



BUREAU OF CUSTOMS

MAKABAGONG ADUANA, MATATAG NA EKONOMIYA



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AOCG Memo No. 409-2022

DOC-09-35828

MEMORANDUM

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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
Philippine Business for Social Progress (PBSP) to
Department of Health – Disease Prevention and Control
Bureau (DOH-DPCB)

DATE : 22 November 2022

Forwarding the herein attached letter dated 11 November 2022 addressed to Anthony B. Cu, MD, MPH-HSD, MPH-EOH, CESE, Director IV, Disease Prevention and Control Bureau, Department of Health (DPCB-DOH) from Jesusa Joyce N. Cirunay, Director IV, Center for Drug Regulation and Research, FDA recommending clearance for the release of donated pharmaceutical products from **PBSP** to the **DOH-DPCB** with the information that the release shall be subject to the following conditions:

1. the 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

11 November 2022

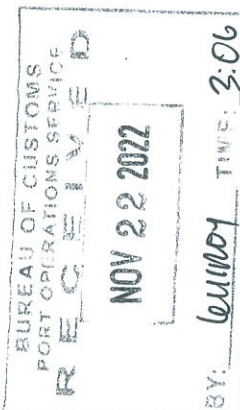
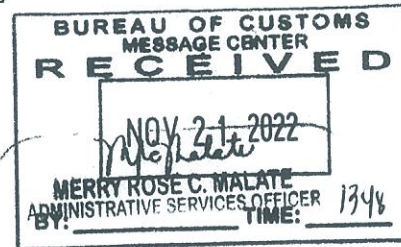


BOC-09-35828

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

Director IV

Disease Prevention Control Bureau
Department of Health, Bldg. 14, 3rd Floor
Infectious Diseases Prevention and Control Division
San Lazaro Compound, Rizal Avenue
Sta. Cruz, Manila, 1003

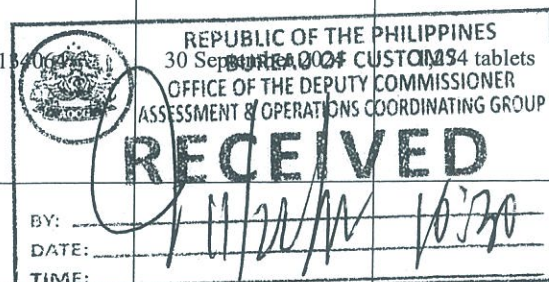


Subject: Clearance of Foreign Drug Donations

Dear Sir/Madam:

Please be informed that this Office recommends clearance for the release of the following products as donation by *Philippine Business for Social Progress* – Unit 1 7th Floor, Citynet Central, Sultan Street Highway Hills, Mandaluyong, Philippines, 1550 to Department of Health (DOH)- Disease Prevention and Control Bureau (DPCB) located at the abovementioned address:

Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Total Quantity (Box)
Pretomanid 200 mg Tablet [Dovprela] Packaging: White HDPE Bottle with Screw Cap x 26's (Box of 1's) Manufactured by: Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad, 431136 Maharashtra State, India Storage conditions: Store at temperatures not exceeding 30°C.	8134069		
Pyrazinamide 500 mg Tablets Packaging: Alu/PVC Blister Pack x 28's (Box of 672's) Manufactured by: Macleods Pharmaceuticals Limited—304, Atlanta Arcade Marol Church Road Andheri (East) Mumbai – 400 059, India Storage conditions: Store at temperatures not exceeding 25°C.	NPA2201C NPA2202A	31 December 2025 31 December 2025	535,584 tablets 76, 608 tablets
p-Aminosalicylate Sodium 5.52 g Powder for Oral Solution [PAS-Na] Packaging: Laminated Paper/PE/Alu Foil/PE Sachet x 5.52 g Manufactured by: Joint-Stock Company OLAINFARM Rupnicu 5 Olaine, LV-2114, Latvia Storage conditions: Store at temperatures not exceeding 25°C.	100322 50322 60322 70322 80322 40122	31 March 2025 31 March 2025 31 March 2025 31 March 2025 31 March 2025 31 January 2025	5,675 sachets 19,450 sachets 19,525 sachets 19,575 sachets 5,800 sachets 12,575 sachets
Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet [Amesol] Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Medochemie Ltd. 1-10 Constantinoupoles Street 3011 Limassol-Cyprus Storage conditions: Store at temperatures not exceeding 25°C.	E6B103 E6B104	28 February 2027 28 February 2027	471,200 tablets 64,600 tablets



<p>Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Macleods Pharmaceuticals Ltd. Atlanta Arcade, Church Road, Near Leela Hotel, Andheri—Kurla Road, Andheri (East), Mumbai—400 059, India Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>BLB72115A BLB72116A</p>	<p>31 October 2025 31 October 2025</p>	<p>480,000 tablets 3,200 tablets</p>
<p>Pyridoxine (Vitamin B6) 50 mg Tablet [Teva] Packaging: Blister Pack x 10's (Box of 50's) Manufactured by: Teva Pharmaceuticals Polska Sp.z.o.o.— 53 Emilii Plater Str., 00-113 Warsaw, Poland Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>16113422</p>	<p>31 March 2025</p>	<p>1,223,400 tablets</p>
<p>Ethambutol 400 mg Tablet Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Cadila Pharmaceuticals Ltd.— Plot No. 1389, Trasad Road, Dholka-382 225, Dist. Ahmedabad Gujarat State, India Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>ET075E2002 ET075E2003 ET075E2004 ET075E2005 ET075E2006</p>	<p>31 December 2025 31 December 2025 31 December 2025 28 February 2026 28 February 2026</p>	<p>90,720 tablets 16,128 tablets 436,128 tablets 973,056 tablets 282,240 tablets</p>
<p>Bedaquiline 100 mg Tablet [Sirturo] Packaging: White HDPE Bottle with Screw Cap x 188's (Box of 1's) Manufactured by: Recipharm Pharmservices Pvt. Ltd.— Khata No. 845/713 and 1108/970/1, 34th K.M. Tumkur Road, T-Begur, Nelamangala, Bangalore, 562 123, India Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>TMC21060 TMC21069</p>	<p>30 June 2024 31 July 2024</p>	<p>6,204 tablets 114,116 tablets</p>
<p>Cycloserine 125 mg Capsule Packaging: Alu/Alu Blister Pack x 10's (Box of 100's) Manufactured by: Macleods Pharmaceuticals Ltd.—Phase II, Unit II, Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman, 369 210 India Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>ECF722001A</p>	<p>31 January 2024</p>	<p>3,500 capsules</p>
<p>Cycloserine 250 mg Capsule Packaging: Alu/Alu Blister Pack x 10's (Box of 100's) Manufactured by: Dong-A ST Co., Ltd. 200-23, Baekseogongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>CSP21125194</p>	<p>13 December 2025</p>	<p>30,000 capsules</p>
<p>Levofloxacin (as Levofloxacin) [None] 100 mg Dispersible Tablet Packaging: Blister pack x 10's (Box of 100's) Manufactured by: Micro Labs Limited Unit-03 92, Sipcot Industrial Complex, Hosur-635 126, India Storage conditions: Store at temperatures not exceeding 30°C.</p>	<p>LFAH013 LFAH015 LFAH016</p>	<p>30 September 2024 31 December 2024 31 January 2025</p>	<p>2,800 tablets 16,200 tablets 3,800 tablets</p>

-----NOTHING FOLLOWS-----

AOCG Memo No. 409-2022

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The release of said donated pharmaceutical products, intended for patients, 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 510.00
OR#: Seq#102822513598
Date: 28 October 2022



20221024074433

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

Yogi Filemon L. Ruiz
Acting Commissioner, Bureau of Customs