



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**

No. 2019-387-A

15 OCT 2019

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

**SUBJECT : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Hindi Rehistradong Gamot na:**

1. OTC ORYZANOL TABLETS
2. FEBUXOSTAT TABLETS
3. AOLITAI ORNIDAZOLE CAPSULES
4. ROXITHROMYCIN CAPSULES
5. OMEPRAZOLE SODIUM FOR INJECTION
6. ADENOSINE DISODIUM TRIPHOSPHATE INJECTION
7. JUCISHAN DEXAMETHASONE SODIUM PHOSPHATE INJECTION
8. CEFTRIAZONE SODIUM FOR INJECTION
9. ALLOPURINOL TABLETS
10. CEFOTAXIME SODIUM FOR INJECTION
11. ZX MOROXYDINE HYDROCHLORIDE TABLETS
12. HUAN QIU FLUCONAZOLE AND SODIUM CHLORIDE INJECTION
13. OTC FISHING PILL
14. LUNDBECK FLUPENTIXOL AND MELITRACEN TABLETS (DEANXIT)
15. ITRACONAZOLE HYDROCHLORIDE CAPSULES
16. NEW LINDANE CREAM
17. LUTEIN
18. OTC PENTOXYVERINE CITRATE TABLETS
19. OXYTETRACYCLINE TABLETS
20. OTC FUFANGGANMAOLINGPIAN
21. DIPYRIDAMOLE TABLETS
22. OTC FUMASUAN TONGTIFEN PIAN
23. OTC HOUKANG SAN
24. OTC WEI C YINQIAO PIAN
25. OTC [Label in Foreign Language]
26. XCQM XUECHA QINGMU
27. YABANG GROUP CARBAZOCHROME TABLETS
28. ZN MENADIOL DIACETATE TABLETS
29. BAOZHUPAI® [Label in Foreign Language]
30. TRIVITAMINS B TABLETS [as reflected in the package insert]



31. HUANQIU OFLOXACIN EAR DROPS [as reflected in the primary packaging and package insert]
32. PR® RACEANISODAMINE TABLETS
33. JINGKANG JIAONANG
34. 1 YI LHENG
35. OTC [Label in Foreign Language]
36. AZITHROMYCIN DISPERSIBLE TABLETS
37. OTC NAPHAZOLINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND VITAMIN B<sub>12</sub> EYE DROPS EYE SIGHT
38. KOUQIANGYAN PENWUJI
39. OTC NYTH
40. OTC ACUTE BRONCHITIS SYRUP
41. OTC HUAHONG® XIAOZHONGZHITONGDING
42. YUNNAN BAIYAO JIAONANG
43. LOMEFLOXACIN HYDROCHLORIDE EYE DROPS
44. OTC [Label in Foreign Language]
45. OTC LORATADINE TABLETS [as reflected in the package insert]
46. SPH DING LU BRAND® QINGGAN CHUANXINLIAN PIAN
47. OTC 999® ZHENG Tian WAN

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



**OTC Oryzanol Tablets**

Larawan 1. Hindi rehistradong gamot



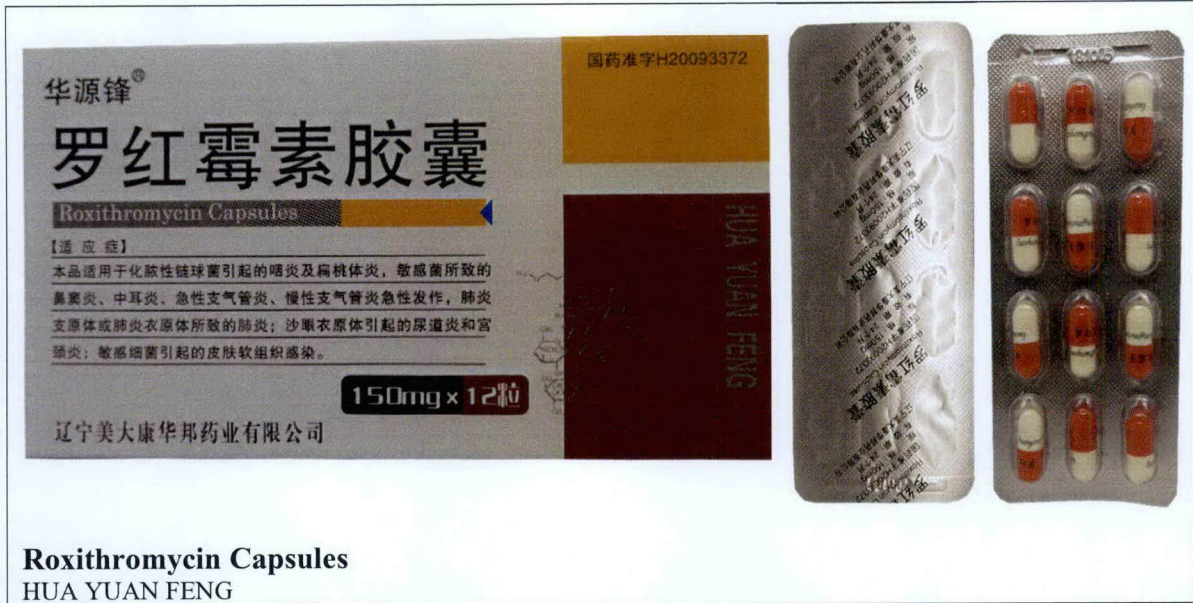
**Febuxostat Tablets**

Larawan 2. Hindi rehistradong gamot



**AOLITAI ORNIDAZOLE CAPSULES**  
Xi'an Wanlong Pharmaceutical Company, Ltd

Larawan 3. Hindi rehistradong gamot




**Roxithromycin Capsules**  
HUA YUAN FENG

Larawan 4. Hindi rehistradong gamot



**Omeprazole Sodium for Injection**  
HUNAN WZT PHARMACEUTICAL CO., LTD.


Larawan 5. Hindi rehistradong gamot



## 三磷酸腺苷二钠注射液

2ml×10支

ADENOSINE DISODIUM TRIPHOSPHATE INJECTION



**【性 状】** 本品为无色至微黄色的澄明液体。 国药准字H35020101

**【成 份】** 三磷酸腺苷二钠；

**【适 症】** 辅酶类药。用于进行性肌萎缩、脑出血后遗症、心功能不全、心肌疾患及肝炎等的辅助治疗。

**【用法用量】** 肌内注射或静脉注射，一次10~20mg，一日10~40mg。

**【禁 忌】** 本药对窦房结有明显抑制作用。因此对房室综合征、窦房结功能不全者及老年人慎用或不用。

**【注意事项】** 静注宜缓慢，以免引起头晕、头胀、胸闷及低血压等。心肌梗死和脑出血患者在发病期慎用。

**【不良反应】**

**【贮 藏】** 凉暗处(避光并不超过20℃)密闭保存。


**【规 格】** 2ml:20mg (按C<sub>10</sub>H<sub>16</sub>N<sub>5</sub>Na<sub>2</sub>O<sub>13</sub>P<sub>3</sub>计)

**【包 装】** 安瓿装，10支/盒

**福建古田药业有限公司**

**ADENOSINE DISODIUM TRIPHOSPHATE INJECTION**


Larawan 6. Hindi rehistradong gamot



国药准字H41020055

## 地塞米松磷酸钠注射液

Dexamethasone Sodium Phosphate Injection



**【成份】** 本品主要成份为：地塞米松磷酸钠，辅料为：磷酸氢二钠、亚硫酸氢钠、丙二醇、注射用水。

**【性状】** 本品为无色的澄明液体。

**【适应症】** 主要用于过敏性与自身免疫性炎症性疾病。多用于结缔组织病、活动性风湿病、类风湿性关节炎、红斑狼疮、严重支气管哮喘、严重皮炎、溃疡性结肠炎、急性白血病等，也用于某些严重感染及中毒、恶性肿瘤的综合治疗。

**【用法用量】** 一般剂量静脉注射每次2~20mg；静脉滴注时，应以5%葡萄糖注射液稀释，可2~6小时重复给药至病情稳定，但大剂量连续给药一般不超过72小时。还可用于缓解恶性肿瘤所致的脑水肿，首剂静脉推注10mg，随后每6小时肌内注射4mg.....详见说明书。

**【不良反应】**、**【禁忌】**、**【注意事项】** 详见说明书。

**【贮藏】** 避光，密闭保存。

1ml:5mg 10支

**郑州卓峰制药有限公司**

ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO.,LTD.

**JUCISHAN Dexamethasone Sodium Phosphate Injection**  
**ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD.**

Larawan 7. Hindi rehistradong gamot



**Ceftriaxone Sodium for Injection**  
 ZHEJIANG YATAI PHARMACEUTICAL CO., LTD.

Larawan 8. Hindi rehistradong gamot



**Allopurinol Tablets**

Larawan 9. Hindi rehistradong gamot



**Cefotaxime Sodium for Injection**  
 GUANGXI KELUN PHARMACEUTICAL CO., LTD.

Larawan 10. Hindi rehistradong gamot



**ZX Moroxydine Hydrochloride Tablets**

Larawan 11. Hindi rehistradong gamot



**HUAN QIU Fluconazole and Sodium Chloride Injection**

Larawan 12. Hindi rehistradong gamot



**OTC Fishing Pill**

Lee Buan Soa Dispensary (Fishing Brand) Ltd., Part. - 49/50 Leamchabang Industrial Estate Moo 5, Toongsukhla Sub-District, Sriracha District, Cholburi 20230, Thailand

Larawan 13. Hindi rehistradong gamot

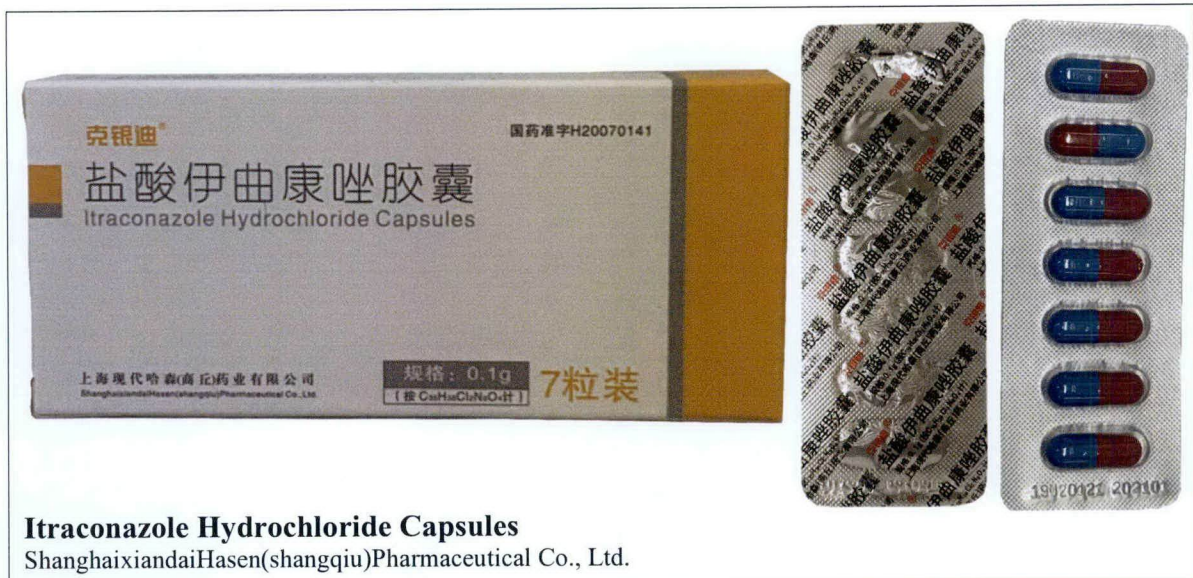


**Lundbeck Flupentixol and Melitracen Tablets (Deanxit)**

H. Lundbeck A/S - Ottiliavej 9, DK-2500, Valby, Denmark

Larawan 14. Hindi rehistradong gamot





**Itraconazole Hydrochloride Capsules**  
 ShanghaixiandaiHasen(shangqiu)Pharmaceutical Co., Ltd.

Larawan 15. Hindi rehistradong gamot



**New Lindane Cream**

Larawan 16. Hindi rehistradong gamot



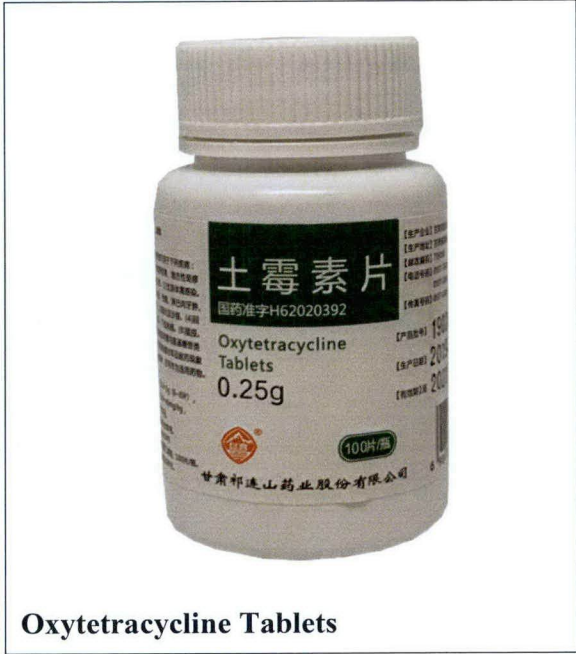
**LUTEIN**

Larawan 17. Hindi rehistradong gamot



**OTC Pentoxyverine Citrate Tablets**

Larawan 18. Hindi rehistradong gamot



**Oxytetracycline Tablets**

Larawan 19. Hindi rehistradong gamot



**OTC FUFANGGANMAOLINGPIAN**  
Guangxi jinnuozhi yaoyouxian gongsi

Larawan 20. Hindi rehistradong gamot



**Dipyrindamole Tablets**  
YABAO PHARMACEUTICAL GROUP  
CO.,LTD.

Larawan 21. Hindi rehistradong gamot



**OTC Fumasuan Tongtifen Pian**

Larawan 22. Hindi rehistradong gamot



**OTC Houkang San**

Larawan 23. Hindi rehistradong gamot



**OTC WEI C YINQIAO PIAN**

Larawan 24. Hindi rehistradong gamot



**OTC [Label in Foreign Language]**

CISEN

Larawan 25. Hindi rehistradong gamot



**XCQM Xuecha Qingmu**  
 XI' ANQICAOTANGYIYAOKEJIYOUXIANGONGSI

Larawan 26. Hindi rehistradong gamot



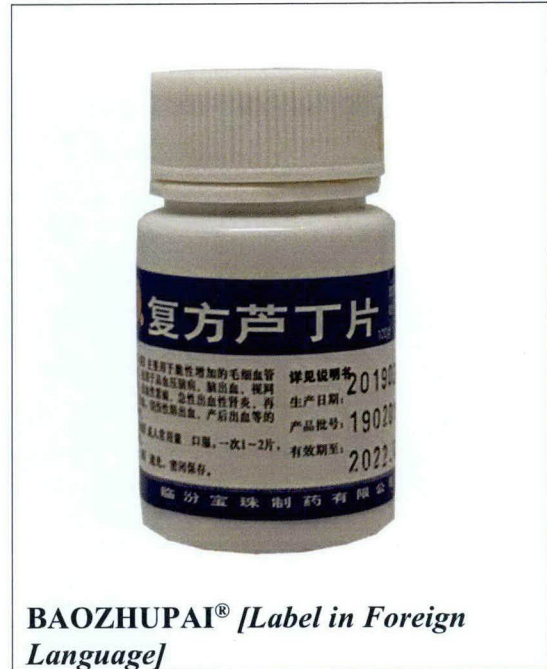
**YABANG GROUP Carbazochrome Tablets**  
 YABANG PHARMA

Larawan 27. Hindi rehistradong gamot



**ZN Menadiol Diacetate Tablets**

Larawan 28. Hindi rehistradong gamot



**BAOZHUPAI® [Label in Foreign Language]**

Larawan 29. Hindi rehistradong gamot



**Trivitamins B Tablets [as reflected in the package insert]**

Larawan 30. Hindi rehistradong gamot



**HUANQIU Ofloxacin Ear Drops** [as reflected in the primary packaging and package insert]

Larawan 31. Hindi rehistradong gamot



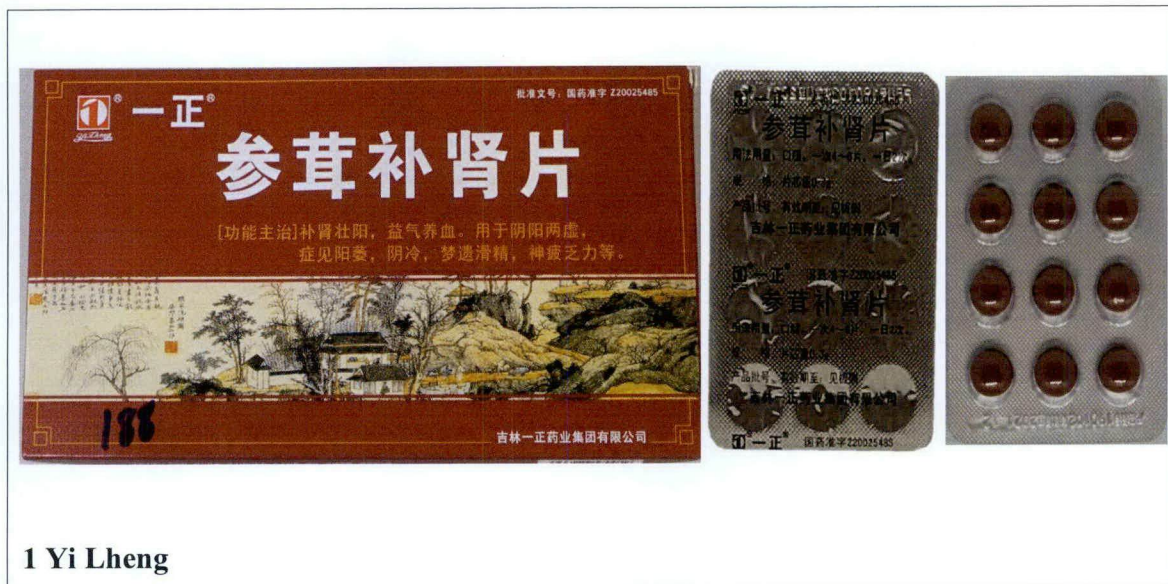
**PR® RACEANISODAMINE TABLETS**  
HENANPURUIZHUYAOYOUXIANGONGSI

Larawan 32. Hindi rehistradong gamot



**Jingkang Jiaonang**

Larawan 33. Hindi rehistradong gamot



**1 Yi Lheng**

Larawan 34. Hindi rehistradong gamot





OTC [Label in Foreign Language]

Larawan 35. Hindi rehistradong gamot



Azithromycin Dispersible Tablets

Larawan 36. Hindi rehistradong gamot



**OTC Naphazoline Hydrochloride, Chlorphenamine maleate and Vitamin B<sub>12</sub> Eye Drops Eye Sight**  
SHIJIAZHUANGGREATPHARMACEUTICALCO.,Ltd

Larawan 37. Hindi rehistradong gamot



**Kouqiangan penwuji**

Larawan 38. Hindi rehistradong gamot

NYTH 宛衡

OTC

请仔细阅读说明书并按说明使用或在药师指导下购买和使用

批准文号：国药准字H19994088

# 氢溴酸右美沙芬片

适应症：用于干咳，包括上呼吸道感染（如感冒和咽炎）、支气管炎等引起的咳嗽。

北京天衡药物研究院南阳天衡制药厂 1×24片/板/盒

OTC

氢溴酸右美沙芬片

规格：15毫克

产品批号、有效期至：见铝塑板

北京天衡药物研究院南阳天衡制药厂

请仔细阅读说明书并按说明使用或在药师指导下购买和使用

OTC

氢溴酸右美沙芬片

规格：15毫克

产品批号、有效期至：见铝塑板

北京天衡药物研究院南阳天衡制药厂

请仔细阅读说明书并按说明使用或在药师指导下购买和使用

OTC

氢溴酸右美沙芬片

规格：15毫克

产品批号、有效期至：见铝塑板

北京天衡药物研究院南阳天衡制药厂



OTC NYTH

Larawan 39. Hindi rehistradong gamot



**OTC Acute Bronchitis Syrup**  
 TAJI GROUP, CHONGQING FULING PHARMACEUTICAL FACTORY CO., LTD

Larawan 40. Hindi rehistradong gamot



**OTC HUAHONG® XIAOZHONGZHITONGDING**

Larawan 41. Hindi rehistradong gamot



**Yunnan Baiyao Jiaonang**  
YUNNAN BAIYAO GROUP CO.,LTD. - Chengong New District, Kunming, Yunnan Province, China

Larawan 42. Hindi rehistradong gamot



**Lomefloxacin Hydrochloride Eye Drops**

Larawan 43. Hindi rehistradong gamot



OTC [Label in Foreign Language]

Larawan 44. Hindi rehistradong gamot



OTC Loratadine Tablets [as reflected in the package insert]  
Xian Janssen Pharmaceutical Ltd.

Larawan 45. Hindi rehistradong gamot



**SPH DING LU BRAND® Qinggan Chuanxinlian Pian**  
SHANGHAI PHARMA

Larawan 46. Hindi rehistradong gamot



**OTC 999® Zhengtian Wan**

Larawan 47. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang nasabing mga gamot ay hindi dumaan sa proseso ng rehistrasyon o pag-eeksamin ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Samakatuwid, hindi masisiguro ng Ahensya ang kalidad at kaligtasan nito. Ang nasabing mga ilegal na produkto ay maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito.

Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

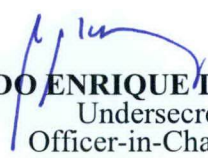
Ang publiko ay pinapaalalahanang huwag bumili ng nasabing mga ilegal na produkto at maging maingat laban sa mga ito. Ugaliing tingnan kung ang gamot ay rehistrado sa FDA bago bilhin, sa pamamagitan ng paggamit ng *Search feature* ng FDA *website* sa [www.fda.gov.ph](http://www.fda.gov.ph). Maaari ring tingnan ang FDA *Registration number* sa *label* ng produkto.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon, sapagkat kaukulang parusa ay mahigpit na ipatutupad.

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

Para sa karagdagang impormasyon at katanungan, maaaring mag-*email* sa [info@fda.gov.ph](mailto:info@fda.gov.ph). Upang mag-*report* ng patuloy na pagtitinda o pangangalakal ng mga Hindi rehistradong 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* (CDRR) sa numerong **(02) 809-5596**. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, *i-report* agad sa FDA gamit ang *link* na ito: [www.fda.gov.ph/adr-report-new](http://www.fda.gov.ph/adr-report-new) at kumpletuhin ang mga kinakailangang impormasyon.

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

  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**  
Undersecretary of Health  
Officer-in-Charge, Director General

DTN: 

20190809132914