AOCG Memo No. 19-2024





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BOC-09-45761

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 WORLD HEALTH ORGANIZATION (WHO) PHILIPPINE COUNTRY OFFICE TO THE DEPARTMENT OF HEALTH - DISEASE PREVENTION

AND CONTROL BUREAU (DOH-DPCB)

DATE

17 January 2024

Forwarding the herein attached letter dated 14 December 2023 from Jesusa Joyce N. Cirunay, Director IV, Center for Drug Regulation and Research, FDA, addressed to Cherylle G. Gavino, MD, MPM-HSD, CESE, Director III, DOH-DPCB recommending clearance for the release of donated pharmaceutical products from WHO to DOH-DPCB.

Product Description (Generic/Dosage Strength and Form/Brand)	Batch / Lot No.	Expiry Date	Quantity
Multidrug Therapy (MDT) Multibacillary (MB) Adult [MDT-Combi] Each Blister Pack contains: 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:		31 December 2024 30 November 2024	25,824 Blister Packs 8,736 blister packs

			1 '
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.			
Multidrug Therapy (MDT) Multibacillary (MB) Child [MDT-Combi] Each Blister Pack contains: Rifampicin (Rimactane) 300 mg Capsule x 1 + Rifampicin (Rimactane) 150 mg Capsule x 1 + Clofazimine (Lamprene) 50 mg Capsule x 16 + Dapsone 50 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.	LL4312	31 August 2024	1,728 Blister Packs
Clofazimine 100 mg Soft Capsules [Lamprene] Packaging: White HDPE Bottle with Screw Cap x 500's (Box of 1's) Manufacturer/ Address: Sandoz Private Limited – Plot No. 8 A/2 and 8-B TTC Industrial Area, Kalwe Block, Village Dighe, 400708 Navi Mumbai, India Storage Conditions: Store at temperatures not exceeding 25°C.	LK5566	31 January 2026	96 bottles

The release of the donated pharmaceutical products, intended for patients with Leprosy, 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.

AOCG 13emo No. 19- 2024 p. 3



Republic of the Philippines Department of Health

FOOD AND DRUG ADMINISTRATION



CLEARANCE LETTER

09-45761

14 December 2023

CHERYLLE G. GAVINO, MD, MPM-HSD, CESE

Director III

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. Gavino:



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:

(Ger	roduct Description neric/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Quantity	
Multible [MDT Each Rifamp Capsul (Lamp Clofaz Capsul Tablet Packas Boxes (48 Bli Manus Private and 8-l Kalwe Mumb: Storag	drug Therapy (MDT) cacillary (MB) Adult -Combi] Blister Pack contains: cicin (Rimactane) 300 mg de x 2 + Clofazimine rene) 100 mg Capsule x 3 + imine (Lamprene) 50 mg de x 27 + Dapsone 100 mg x 28 ging: Per Large Box: 8 of 6 Alu-PVC Blister Packs dister Packs) facturer/ Address: Sandoz de Limited – Plot No. 8 A/2 B, TTC Industrial Area, Block, Village Dighe, Navi ai, 400708, India de conditions: Store at fatures not exceeding 25°C.	LL7112 LR7830	31 December 2024 30 November 2024	BY:	CUSTOMS Y COMMISSIONER GRAINATING GROUP (AO
Multi [MDT Each Rifamp Capsul (Rimac Clofazi Capsul Tablet Packag Boxes	etane) 150 mg Capsule x 1 + imine (Lamprene) 50 mg e x 16 + Dapsone 50 mg	LL4312	31 August 2024	JAN 08 Zuz4 Noviel Extragalist Pos Aoce TIME 1,728 Blister Packs	1034

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900

Website: www.fda.gov.ph

Fax +63 2 807 0751

Email: info@fda.gov.ph







AOCG Memo No. 19-2024 p. 4

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.			7
Clofazimine 100 mg Soft Capsules			
[Lamprene]			
Packaging: White HDPE Bottle		./	1
with Screw Cap x 500's (Box of 1's)	,		•
Manufacturer/ Address:			
Sandoz Private Limited	LK5566	31 January 2026	96 bottles
Plot No. 8-A/2 & 8-B, T.T.C.		A-44	
Industrial Area, Kalwe Block,			
Village Dighe, 400708 Navi			
Mumbai, India			
Storage conditions: Store at			
temperatures not exceeding 25°C.			

The release of said donated pharmaceutical products, intended for patients with Leprosy, is on the condition that the said products shall have:

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

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

Very truly yours,

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

JESUSA JOYCE N. CIRUNAY, RPh

Director IV, Center for Drug Regulation and Research

Other DTN: 20230712130519 Amt. Paid: PHP 1,530.00 OR#: SEO#71323620975 Date: 13 July 2023

20231009175434

cc: Anna Marie Celina G. Garfin, MD, MM

Director IV, Bureau of International Health Cooperation

Bienvenido Y. Rubio

Commissioner, Bureau of Customs