



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2020-1434-A

JUL 29 2020

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

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

1. Chloramphenicol Eye Drops Eye Sight 8ml:20mg
2. Levofloxacin Hydrochloride Tablets 0.1g
3. OTC Sucralfate Chewable Tablets
4. Folic Acid Tablets 5mg
5. SINE® Calcium Gluconate Injection 10ml:1g
6. HUAYI® Vitamin C Injection 2ml:0.5g
7. WY® Metronidazole Tablets 0.2 g
8. Sodium Chloride Injection 0.9% 100 ml
9. Glucose Injection 5% 100 ml
10. QIANGSHEN® Amikacin Sulfate Injection 2ml:0.2g
11. TS® Ribavirin Injection 1ml:0.1g
12. Micronomicin Sulfate Injection 2ml:60mg
13. Jucishan® Ribavirin Injection 1ml:100mg
14. Oxytocin Injection 1ml:10
15. Ceftriaxone Sodium for Injection 1.0g
16. Lysine Acetylsalicylate for Injection 0.9g
17. Potassium Sodium Dehydroandrographolide Succinate for Injection - Zhusheyong Yanhuning 80 mg
18. Progesterone Injection 1ml :20mg
19. OTC Jinsangzi Houpian
[as reflected in the primary packaging]
OTC Golden Throat Lozenge
[as reflected in the secondary packaging]
20. Ornidazole and Sodium Chloride Injection 100 ml
21. Azithromycin for Injection 0.25 g
22. Azithromycin Dispersible Tablets 6's
23. Wing Long Red Flower Oil
24. OTC Ibuprofen Sustained Release Capsule
25. JUCISHAN® Ofloxacin Eye Drops 5ml:15mg
26. Doxycycline Hyclate Tablets



27. yatai® Aciclovir Tablets 0.1 g
28. Imodium® 2mg
29. SPH Furazolidone Tablets
30. Metronidazole and Sodium Chloride Injection 100 ml
31. Methyrosanilinium Chloride Solution
32. Merbromin Solution
33. Fat Emulsion Injection 20% 250 ml
34. OTC Anti-Hemorrhoids Suppository
35. Compound Aminophenazone and Barbitol Injection 2ml
36. Compound Amionpyrine and Antipyrine Injection 2ml
37. Raceanisodamine Hydrochloride Injection 1ml

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



Larawan 1. Hindi rehistradong gamot



Larawan 2. Hindi rehistradong gamot



Larawan 3. Hindi rehistradong gamot



Folic Acid Tablets 5 mg

Larawan 4. Hindi rehistradong gamot



SINE® Calcium Gluconate Injection 10ml:1g

Larawan 5. Hindi rehistradong gamot



Larawan 6. Hindi rehistradong gamot

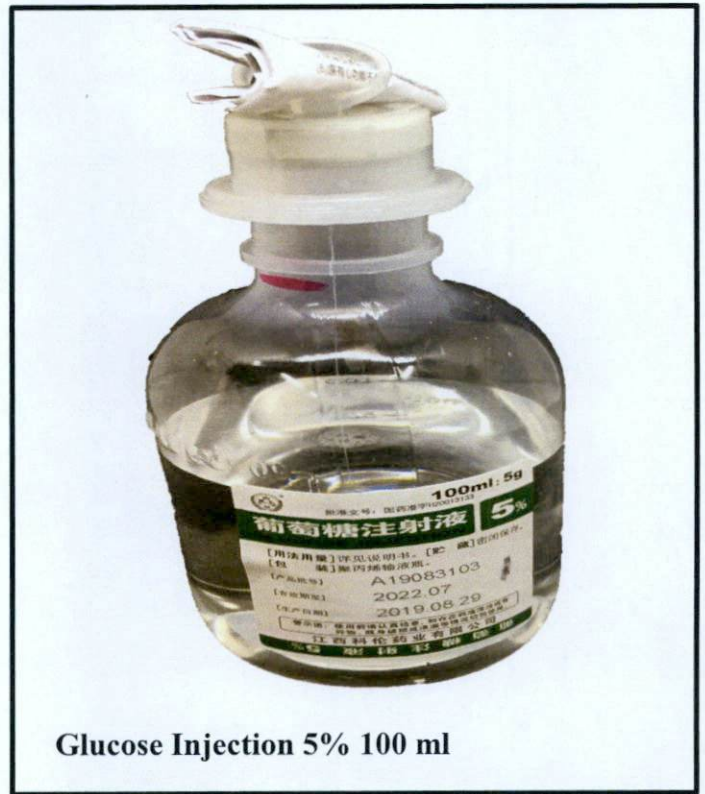


Larawan 7. Hindi rehistradong gamot



Sodium Chloride Injection 0.9% 100 ml

Larawan 8. Hindi rehistradong gamot



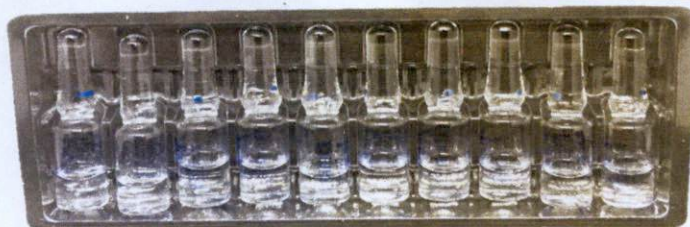
Glucose Injection 5% 100 ml

Larawan 9. Hindi rehistradong gamot



QIANGSHEN® Amikacin Sulfate Injection 2ml:0.2g

Larawan 10. Hindi rehistradong gamot



TS® Ribavirin Injection 1ml:0.1g

by: Hubei Tiansheng Pharmaceutical CO.,LTD.

Larawan 11. Hindi rehistradong gamot



Micronomicin Sulfate Injection 2ml:60mg

by: Jiangxi Pharmaceutical Co. Ltd.

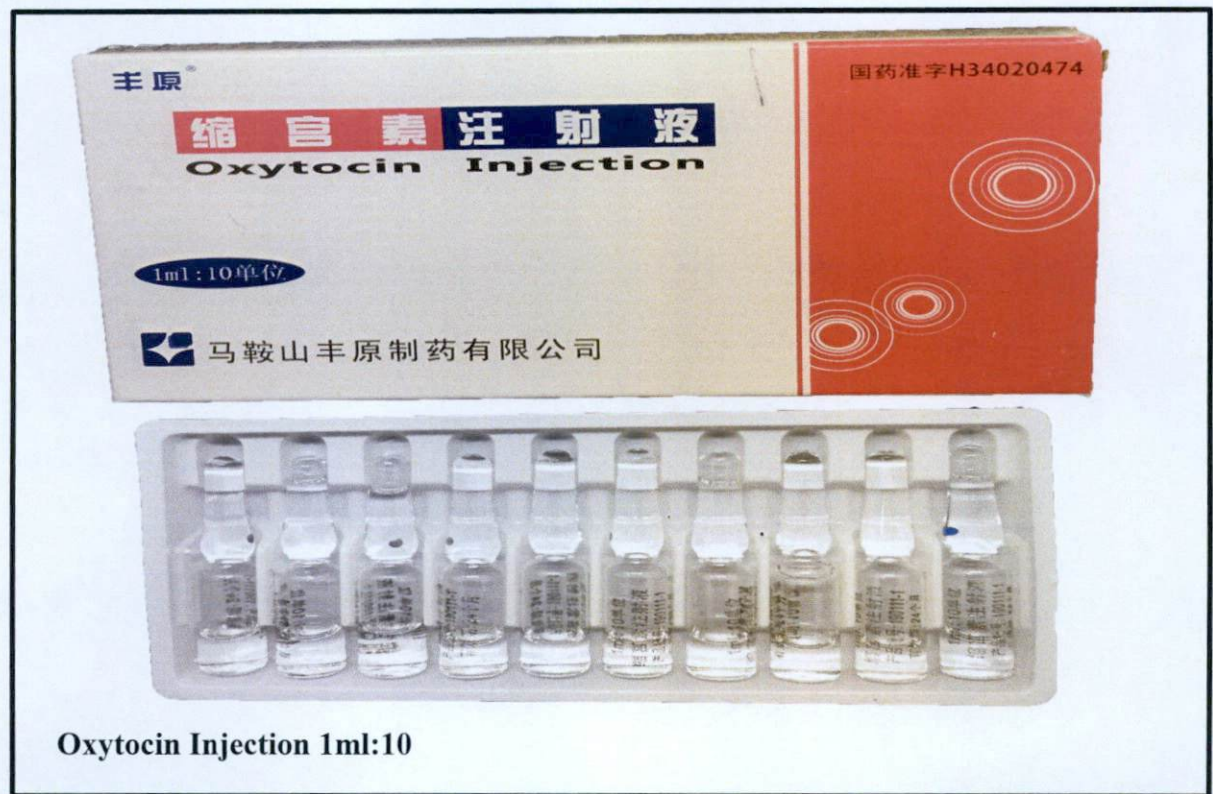
Larawan 12. Hindi rehistradong gamot



Jucishan® Ribavirin Injection 1ml:100mg

by: ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD.

Larawan 13. Hindi rehistradong gamot



Oxytocin Injection 1ml:10

Larawan 14. Hindi rehistradong gamot



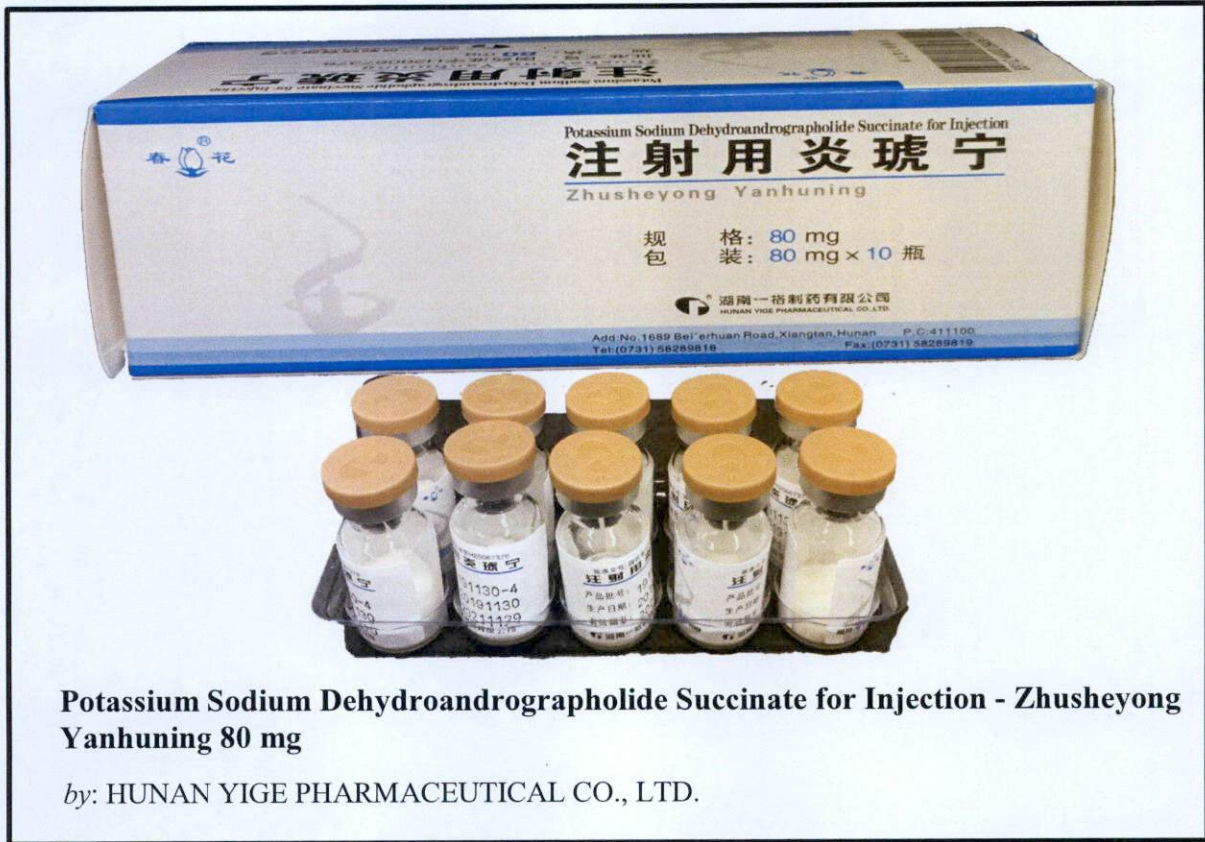
Ceftriaxone Sodium for Injection 1.0g

Larawan 15. Hindi rehistradong gamot



Lysine Acetylsalicylate for Injection 0.9g

Larawan 16. Hindi rehistradong gamot



Larawan 17. Hindi rehistradong gamot



Larawan 18. Hindi rehistradong gamot



Larawan 19. Hindi rehistradong gamot



Larawan 20. Hindi rehistradong gamot



Azithromycin for Injection 0.25 g

by: BRILLIANT PHARMACEUTICAL CO., LTD. HAINAN

Larawan 21. Hindi rehistradong gamot



Azithromycin Dispersible Tablets 6's

Larawan 22. Hindi rehistradong gamot



Wing Long Red Flower Oil

Larawan 23. Hindi rehistradong gamot



OTC Ibuprofen Sustained Release Capsule

Larawan 24. Hindi rehistradong gamot



Larawan 25. Hindi rehistradong gamot



Larawan 26. Hindi rehistradong gamot



yatai® Aciclovir Tablets 0.1 g

by: ZHEJIANG YATAI PHARMACEUTICAL CO., LTD.

Larawan 27. Hindi rehistradong gamot



imodium® 2mg

by: Xian Janssen Pharmaceutical Ltd.

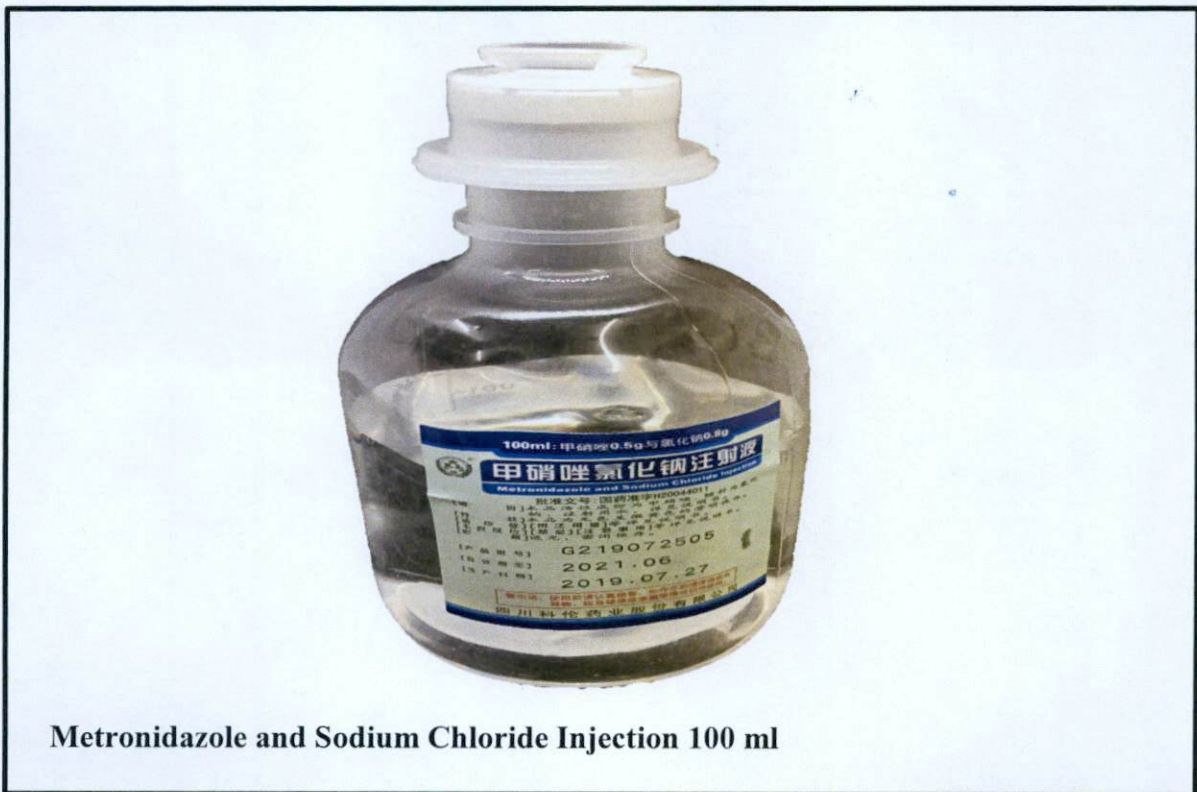
Larawan 28. Hindi rehistradong gamot



SPH Furazolidone Tablets

by: SHANGHAI PHARMA

Larawan 29. Hindi rehistradong gamot



Metronidazole and Sodium Chloride Injection 100 ml

Larawan 30. Hindi rehistradong gamot



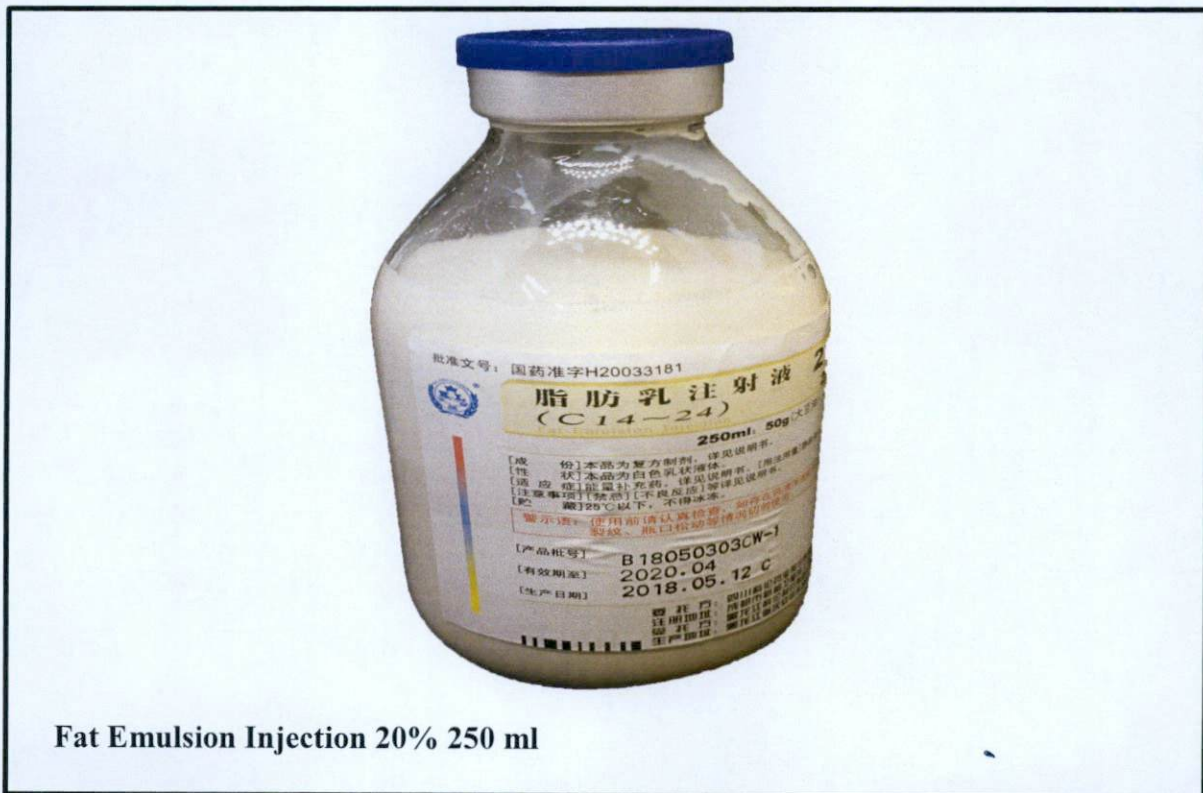
Methyrosanilinum Chloride Solution

Larawan 31. Hindi rehistradong gamot



Merbromin Solution

Larawan 32. Hindi rehistradong gamot



Fat Emulsion Injection 20% 250 ml

Larawan 33. Hindi rehistradong gamot



OTC Anti-Hemorrhoids Suppository

by: YANTAI RONGCHANG PHARMACEUTICAL CO., LTD

Larawan 34. Hindi rehistradong gamot



Compound Aminophenazone and Barbitol Injection 2ml

by: ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD.

Larawan 35. Hindi rehistradong gamot



复方氨林巴比妥注射液
Compound Amionpyrine and Antipyrene Injection

国药准字 H41025231

10支

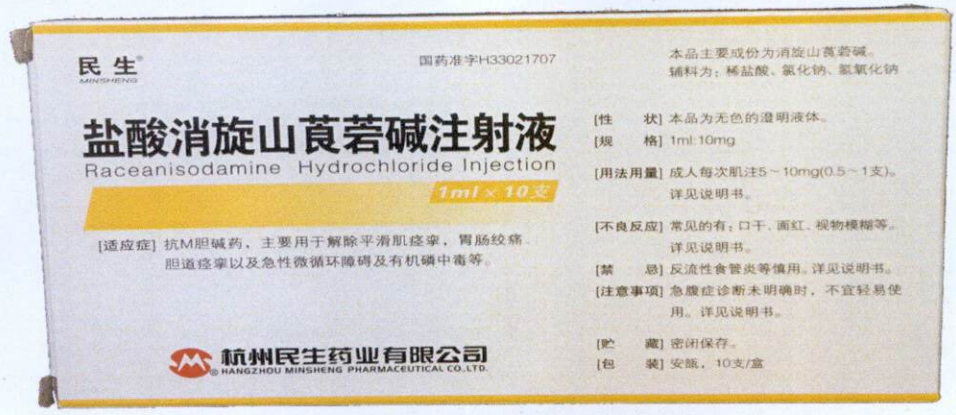
上海现代哈森(商丘)药业有限公司
SHANGHAI XIANDAI HASEN(SHANGQIU)PHARMACEUTICAL CO.,LTD.



Compound Amionpyrine and Antipyrene Injection 2ml

by: SHANGHAI XIANDAI HASEN (SHANGQIU) PHARMACEUTICAL CO.,LTD.

Larawan 36. Hindi rehistradong gamot



民生
MINSHENG

国药准字H33021707

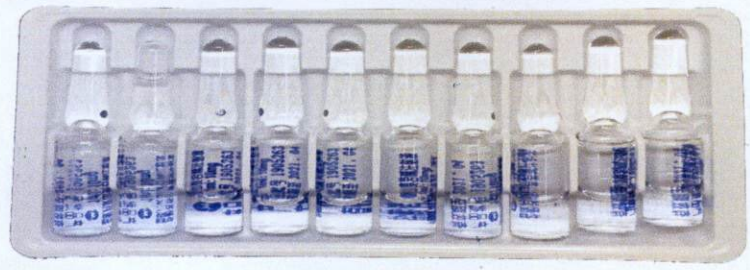
本品主要成份为消旋山莨菪碱。
辅料为：稀盐酸、氯化钠、氢氧化钠

盐酸消旋山莨菪碱注射液
Raceanisodamine Hydrochloride Injection
1ml x 10支

- [性状] 本品为无色的澄明液体。
- [规格] 1ml:10mg
- [用法用量] 成人每次肌注5-10mg(0.5-1支)。详见说明书。
- [不良反应] 常见的有：口干、面红、视物模糊等。详见说明书。
- [禁忌] 反流性食管炎等慎用。详见说明书。
- [注意事项] 急腹症诊断未明确时，不宜轻易使用。详见说明书。
- [贮藏] 密闭保存。
- [包装] 安瓶，10支/盒

[适应症] 抗M胆碱药，主要用于解除平滑肌痉挛，胃肠绞痛、胆道痉挛以及急性微循环障碍及有机磷中毒等。

杭州民生药业有限公司
HANGZHOU MINSHENG PHARMACEUTICAL CO.,LTD.



Raceanisodamine Hydrochloride Injection 1ml

by: HANGZHOU MINSHENG PHARMACEUTICAL CO., LTD.

Larawan 37. Hindi rehistradong gamot

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

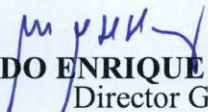
Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

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

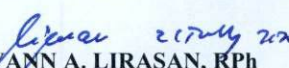

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

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 ereport@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) 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.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 
20200625141933

Center for Drug Regulation and Research	
 MARK RYANN A. LIRASAN, RPh OIC-Chief, PRSDD-CDRR	 JESUSA JOYCE N. CIRUNAY, RPh Director IV

Keywords	<p>Chloramphenicol Eye Drops Eye Sight 8 ml:20mg, by: SHIJIAZHUANGGREA TPHARMACEUTICALCO.,Ltd, Lovofloxacin Hydrochloride Tablets 0.1 g, OTC Sucralfate Chewable Tablets, Folic Acid Tablets 5mg, SINE® Calcium Gluconate Injection 10 ml:1g, HUAYI® Vitamin C Injection 2ml:0.5g, by: Huazhong Pharmaceutical Co., Ltd., WY® Metronidazole Tablets 0.2 g, Sodium Chloride Injection 0.9% 100 ml, Glucose Injection 5% 100 ml, QIANGSHEN® Amikacin Sulfate Injection 2ml:0.2g, TS® Ribavirin Injection 1ml:0.1g, by: Hubei Tiansheng Pharmaceutical CO.,LTD., Micronomicin Sulfate Injection 2ml:60mg, by: Jiangxi Pharmaceutical Co. Ltd., Jucishan® Ribavirin Injection 1ml:100mg, by: ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD., Oxytocin Injection 1ml:10, Ceftriaxone Sodium for Injection 1.0g, Lysine Acetylsalicylate for Injection 0.9g, Potassium Sodium Dehydroandrographolide Succinate for Injection - Zhusheng Yanhuning 80 mg, by: HUNAN YIGE PHARMACEUTICAL CO., LTD., Progesterone Injection 1ml :20mg, OTC Jinsangzi Houpian [as reflected in the primary packaging] OTC Golden Throat Lozenge [as reflected in the secondary packaging], Ornidazole and Sodium Chloride Injection 100 ml, Azithromycin for Injection 0.25 g, by: BRILLIANT PHARMACEUTICAL CO., LTD. HAINAN, Azithromycin Dispersible Tablets 6's, Wing Long Red Flower Oil, OTC Ibuprofen Sustained Release Capsule 20's, JUCISHAN® Ofloxacin Eye Drops 5ml:15mg, by: ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD., Doxycycline Hyclate Tablets, yatai® Aciclovir Tablets 0.1 g, by: ZHEJIANG YATAI PHARMACEUTICAL CO., LTD., imodium® 2mg, by: Xian Janssen Pharmaceutical Ltd., SPH Furazolidone Tablets, by: SHANGHAI PHARMA, Metronidazole and Sodium Chloride Injection 100 ml, Methylrosanilinium Chloride Solution, Merbromin Solution, Fat Emulsion Injection 20% 250 ml, OTC Anti-Hemorrhoids Suppository, by: YANTAI RONGCHANG PHARMACEUTICAL CO., LTD, Compound Aminophenazone and Barbitol Injection 2ml, by: ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO. , LTD., Compound Amionpyrine and Antipyrene Injection 2ml, by: SHANGHAI XIANDAI HASEN (SHANGQIU) PHARMACEUTICAL CO.,LTD., Raceanisodamine Hydrochloride Injection 1ml, by: HANGZHOU MINSHENG PHARMACEUTICAL CO., LTD.</p>
Related issuances, laws, directives	Republic Act No. 9711 and its Implementing Rules and Regulations