



BOC-01-10549

MASTER

REPUBLIC OF THE PHILIPPINES DEPARTMENT OF FINANCE

BUREAU OF CUSTOMS

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MEMORANDUM

TO : ALL DISTRICT AND SUBPORT COLLECTORS ALL SUBPORT COLLECTORS ALL OTHERS CONCERNED



FROM : ATTY. VENER S. BAQUIRAN Deputy Commissioner, AOCO

SUBJECT : PROPOSED EXPORTATION OF GENPHARM INC., OF THE CONFIRMED COUNTERFEIT VACCINE

DATE : 27 January 2025

This has reference to the letter dated 17 December 2024 of Ms. Maria Cecilia C. Matienzo, Director IV, Center for Drug Regulation and Research, Food and Drug Administration (FDA), Department of Health (DOH), in connection to the proposed exportation of Genpharm, Inc. (Genpharm, for brevity) of the confirmed counterfeit vaccine to the manufacturer of the authentic vaccine, Serum Institute of India Pvt., Ltd., India:

Drug Product			
Hepatitis B'Vaccine (Recombinant DNA) 20 mcg/ml [Genvac-B] 20 mcg/ml Suspension for Injection (I.M.) (Single Dose) (Adult) [BR-574] Lot No.: 0343Q012B Expiry Date: August 2026 Manufacturer as reflected on the label: Serum Institute of India Pvt.,	1 box with 10 vials		
Ltd., India Specific Complaint: the vaccine and variable data (serial number, print appearance) referenced are falsified			

Relative thereto, please be informed that the FDA interposes **no objection** to the abovementioned proposed exportation of Genpharm.

It is emphasized, however, that:

- 1. The abovementioned product is a confirmed counterfeit/falsified vaccine and shall be submitted to the quality site of the manufacturer for laboratory analysis;
- 2. FDA shall not be held liable for any untoward reaction that may arise with the inadvertent use of such a product; and



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 This permit shall be used <u>only once</u> and is <u>valid for 1 year</u> from the date of issue.

For information and guidance.



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Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



17 December 2024

Bienvenido Y. Rubio Commissioner **Bureau of Customs** Office of the Commissioner G/F OCOM Building, 16th Street South Harbor, Port Area, Manila

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Dear Commissioner Rubio:

This is to inform you that the Food and Drug Administration (FDA) interposes no objection to the proposed exportation of **Genpharm**, **Inc.** of the confirmed counterfeit vaccine to the manufacturer of the authentic vaccine, **Serum Institute of India Pvt.**, **Ltd.**, **India**, with address at 212/2 Hadapsar, Pune, 411028 Maharashtra State, India:

Drug Product	Quantity	
Hepatitis B Vaccine (Recombinant DNA) 20 mcg/mL [Genvac-B] 20 mcg/mL Suspension for Injection (I.M.) (Single Dose) (Adult) [BR-574]		
Lot No.: 0343Q012B Expiry Date: AUG.2026	1 box with 10	
Manufacturer as reflected on the label : Serum Institute of India	vials	
Pvt., Ltd., India		
Specific complaint: the vaccine and variable data (serial number,		
print appearance) referenced are falsified		

It is emphasized however, that:

- 1. The abovementioned product is a confirmed counterfeit/falsified vaccine and shall be submitted to the quality site of the manufacturer for laboratory analysis.
- 2. This Office shall not be held liable for any untoward reaction that may arise with the inadvertent use of such product.
- 3. This permit shall be used **only once** and is **valid for 1 year** from the date of issue.

Very truly yours,

By Authority of the Director Gener	ral:			
MARIA CECILIA C. MATIENZ Director IV	ZO	IAN 1		
Center for Drug Regulation BURE	AOCG #245-25 JAN 1 7 2025	D 202412	16161436	2 0 2023
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Trunk Line +63 2 857 1900 Website : www.fda.gov.ph		2 807 0751 nfo@fda.gov.ph	TÜVRheinland CERTIFIED www.tuv.com ID 9105073396	1 6 JAN 2025