Republic of the Philippines
Department of Health
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCT

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988 and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number:	**BRP-076-04**
Generic Name:	Epoetin alfa
Brand Name:	Ematep
Dosage Strength & Form:	4000 IU/0.5 mL Solution for Injection (IV/SC)
Pharmacologic Category:	Hematopoietic Growth Factors
Classification:	Prescription Drug (Rx)
Approved Shelf-life:	24 months
Storage Condition:	Store at temperatures between 2-8°C.
Packaging:	Type I glass pre-filled syringe containing 0.5 mL solution Box of 10's
Marketing Conditions:	
Manufacturer:	HK Bioinnovation Co., Ltd. 729 Osonggarak-ro, Oksan-myeon, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea
Packer:	Dongkook Pharmaceutical Co., Ltd. 1103, Jingwang-ro, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Korea
Importer:	H & B Pharma International Inc. Unit 603 Tycoon Centre Condominium Pearl Drive-Ortigas Center, San Antonio, District 1, Pasig City
Distributor:	Ellebasy Medicale Trading Unit 201 DMC Bldg., Diamond St., cor. Felix Ave. CVS Homes 1, Brgy. Sto. Domingo, Cainta, Rizal

The Certificate of Listing to the above Distributor shall be valid until **23 August 2026,** which covers the unexpired term of the Principal CPR, subject to the conditions listed on the reverse side. No changes in the ownership, registrant's address/location, manufacturer, excipients, formulation, dosage form, strength, therapeutic indication, manufacturing process, labelling and commercial presentation, and packaging of the Principal product covered by the Principal CPR without prior approval of this Office.

This Certificate of Listing is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **17 September 2021**

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

Jesusa Joyce N. Cirunay, RPh

Director IV, Center for Drug Regulation and Research

This electronic-CLIDP (eCLIDP) is computer generated and does not require signature

Registration Number: **BRP-076-04**

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that registrant has the right or privilege to the use of the name or brand so registered, Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

REMARKS:

This Certificate of Listing of Identical Drug Product (CLIDP) is revalidated to reflect the full validity until 23 August 2027.