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AOCG Memo No. 88-2023

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BOC-09-37983 *hmo*

MEMORANDUM

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

FROM : ATTY. EDWARD JAMES A. DY BUCO
Deputy Commissioner
Assessment and Operations Coordinating Group

SUBJECT : Food and Drug Administration (FDA) Recommendation for
The Release of Donated Pharmaceutical Products from
World Health Organization (WHO) to Department of Health
(DOH)

DATE : 10 February 2023

Forwarding the herein attached letter dated 24 January 2023 from Director Jesusa Joyce N. Cirunay, Center for Food Regulation and Research, FDA, addressed to Anthony B. Cu, MD, MPM-HSD, MPH-EOH, CESE, Director IV, Department of Health-Disease Prevention and Control Bureau, recommending clearance for the release of foreign drug donations from WHO to the DOH with the information that the release shall be subject to the following conditions:

1. the release of the said pharmaceutical products is intended for patients with Leprosy,
2. shall have a shelf-life of not less than 12 months at the time of arrival;
3. the labels (primary, secondary, and product information) shall be in the English language; and
4. the clearance is without prejudice to tariff rules and customs regulations.

For information and appropriate action.



AOCG Memo No. 88-2023 p. 2

Republic of the Philippines
Department of Health

FOOD AND DRUG ADMINISTRATION

CLEARANCE LETTER

MASTER COPY



24 January 2023



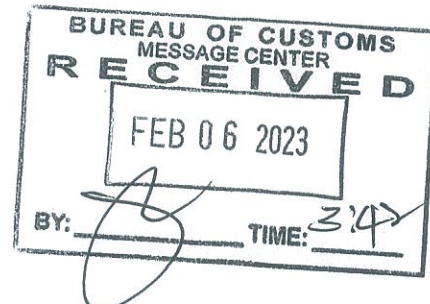
ANTHONY B. CU, MD, MPM-HSD, MPH-EOH, CESE

Director IV

Department of Health- Disease Prevention and Control Bureau
San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila, 1003

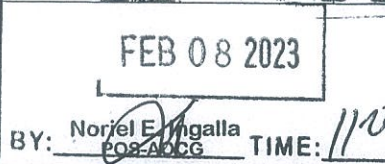
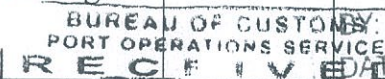
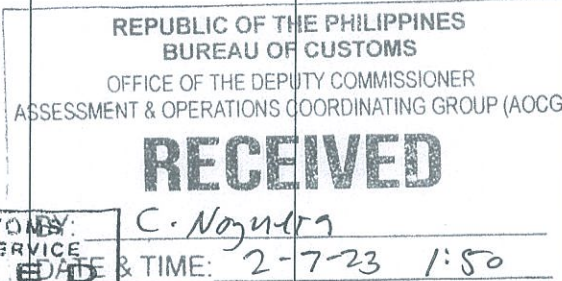
Subject: Clearance of Foreign Drug Donations

Dear **Dr. Cu**:



Please be informed that this Office recommends clearance for the release of the following products as donation by the *World Health Organization (WHO) Philippine Country Office* – Bldg. 3, DOH, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila 1003 to the *Department of Health (DOH) – Disease Prevention and Control Bureau* located at the abovementioned address:

Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Quantity
Multidrug Therapy (MDT) Multibacillary (MB) Adult [MDT-Combi] <u>Each Blister Pack contains:</u> Rifampicin (Rimactane) 300 mg Capsule x 2 + Clofazimine (Lamprene) 100 mg Capsule x 3 + Clofazimine (Lamprene) 50 mg Capsule x 27 + Dapsone 100 mg Tablet x 28 Packaging : Per Large Box: 8 Boxes of 6 Alu-PVC Blister Packs (48 Blister Packs) Manufacturer/ Address: Sandoz Private Limited – Plot No. 8 A/2 and 8-B, TTC Industrial Area, Kalwe Block, Village Dighe, Navi Mumbai, 400708, India Storage conditions: Store at temperatures not exceeding 25°C.	MB7575	31 January 2026	14,976 Blister Packs



08 FEB 2023

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Website: www.fda.gov.ph

Email: info@fda.gov.ph



Management System ISO 9001:2015



www.tuv.com ID 91667336

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<p>Multidrug Therapy (MDT) Multibacillary (MB) Child [MDT - Combi] Each Blister Pack <u>contains:</u> Rifampicin (Rimactane) 300 mg Capsule x 1 + Rifampicin (Rimactane) 150 mg Capsule x 1 + Clofazimine (Lamprene) 50 mg Capsule x 16 + Dapsone 100 mg Tablet x 28 Packaging: Per Large Box: 8 Boxes of 6 Alu-PVC Blister Packs (48 Blister Packs) Manufacturer/ Address: Sandoz Private Limited – Plot No. 8 A/2 and 8-B, TTC Industrial Area, Kalwe Block, Village Dighe, Navi Mumbai, 400708, India Storage conditions: Store at temperatures not exceeding 25°C.</p>	<p>MF9008</p>	<p>31 October 2025</p>	<p>1,152 Blister Packs</p>
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The release of said donated pharmaceutical products, intended for patients with Leprosy, is on the condition that the said products shall have:

1. a 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

Amt. Paid: PHP 1,020,00
 OR#: Sequence Number: 11723543330
 Date: 17 January 2023



cc: **Maria Soledad Q. Antonio, MD, PhD, MPH,**
DPAFP, CESE
 Director IV, Bureau of International Health Cooperation

Yogi Filemon L. Ruiz
 Commissioner, Bureau of Customs