



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2019-385-A

15 OCT 2019

PARA : SALAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

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

1. OTC XIAOYAO WAN
2. POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS
[as reflected in the package insert]
DANGSHIPIAN *[as reflected in the secondary packaging]*
3. CIMETIDINE INJECTION
4. 999® C₁₆H₁₇N₅O₇S₂ *[as reflected in the primary packaging]*
5. XUEFU ZHUYU JIAONANG
6. OTC TASLY® YANGXUE QINGNAO KELI
7. OTC XIAOYAN TUIRE KELI
8. OTC CONCENTRATED TINIDAZOLE GARGLES
9. OTC FANGFENGTONGSHENGWAN
10. QI LU AMIKACIN SULFATE INJECTION
11. PROGESTERONE INJECTION
12. VITAMIN C INJECTION
13. CEFIXIME CAPSULES TOUBAOKEWO JIAONANG
14. POTASSIUM CHLORIDE SUSTAINED-RELEASE TABLETS
15. *[LABEL IN FOREIGN LANGUAGE]*
16. MINGMU JILI WAN *[as reflected in the package insert]*
17. CSPC YANGXUE SHENGFA JIAONANG
18. XIAO YAN LI DAN PIAN
19. LAITING PROGESTERONE SOFT CAPSULES
20. SHENSHITONG KELI
21. JINSUO GU JING WAN
22. *[LABEL IN FOREIGN LANGUAGE]*
23. OTC *[LABEL IN FOREIGN LANGUAGE]*
24. LEVOFLOXACIN HYDROCHLORIDE AND SODIUM CHLORIDE INJECTION
25. GLUCOSE INJECTION 5%
26. LEVOFLOXACIN LACTATE AND SODIUM CHLORIDE INJECTION
27. SODIUM CHLORIDE INJECTION 0.9%
28. OTC PIEN TZE HUANG® HUO XIANG ZHENG QI SHUI



29. HASEN INOSINE INJECTION
30. FUFANG ANLIN BABITUO ZHUSHEYE
31. HASEN CHLORPHENAMINE MALEATE INJECTION
32. OTC BANLANGEN KELI
33. OTC YINGIAO JIEDU KELI
34. [LABEL IN FOREIGN LANGUAGE]
35. OTC NIUHUANGSHANGQINGPIAN
36. OTC 999®
37. CARSICK TAPE
38. YATAI® AMOXICILLIN CAPSULES
39. YATAI® CEFTRIAZONE SODIUM FOR INJECTION
40. YATAI® CEFALEXIN CAPSULES
41. OTC FUFANG LUOHANGUO ZHIKE KELI
42. OTC DONG LING CAO PIAN
43. OTC WU SHI CHA KE LI
44. YU LONG MINIAONING CAPSULE
45. OTC SHENGMAI YIN (DANG SHEN FANG)
46. YABAO NIUHUANG JIEDU PIAN
47. OTC HUMANWELL HEALTHCARE [as reflected in the secondary packaging]
48. OTC XUANMEI GANJIE KELI

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

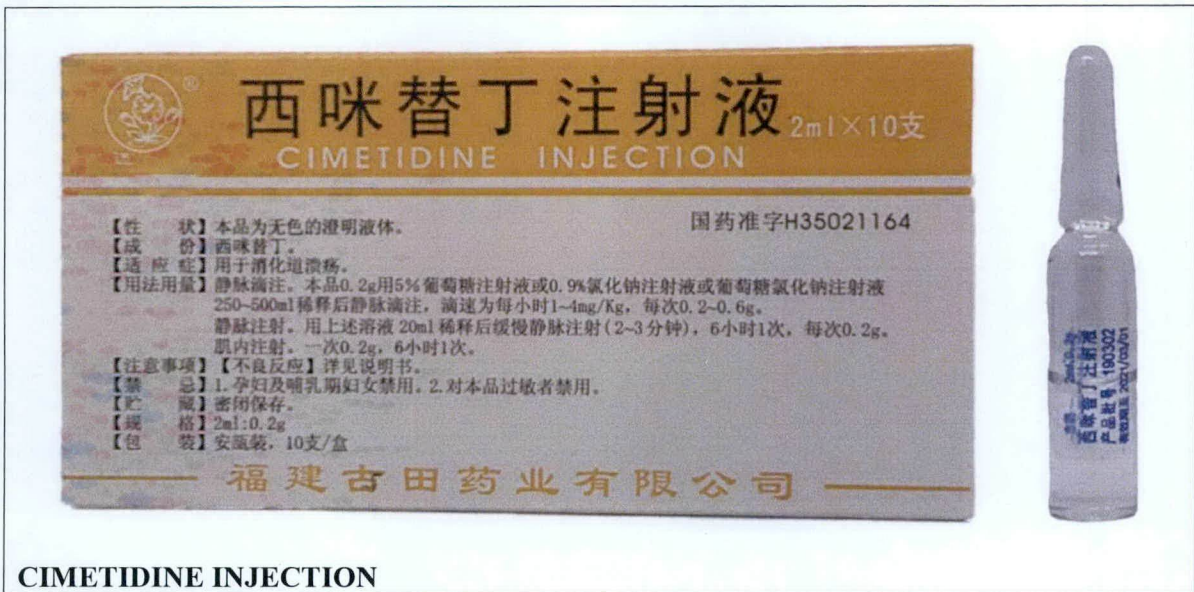


OTC Xiaoyao Wan

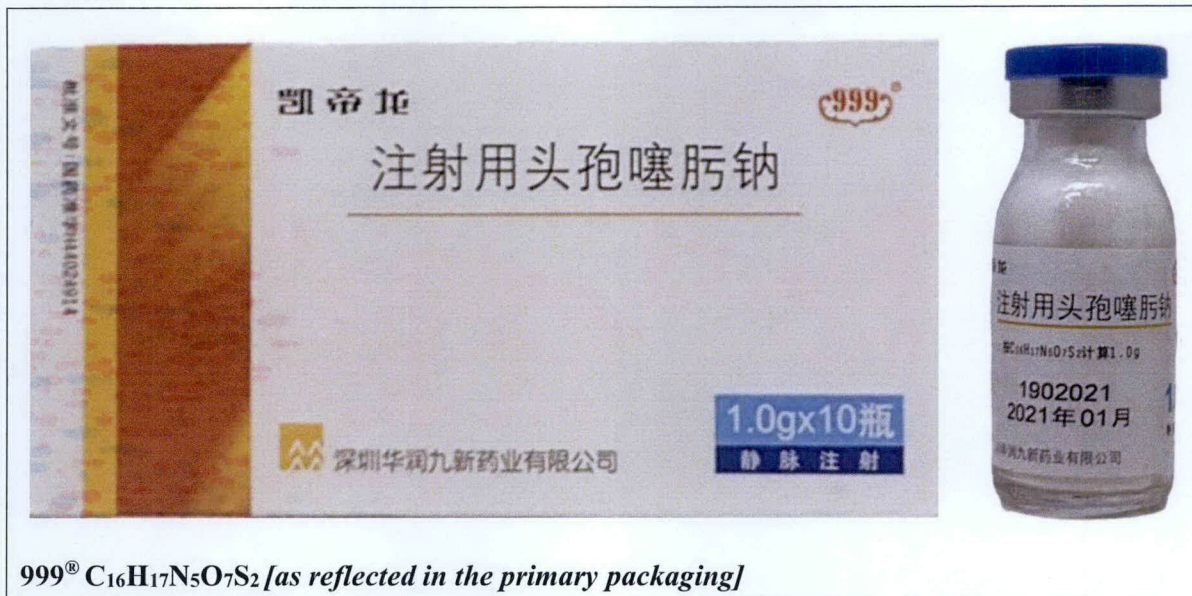
Larawan 1. Hindi rehistradong gamot



Larawan 2. Hindi rehistradong gamot



Larawan 3. Hindi rehistradong gamot



999® C₁₆H₁₇N₅O₇S₂ [as reflected in the primary packaging]

Larawan 4. Hindi rehistradong gamot



Xuefu Zhuyu Jiaonang
TIANJIN HONGRENTANG PHARMACEUTICAL CO., LTD.

Larawan 5. Hindi rehistradong gamot



OTC TASLY® Yangxue Qingnao Keli
TASLY PHARMACEUTICAL GROUP CO., LTD.

Larawan 6. Hindi rehistradong gamot



OTC Xiaoyan Tuire Keli
GUILIN GEXIANWENG PHARMACEUTICAL CO., LTD.

Larawan 7. Hindi rehistradong gamot



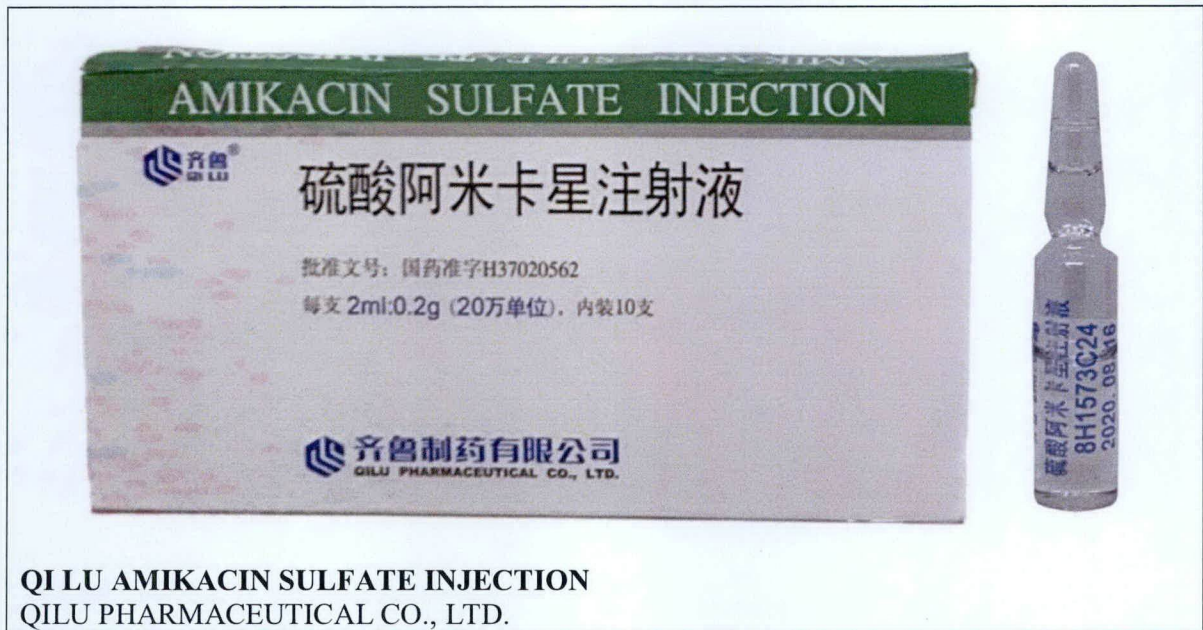
OTC Concentrated Tinidazole Gargles
 ZHEIJANG HACON PHARMACEUTICAL CO., LTD.

Larawan 8. Hindi rehistradong gamot



OTC FANGFENGTONGSHENGWAN

Larawan 9. Hindi rehistradong gamot



Larawan 10. Hindi rehistradong gamot



Larawan 11. Hindi rehistradong gamot



VITAMIN C INJECTION

FUZHOUNEPTUNUS FUYAO PHARMACUTICALS CO., LTD.

Larawan 12. Hindi rehistradong gamot



CEFIXIME CAPSULES Toubaokewo Jiaonang
KUNMING JIDA PHARMACEUTICAL CO., LTD

Larawan 13. Hindi rehistradong gamot



Potassium Chloride Sustained-release Tablets
 Shanghai Haihong Group Chaochu C-Dragon Pharmaceutical Co., Ltd.
 Larawan 14. Hindi rehistradong gamot



[Label in foreign language]
 Guangzhou GloriaJD Healthcare Pharmaceutical CO.LTD
 Larawan 15. Hindi rehistradong gamot



MINGMU JILI WAN [as reflected in the package insert]

Larawan 16. Hindi rehistradong gamot



CSPC Yangxue Shengfa Jiaonang

Larawan 17. Hindi rehistradong gamot



Xiao yan li dan pian

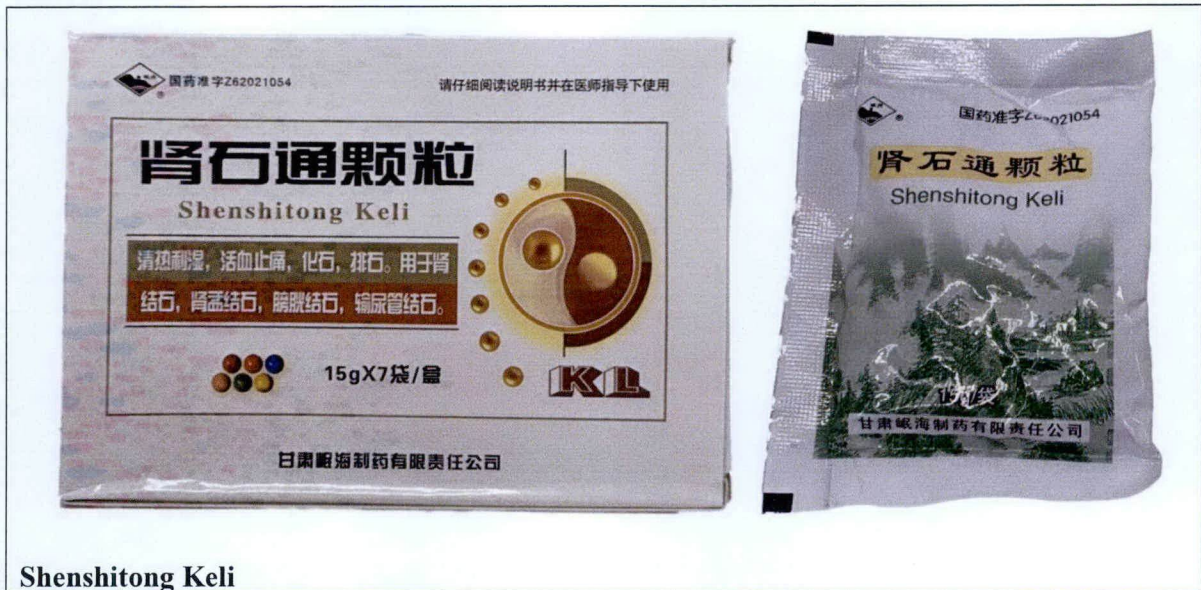
Larawan 18. Hindi rehistradong gamot



Laiting Progesterone Soft Capsules

ZHEIJANG MEDICINE CO., LTD. XINCHANG PHARMACEUTICAL FACTORY

Larawan 19. Hindi rehistradong gamot



Shenshitong Keli

Larawan 20. Hindi rehistradong gamot



Jinsuo Gu Jing Wan

Larawan 21. Hindi rehistradong gamot



[Label in foreign language]
SHINEWAY

Larawan 22. Hindi rehistradong gamot



OTC *[Label in foreign language]*

Larawan 23. Hindi rehistradong gamot



Levofloxacin Hydrochloride and Sodium Chloride Injection

Larawan 24. Hindi rehistradong gamot



Levofloxacin Lactate and Sodium Chloride Injection

Larawan 26. Hindi rehistradong gamot



GLUCOSE INJECTION 5%

Larawan 25. Hindi rehistradong gamot

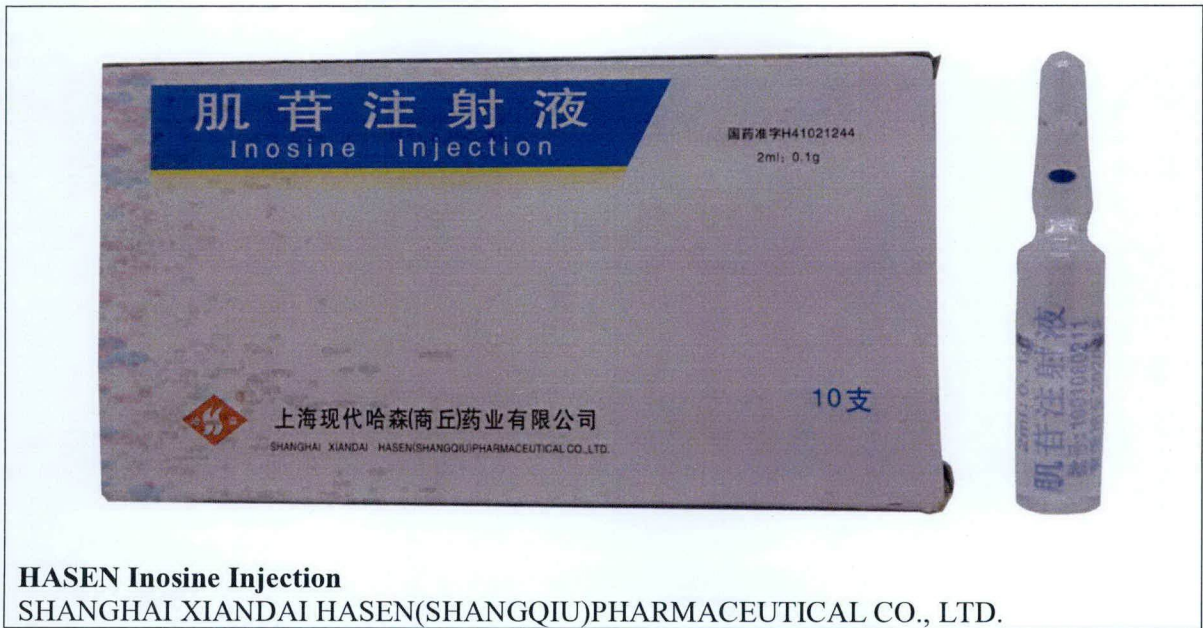


Sodium Chloride Injection 0.9%

Larawan 27. Hindi rehistradong gamot



OTC PIEN TZE HUANG® HUO XIANG ZHENG QI SHUI
 Larawan 28. Hindi rehistradong gamot



HASEN Inosine Injection
 SHANGHAI XIANDAI HASEN(SHANGQIU)PHARMACEUTICAL CO., LTD.
 Larawan 29. Hindi rehistradong gamot

Fufang Anlin Babituo Zhusheyeye 2ml × 10支
每支含氨基比林100mg, 安替比林40mg, 巴比妥18mg

海王 复方氨基比林巴比妥注射液 国药准字H35021458

【成份】本品为复方制剂。其组分为每支含氨基比林100mg, 安替比林40mg, 巴比妥18mg。
【适应症】主要用于急性高热时的紧急退热, 对发热时的头痛症状也有缓解作用。
【性状】本品为无色或微黄色的澄明液体。
【用法用量】肌肉注射 成人一次2ml, 或遵医嘱。在监护情况下极量为一日6ml。 2岁以下: 一次0.5~1ml; 2~5岁: 一次1~2ml; 大于5岁: 一次2ml。 本品不宜连续使用。
【不良反应】过敏性休克, 应立即停药并抢救。(详见说明书)
【禁忌】对吡唑酮类或巴比妥类药物过敏者禁用。(详见说明书)
【注意事项】肌肉注射前应向病人询问是否有吡唑酮类或巴比妥类药物过敏史, 有过敏史者应避免使用本品。(详见说明书)

福州海王福药制药有限公司
FUZHOU NEPTUNUS FUYAO PHARMACEUTICALS CO., LTD.

6 922943 802883

Fufang Anlin Babituo Zhusheyeye
FUZHOU NEPTUNUS FUYAO PHARMACEUTICALS CO., LTD

Larawan 30. Hindi rehistradong gamot

马来酸氯苯那敏注射液 10支
Chlorphenamine Maleate Injection 国药准字H41022116
1ml: 10mg

上海现代哈森(商丘)药业有限公司
SHANGHAI XIANDI HASEN SHANGQI PHARMACEUTICAL CO., LTD.

HASEN Chlorphenamine Maleate Injection
SHANGHAI XIANDI HASEN SHANGQI PHARMACEUTICAL CO., LTD

Larawan 31. Hindi rehistradong gamot



OTC BANLANGEN KELI

Larawan 32. Hindi rehistradong gamot



OTC YINGQIAO JIEDU KELI
GUANGDONG MEDIHEALTH PHARMACEUTICAL CO., LTD.

Larawan 33. Hindi rehistradong gamot



[Label in foreign language]

Larawan 34. Hindi rehistradong gamot



OTC NIUHUANGSHANGQINGPIAN

HENANSHENGBAIQUANZHIIYAOUYOUXIANGONGSI

Larawan 35. Hindi rehistradong gamot



Larawan 36. Hindi rehistradong gamot



Larawan 37. Hindi rehistradong gamot



yatai® Amoxicillin Capsules
ZHEJIANG YATAI PHARMACEUTICAL CO., LTD.

Larawan 38. Hindi rehistradong gamot



yatai® Ceftriaxone Sodium for Injection
Manufacturer: ZHEJIANG YATAI PHARMACEUTICAL CO., LTD.
Zhusheyong Toubaoqusongna

Larawan 39. Hindi rehistradong gamot



yatai® Cefalexin Capsules
ZHEJIANG YATAI PHARMACEUTICAL CO., LTD

Larawan 40. Hindi rehistradong gamot



Fufang Luohanguo Zhike Keli
Guilin Otigh Natural Medicine Company Limited

Larawan 41. Hindi rehistradong gamot



OTC Dong ling cao pian

Larawan 42. Hindi rehistradong gamot



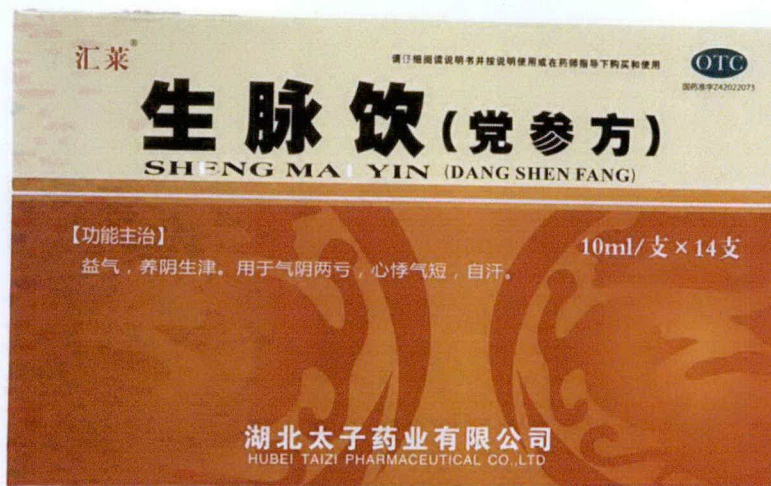
OTC Wu Shi Cha Ke Li

Larawan 43. Hindi rehistradong gamot



Yu Long MINIAONING CAPSULE
EASTANTAI PAHRMACEUTICAL CO., LTD.

Larawan 44. Hindi rehistradong gamot



OTC SHENG MAI YIN (DANG SHEN FANG)
HUBEI TAIZI PHARMACEUTICAL CO., LTD.

Larawan 45. Hindi rehistradong gamot



YABAO Niu Huang Jie Du Pian
Larawan 46. Hindi rehistradong gamot



OTC HUMANWELL HEALTHCARE [as reflected in the secondary packaging]
Larawan 47. Hindi rehistradong gamot



OTC XUANMEI GANJIE KELI

Figure 48. Unregistered drug product

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang nasabing mga gamot ay hindi dumaaan sa proseso ng rehistrasyon o pag-eekamin 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 iligal 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 iligal 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. Maaari ring tingnan ang FDA *Registration number* sa label ng produkto.

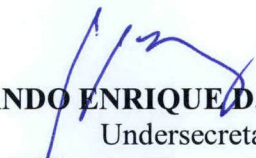
Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga iligal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon, sapagkat kaukulang parusa ay mahigpit na ipatutupad.

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. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-email sa report@fda.gov.ph, o mag-report gamit ang aming *online reporting facility*, *eReport*, sa 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** 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: 
20190809091840