



16 MAR 2022

**FDA ADVISORY**  
No. 2022-0611-A

**PARA** : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

**PAKSA** : Babala sa Publiko tungkol sa Paggamit ng mga sumusunod na Beripikadong Pekeng Gamot na:

1. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg / 2 mg / 500 mg Film-Coated Tablet
2. Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule
3. Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule
4. Phenylpropanolamine HCl / Chlorphenamine Maleate / Paracetamol (Decolgen® Forte) 25 mg / 2 mg / 500 mg Tablet
5. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg / 2 mg / 500 mg Tablet
6. Dextromethorphan HBr / Phenylephrine HCl / Paracetamol (Tuseran® Forte) 15 mg / 25 mg / 325 mg Capsule
7. Naproxen Sodium (Flanax® Forte) 550 mg Tablet
8. Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet
9. Mefenamic Acid (Gardan®) 500 mg Tablet
10. Loperamide (Diatabs®) 2 mg Capsule
11. Loperamide (Imodium®) 2 mg Capsule
12. D-Alpha Tocopherol (Vitamin E) (Myra E) 400 IU Capsule
13. Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na beripikadong pekeng gamot:

**TUNAY/AUTHENTIC**

**FORMULATION**

Each film-coated tablet contains:

Phenylephrine HCl 10 mg

Chlorphenamine Maleate 2 mg

Paracetamol 500 mg

**INDICATIONS**

This medicine is used for the relief of coughs, runny nose, sinusitis, sore throat, fever and various respiratory conditions, and when taken in conjunction with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps to relieve nasal congestion and pain.

**USAGE AND ADMINISTRATION**

Adults and Children 12 years and older:

Take 1 tablet every 6 hours, or as recommended by a doctor.

**CONTRAINDICATIONS**

- If you are allergic to any ingredient of the product.
- If you have high blood pressure or severe heart disease unless recommended by a doctor.
- If you have serious kidney or liver disease unless recommended by a doctor.
- If you are pregnant or breastfeeding.

**WARNINGS**

Use Bioflu® only if you are certain you have a cold, flu, sinusitis, or other respiratory tract infection. Do not use Bioflu® if you have a fever, sore throat, or other symptoms of a bacterial infection. Do not use Bioflu® if you have a history of high blood pressure, heart disease, or other conditions. Do not use Bioflu® if you are taking other medicines, especially those containing pseudoephedrine, as this may increase the risk of side effects. Do not use Bioflu® if you are taking other medicines, especially those containing pseudoephedrine, as this may increase the risk of side effects. Do not use Bioflu® if you are taking other medicines, especially those containing pseudoephedrine, as this may increase the risk of side effects.

**PHENYLEPHRINE HCl CHLORPHENAMINE MALEATE PARACETAMOL**

**BIOFLU®**

10 mg / 2 mg / 500 mg FILM-COATED TABLET

- Nasal Decongestant
- Antihistamine
- Analgesic / Antipyretic

Manufactured by: **BIOFLU, INC.**  
100 10th Street, Marikina City, Metro Manila, Philippines

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PEKE/COUNTERFEIT



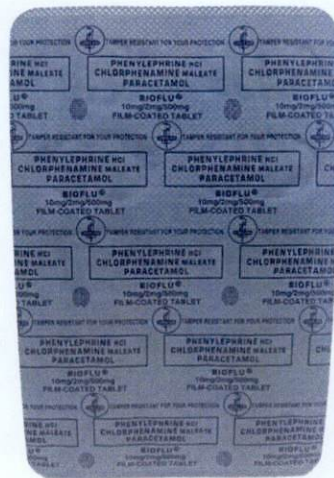
Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 1. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U066300 Exp. OCT 2023) at (Lot No.U2350770 Exp. JUL 2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang tableta, *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 2. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Bioflu®) 10 mg/ 2 mg/ 500 mg Film-Coated Tablet (Lot No. U066300 Exp. OCT 2023) at (Lot No. U2350770 Exp. JUL 2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 3. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Ibuprofen/Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 21623400 Exp. OCT 2024)

### TUNAY/AUTHENTIC



### PEKE/COUNTERFEIT



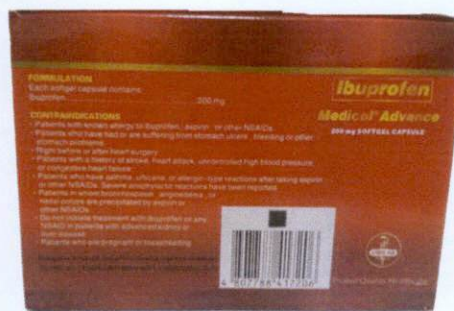
**Peke/Counterfeit** – Ang kapsula, *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 4. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Ibuprofen/ Paracetamol (Alaxan® FR) 200 mg/ 325 mg Tablet (Lot No. 21623400 Exp. OCT 2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



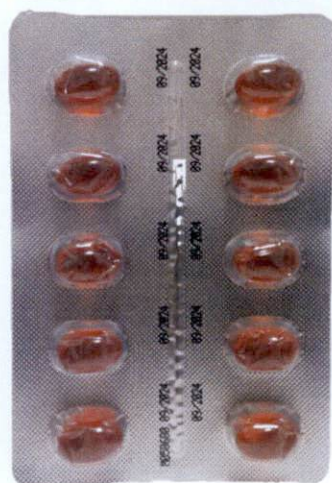
**Peke/Counterfeit** – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 5. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule (Lot No. F000939 Exp. OCT. 2024)

TUNAY/AUTHENTIC



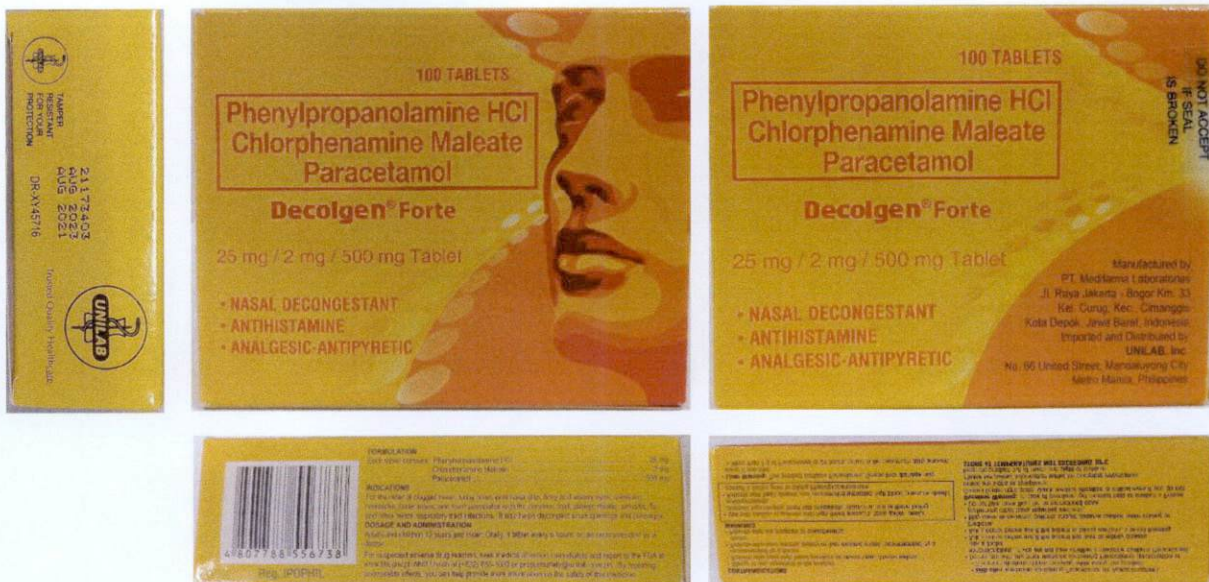
PEKE/COUNTERFEIT



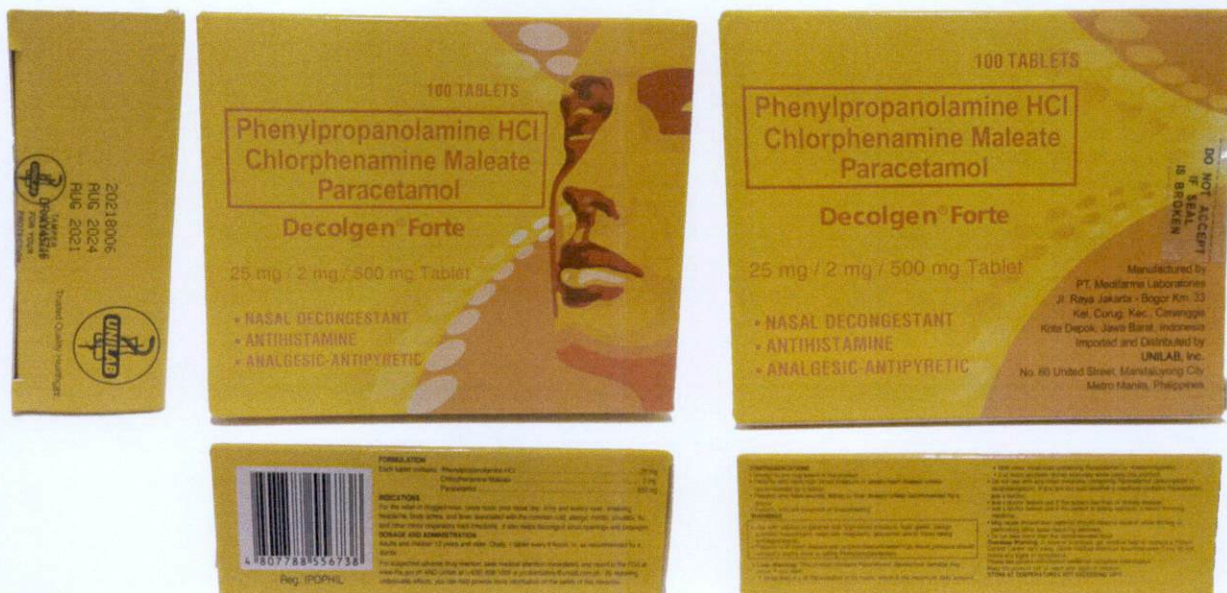
**Peke/Counterfeit** – Ang kapsula, *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 6. . Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule (Lot No. F000939 Exp. OCT. 2024) at (Lot No. M058680 Exp. 09/2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 7. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Phenylpropanolamine HCl, Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot No. 20218006 Exp. AUG 2024)



**TUNAY/AUTHENTIC**



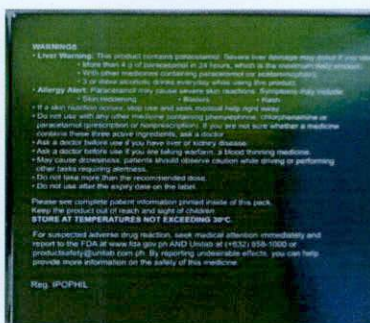
**PEKE/COUNTERFEIT**



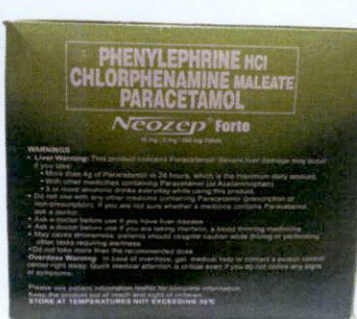
**Peke/Counterfeit** – Ang tableta, *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 8. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Phenylpropanolamine HCl, Chlorphenamine Maleate/ Paracetamol (Decolgen® Forte) 25 mg/ 2 mg/ 500 mg Tablet (Lot No. 20218006 Exp. AUG 2024) at (Lot. No. 22566850 Exp. AUG 2025)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 9. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl, Chlorpheniramine Maleate/ Paracetamol (Neozep® Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 25076022 Exp. Aug 2025)

TUNAY/AUTHENTIC



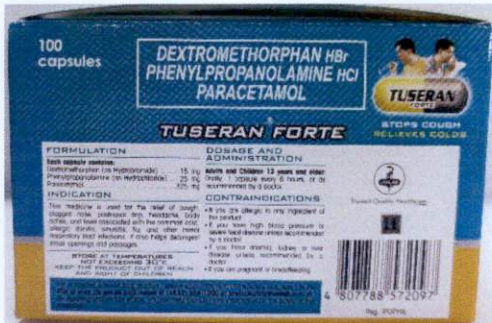
PEKE/COUNTERFEIT



**Peke/Counterfeit** – Ang Tableta, *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 10. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Phenylephrine HCl, Chlorphenamine Maleate/ Paracetamol (Neozep® Forte) 10 mg/ 2 mg/ 500 mg Tablet (Lot No. 25076022 Exp. Aug 2025)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Ang print appearance ng kahon ay hindi tugma sa rehistradong gamot.

Larawan 11. Paghahambing sa kahon ng Tunay/Authentic at Peke/Counterfeit na Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran® Forte 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U260785 Exp. AUG 2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 12. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Dextromethorphan HBr/ Phenylpropanolamine HCl/ Paracetamol (Tuseran<sup>®</sup> Forte 15 mg/ 25 mg/ 325 mg Capsule (Lot No. U260785 Exp. AUG 2024) at (Lot. No. U021822 Exp. JUN 2024)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



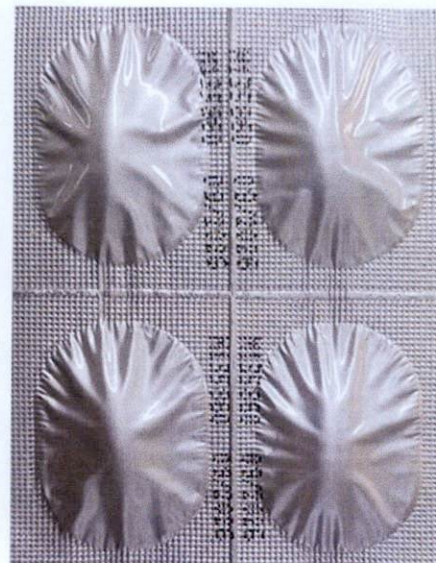
**Peke/Counterfeit** – Ang lot number na ito ay hindi gawa ng Marketing Authorization Holder (MAH).

Larawan 13. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Naproxen Sodium (Flanax<sup>®</sup> Forte) 550 mg Tablet (Lot No. TFF6L458 Exp. JUN 2024)

### TUNAY/AUTHENTIC



### PEKE/COUNTERFEIT



**Peke/Counterfeit** – Ang *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 14. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na Mefenamic Acid (Dolfenal<sup>®</sup>) 500 mg Film-Coated Tablet (Lot No. M135860 Exp. 09/2026)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



Peke/Counterfeit – Hindi lehitimong produkto ng MAH.

Larawan 15. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Mefenamic Acid (Gardan<sup>®</sup>) 500 mg Tablet (Lot No. 19143 Exp. 04/2023)



TUNAY/AUTHENTIC



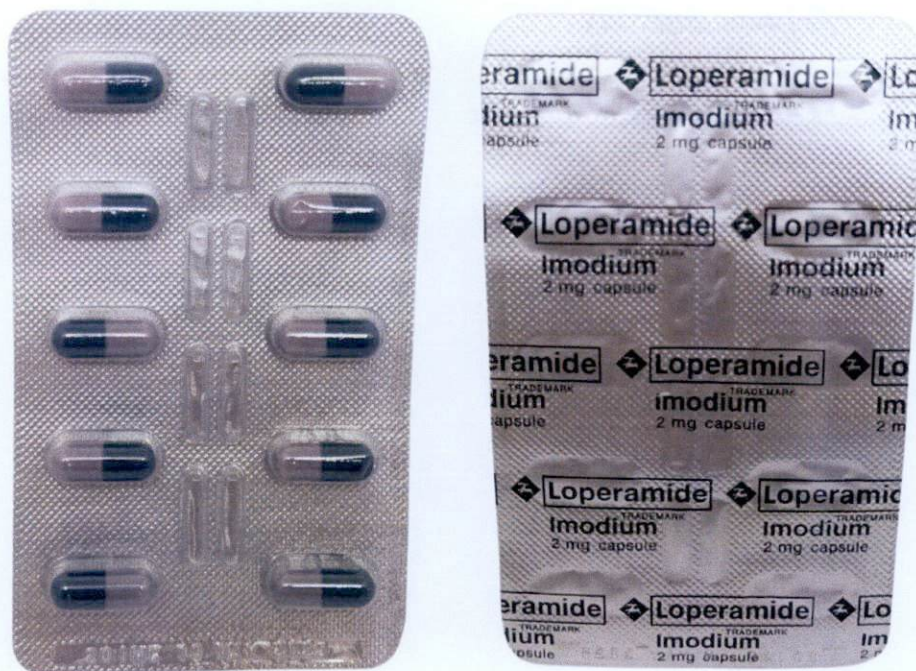
PEKE/COUNTERFEIT



**Peke/Counterfeit** – The knurling, security mark, and print appearance ay hindi tugma sa rehistradong gamot.

Larawan 16. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Loperamide (Diatabs<sup>®</sup>) 2 mg Capsule (Lot No. U022608 Exp. SEP 2026)

TUNAY/AUTHENTIC



PEKE/COUNTERFEIT



**Peke/Counterfeit** – Ang *lot number* na ito ay hindi gawa ng MAH.

Larawan 17. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Loperamide (Imodium<sup>®</sup>) 2 mg Capsule (Lot No. 201MC 0 Exp. OCT 2025)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang *knurling* at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 18. Paghahambing sa Tunay/*Authentic* at Peke/*Counterfeit* na d-Alpha Tocopherol [Vitamin E] (Myra e) 400 IU mg Capsule (Lot No. 0856T2 Exp. 12/2024)

**TUNAY/AUTHENTIC**



**PEKE/COUNTERFEIT**



**Peke/Counterfeit** – Ang *knurling*, *security mark*, at *print appearance* ay hindi tugma sa rehistradong gamot.

Larawan 19. Paghahambing sa Tunay/Authentic at Peke/Counterfeit na Aluminum Hydroxide/ Magnesium Hydroxide/ Simeticone (Kremil-S®) 178 mg/ 233 mg/ 30 mg Chewable Tablet (Lot No. U021860 Exp. AUG 2024) at (U035433 Exp. APR 2024)

Ang lahat ng *healthcare professionals* at publiko ay binabalaan tungkol sa paglipana ng nasabing pekeng gamot sa merkado na maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito. Ang publiko ay pinapaalalahanan ring bumili lamang sa mga establisyementong lisensyado ng FDA.

Gayundin, ang lahat ng establisyemento ay binabalaang huwag magbenta ng pekeng gamot na nagtataglay ng mga nasabing katangian. Ang pagaangkat, pagbebenta at pamamahagi nito ay paglabag sa *Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs*. Ang sino mang mapatunayang nagbebenta ng nasabing pekeng produkto ay mapaparusahan.

Ang lahat ng establisyemento at/o entidad ay binabalaang huwag mamahagi ng nasabing ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag. Ugaliing tignan kung rehistrado ang produkto sa FDA sa pamamagitan ng *FDA Verification Portal feature* na makikita sa <http://verification.fda.gov.ph>.

Hinihiling sa lahat ng *Local Government Units (LGUs) and Law Enforcement Agencies (LEAs)* na tiyaking ang pekeng produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaring mag-email sa [info@fda.gov.ph](mailto:info@fda.gov.ph). Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga pekeng gamot, mag-email sa [report@fda.gov.ph](mailto:report@fda.gov.ph), o mag-report gamit ang aming *online reporting facility, eReport*, sa [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport). Maaari ring tumawag sa *Center for Drug Regulation and Research* sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

  
DR. OSCAR G. GUTIERREZ, JR.  
Officer-in-Charge Director General

DTN: 

20220302133649