AOCG Memo No. 170-2024





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AOCG NO. 3721-24

BOC-09-49819

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 THE WORLD HEALTH ORGANIZATION – UNITED NATIONS AVENUE MANILA TO THE DEPARTMENT OF HEALTH – DISEASE

PREVENTION AND CONTROL BUREAU (DPCB)

DATE

30 August 2024

Forwarding the herein attached letter dated 27 June 2024 from Director Maria Cecilia C. Matienzo, Center for Drug Regulation and Research, FDA, addressed to Director Alleli Annie Grace P. Sudiacal, MD, MPH, CESE, Disease Prevention and Control Bureau, DOH, recommending clearance for the release of the following pharmaceutical products as donation from the World Health Organization — United Nations Avenue Manila, 1000 Philippines, to the Department of Health — Disease Prevention and Control.:

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)	NM4674 NM4675	31 Oct 2026	7,728 Blister Pack 3,792 Blister pack



Manufactured by: Sandoz Private Limited	
Plot No.8-A/2 & 8-B, TTC Industrial area.	
Kalwe Block, Village Dighe, Navi Mumbai,	
Thane 400708 Mahasrashtra State, India	,
Storage Conditions: Store at temperatures	
25°C	

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+		21 Aug 2027	864 Blister Pack
Dapsone 100 mg Tablet x 28	NJ1056		
Packaging: Per Large Box: 8 Boxes of 6 Alu- PVC Blister Packs (48 Blister Packs) Manufactured by: Sandoz Private Limited Plot No.8-A/2 & 8-B, TTC Industrial area, Kalwe Block, Village Dighe, Navi Mumbai, Thane 400708 Mahasrashtra State, India Storage Conditions: Store at temperatures 25°C			

The release of the donated pharmaceutical products, which is intended for adults, is on the condition that:

- 1. The said products shall have 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



CLEARANCE LETTER

09-49219

27 June 2024

ALLELI ANNIE GRACE P. SUDIACAL, MD, MPH, CESE

Director IV

Department of Health-Disease Prevention and Control Bureau (DPCB) Bldg. 3, San Lazaro Compound, Rizal Avenue, Sta. Cruz Manila, 1003, Philippines

Subject: Clearance of Foreign Drug Donations

Dear Dr Garfin:



Please be informed that this Office recommends clearance for the release of the following products donated by World Health Organization - United Nations Avenue Manila, 1000 Philippines to Department of Health-Disease Prevention and Control 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] 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) Manufactured by: Sandoz Private Limited Plot No.8-A/2 & 8-B, TTC Industrial Area, Kalwe Block, Village Dighe, Navi Mumbai, Thane 400708 Maharashtra State, India Storage conditions: Store at temperatures 25°C.	NM4674	31 October	7,728 Blister Pack
	NM4675	2026	3,792 Blister Pack

REPU	Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Quantity
CONTRACTIONS P M P K T	Jultidrug Therapy (MDT) Multibacillary (MB) Julid [MDT-Combi] Sch Blister Pack contains: Ifampicin (Rimactane) 300 mg Capsule x 1 + Ifampicin (Rimactane) 150 mg Capsule x 1 + Ifampicin (Lamprene) 50 mg Capsule x 16 + Ifapsone 50 mg Tablet x 28 Ifackaging: Per Large Box: 8 Boxes of 6 Aluvery C Blister Packs (48 Blister Packs) Ifanufactured by: Sandoz Private Limited Italian Block, Village Dighe, Navi Mumbai, Italian Horage conditions: Store at temperatures 25°C.	NJ1056	31 August 2027	864 Blister Pack

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntimer

Trunk Line +63 2 657 1900 Website: www.fda.gov.ph

Managemen System ISO 9001-2015





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The release of said donated pharmaceutical products intended for patients 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,

MARIA CECILIA C. MATIENZO
Director IV, Center for Drug Regulation and Research

Amt. Paid: PHP 510.00 OR#: SEQ#61424753683 Date: 18 June 2024

20240605144147

cc: Bienvenido Y. Rubio Commissioner, Bureau of Customs