.ph Email: info@fda.gov.ph



21 JUN 2023

AOCG Memo No. 182-2023

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The release of said donated pharmaceutical products, intended for patients with lysosomal storage disorders, on the condition that the said products shall have:

1. shelf-life of not less than 12 months at the time of arrival; and
2. labels (primary, secondary, and product information) in English language. //

This clearance is without prejudice to tariff rules and customs regulations.

Very truly yours,

**By Authority of the Director General:**  
Per FDA Order No. 2016-005

  
**JESUSA JOYCE N. CIRUNAY, RPh**  
Director IV, Center for Drug Regulation and Research

Amount: Php 1,530.00  
OR Number: Ref# 00005192023162056223  
Date: 19 May 2023



20230518162655

cc: **Anna Marie Celina G. Garfin, MD, MM**  
Director IV, Bureau of International Health Cooperation

**Bienvenido Y. Rubio**  
Commissioner, Bureau of Customs



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**

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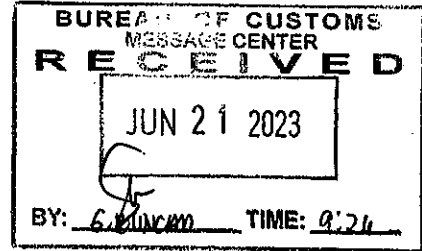
**CLEARANCE LETTER**



BOC-09-41508

31 May 2023

**MARIA MELANIE LIBERTY B. ALCAUSIN, MD, FPPS**  
Director  
Insitute of Human Genetics-University of the Philippines Manila  
625 Pedro Gil St., Ermita, Manila Philippines



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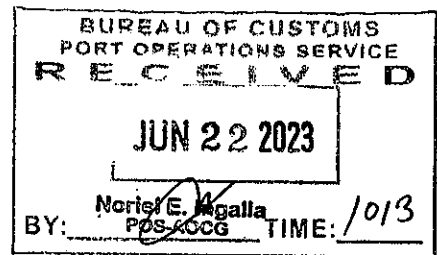
- shelf-life of not less than 12 months at the time of arrival; and
- labels (primary, secondary, and product information) in English language.

This clearance is without prejudice to tariff rules and customs regulations.

Very truly yours,

By Authority of the Director General:  
Per FDA Order No. 2016-005

**JESUSA JOYCE N. CIRUNAY, RPh**  
Director IV, Center for Drug Regulation and Research



Am. Paid: PHP 510.00  
OR#: Ref# 00005192023162450951  
Date: 19 May 2023

cc: Anna Marie Celina G. Garfin, MD, MM  
Director IV, Bureau of International Health Cooperation

Bienvenido Y. Rubio  
Commissioner, Bureau of Customs



Management System  
ISO 9001:2015

