



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-386**

15 OCT 2019

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. OTC YUNNAN BAIYAO QIWUJI
2. CISEN GENTAMICIN SULFATE INJECTION
3. PANTOPRAZOLE SODIUM ENTERIC-COATED TABLETS
4. YATAI® AZITHROMYCIN FOR INJECTION
5. ERYTHROMYCIN ENTERIC-COATED TABLETS
6. OTC NAOXINSHU KOUFUYE
7. OTC YESUANPIAN [as reflected in the primary and secondary packaging]
FOLIC ACID TABLET [as reflected in the package insert]
8. OTC CETIRIZINE HYDROCHLORIDE TABLETS
9. KANGMEI MCKIN VITAMIN C TABLET (WITH LEMON)
10. KANGMEI MCKIN VITAMIN C TABLET (WITH BLUEBERRIES)
11. C
12. BIOHEK BAIHEKANG BRAND VITAMIN C LOZENGE
13. HUAYI® DEXAMETHASONE SODIUM PHOSPHATE INJECTION
14. DONGYAO ETHAMSYLATE INJECTION
15. CEFOPERAZONE SODIUM AND SULBACTAM SODIUM FOR INJECTION
16. SPECTINOMYCIN HYDROCHLORIDE FOR INJECTION [as reflected in the primary and secondary packaging-Vial]
CISEN BENZYL ALCOHOL INJECTION
[as reflected in the package insert-Ampoule]
17. OTC QINGXUAN PIAN
18. YATAI® ACICLOVIR FOR INJECTION
19. OTC ZHIKEPIPA KELI
20. SUXIAOJIUXINWAN
21. XINYAXILE DANSHENZHUSHEYE
22. ZHEN ZHU MING MU YAN BU HU LI YE
23. 1 YI LHENG ZHUIFENGSHU JINGHUO XUEPIAN
24. TONGREN DAHUOLUO WAN
25. YANGXUE SHENGFA JIAONANG
26. CNWM YOUNG UI WAN
27. CONBA JIXUEGANSHUANG RUANGAO



28. YUSHANPAI LONGXUEJIE JIAONANG
29. ORIGINAL® PEPPERMINT AQUA
30. PIFUBING XUEDU WAN
31. ZUYAXI FEBUXOSTAT TABLETS
32. OTC CONCENTRATED TINIDAZOLE GARGLES
33. VALACICLOVIR HYDROCHLORIDE TABLETS
34. ACYCLOVIR EYE DROPS
35. OTC NAPHAZOLINE HYDROCHLORIDE NASAL DROPS
36. SINE® DICLOFENAC SODIUM SUSTAINED-RELEASE TABLETS
37. XIAONUO NORFLOXACIN CAPSULES
38. COMPOUND KETOCONAZOLE LOTION
39. TINIDAZOLE AND SODIUM CHLORIDE INJECTION
40. OTC NIN JIOM PEI PA KOA
41. ROXITHROMYCIN TABLETS
42. CEFUROXIME AXETIL TABLETS
43. YATAI® PHENOXYMETHYLPENICILLIN POTASSIUM TABLETS
44. YATAI® AMOXICILLIN CLAVULANATE POTASSIUM DISPERSIBLE TABLETS
45. HALCINONIDE SOLUTION
46. VITAMIN B6 INJECTION

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:

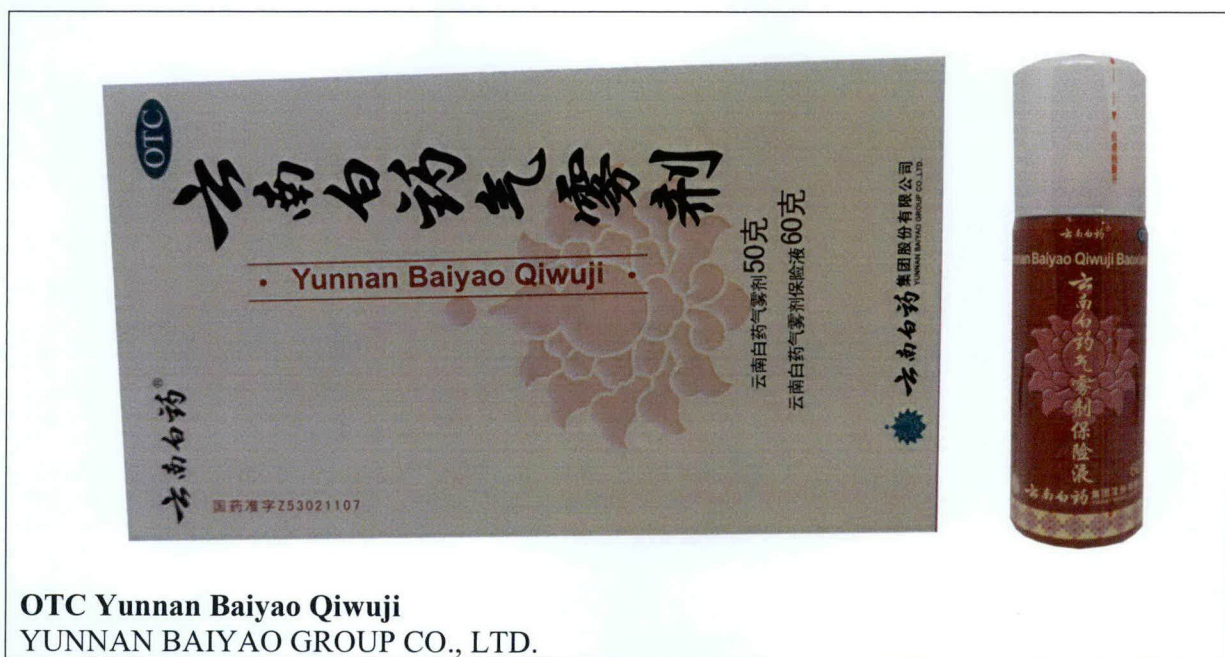


Figure 1. Unregistered drug product



Figure 2. Unregistered drug product



Figure 3. Unregistered drug product



Figure 4. Unregistered drug product



Figure 5. Unregistered drug product

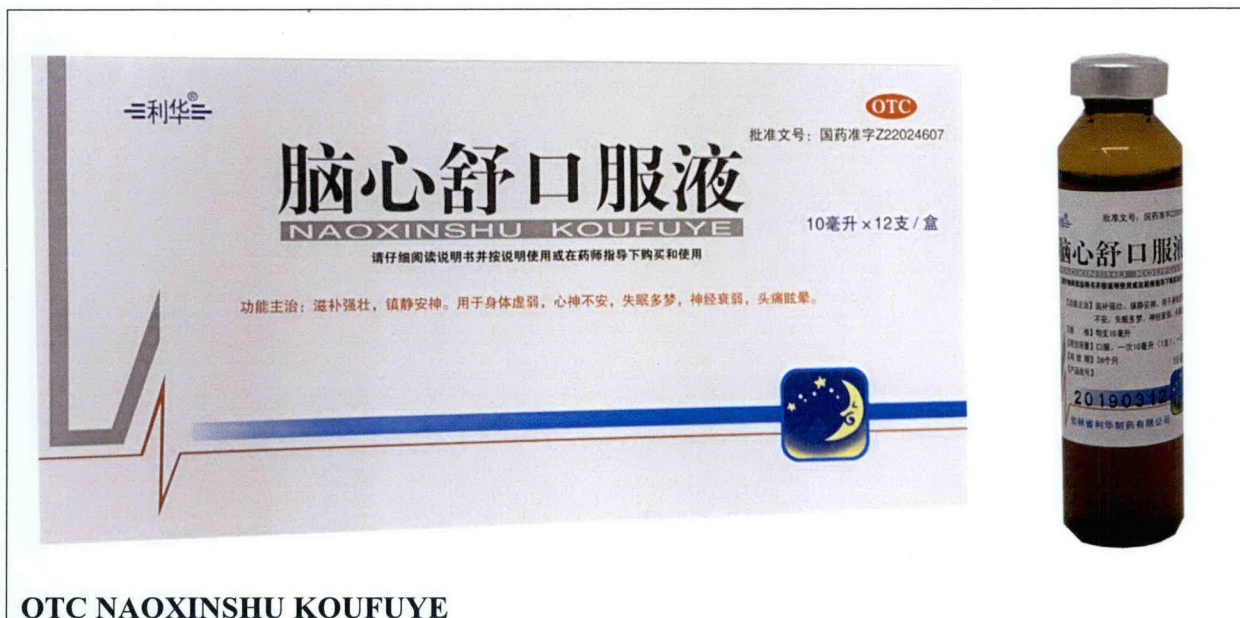
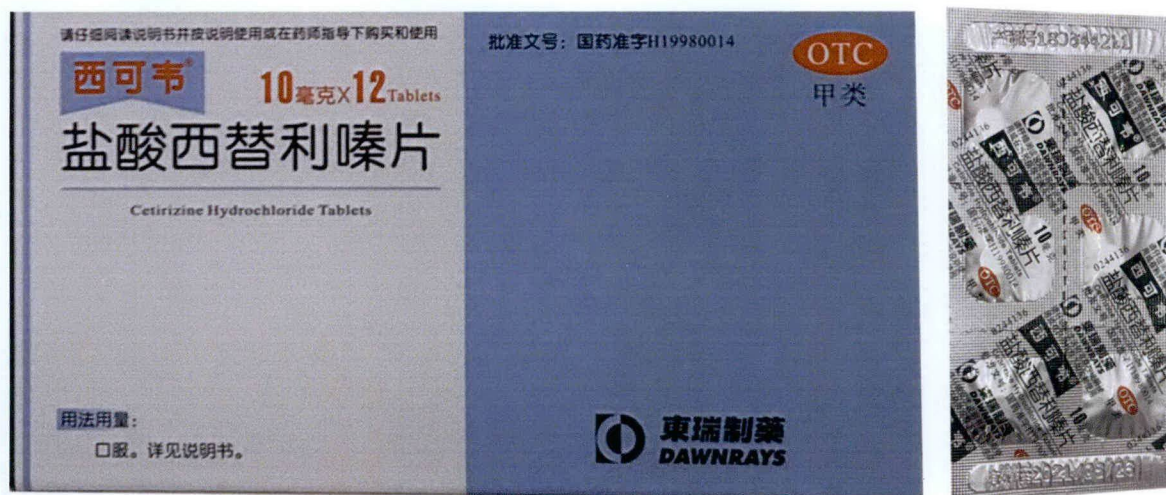


Figure 6. Unregistered drug product



Figure 7. Unregistered drug product



OTC Cetirizine Hydrochloride Tablets
DAWN RAYS

Figure 8. Unregistered drug product



Kangmei MCKIN Vitamin C Tablet (with lemon)

Figure 9. Unregistered drug product



Kangmei MCKIN Vitamin C Tablet (with blueberry)

Figure 10. Unregistered drug product



Figure 11. Unregistered drug product



Figure 12. Unregistered drug product



Figure 13. Unregistered drug product



Figure 14. Unregistered drug product



Figure 15. Unregistered drug product



Spectinomycin Hydrochloride for Injection
 [as reflected in the primary and secondary packaging-Vial]
CISEN Benzyl Alcohol injection [as reflected in the package insert-Ampoule]
 SHANDONG LUKANG PHARMACEUTICAL CO., LTD

Figure 16. Unregistered drug product



OTC Qingxuan Pian
 LongFar

Figure 17. Unregistered drug product



Figure 18. Unregistered drug product

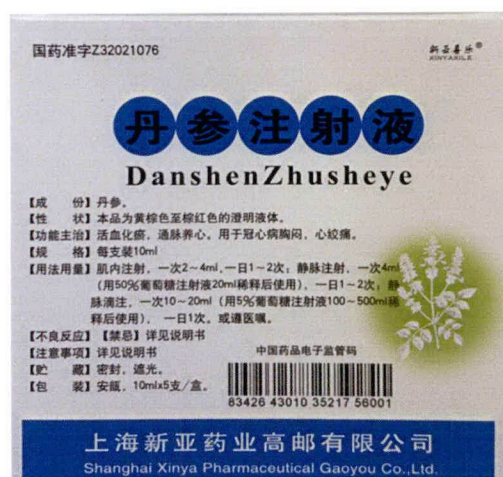


Figure 19. Unregistered drug product



SUXIAOJIUXINWAN

Figure 20. Unregistered drug product



XINYAXILE DanshenZhusheye Shanghai Xinya Pharmaceutical Gaoyou Co., Ltd.

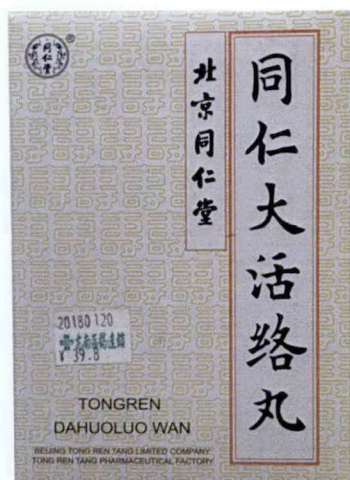
Figure 21. Unregistered drug product



Figure 22. Unregistered drug product

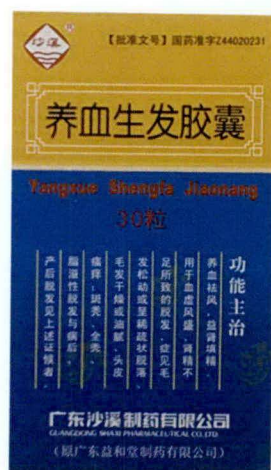


Figure 23. Unregistered drug product



TONGREN DAHUOLUO WAN
 BEIJING TONG REN TANG LIMITED COMPANY
 TONG REN TANG PHARMACEUTICAL FACTORY

Figure 24. Unregistered drug product



Yangxue Shengfa Jiaonang
 GUANGDONG SHAXI PHARMACEUTICAL CO., LTD

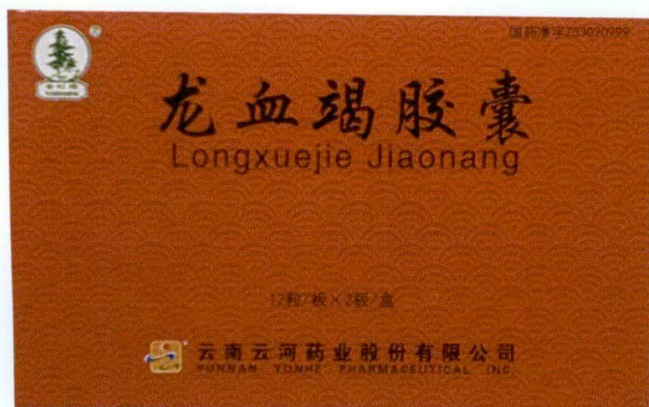
Figure 25. Unregistered drug product



Figure 26. Unregistered drug product



Figure 27. Unregistered drug product



YUSHANPAI Longxuejie Jiaonang
YUNNAN YUNHE PHARMACEUTICAL INC.

Figure 28. Unregistered drug product



ORIGINAL® PEPPERMINT AQUA

Figure 29. Unregistered drug product



Pifubing Xuedu Wan
Figure 30. Unregistered drug product



ZUYAXI FEBUXOSTAT TABLETS
HANGZHOU ZHUYANGXIN PHARMACEUTICAL CO., LTD.
Figure 31. Unregistered drug product



Figure 32. Unregistered drug product



Figure 33. Unregistered drug product



Figure 34. Unregistered drug product



Figure 35. Unregistered Drug Product



Figure 36. Unregistered drug product



Figure 37. Unregistered Drug Product



Figure 38. Unregistered drug product

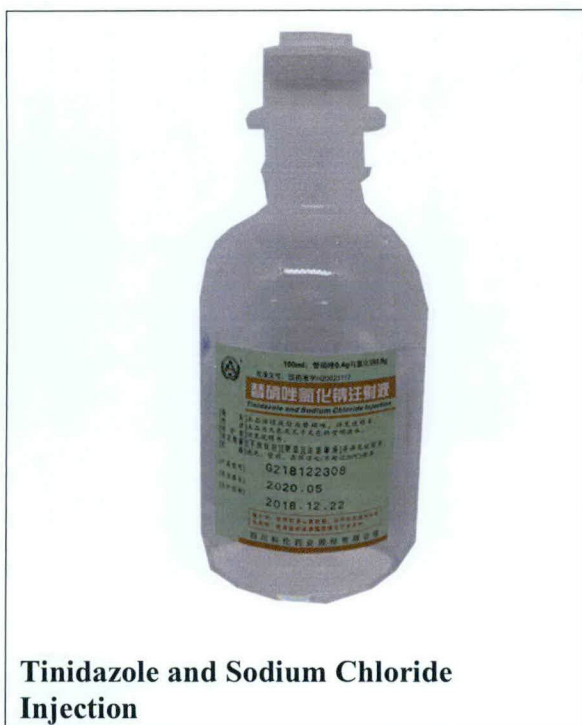


Figure 39. Unregistered drug product

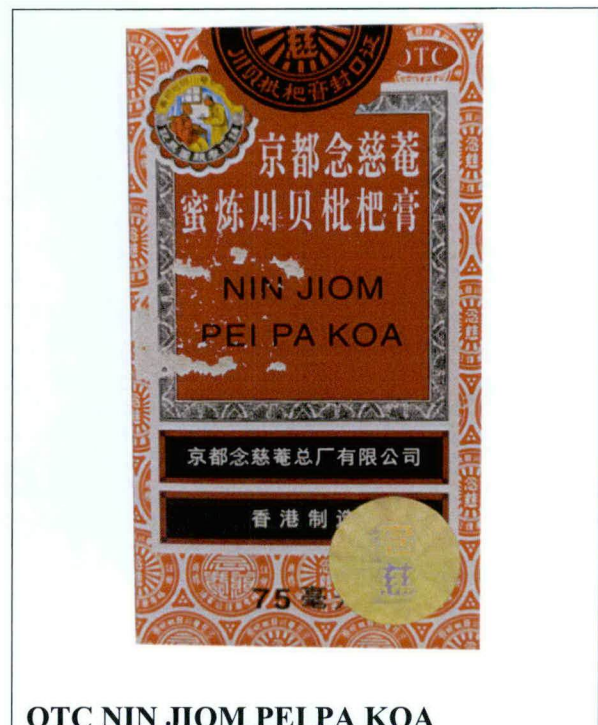


Figure 40. Unregistered Drug Product



Figure 43. Unregistered drug product



Figure 44. Unregistered drug product



Figure 45. Unregistered drug product

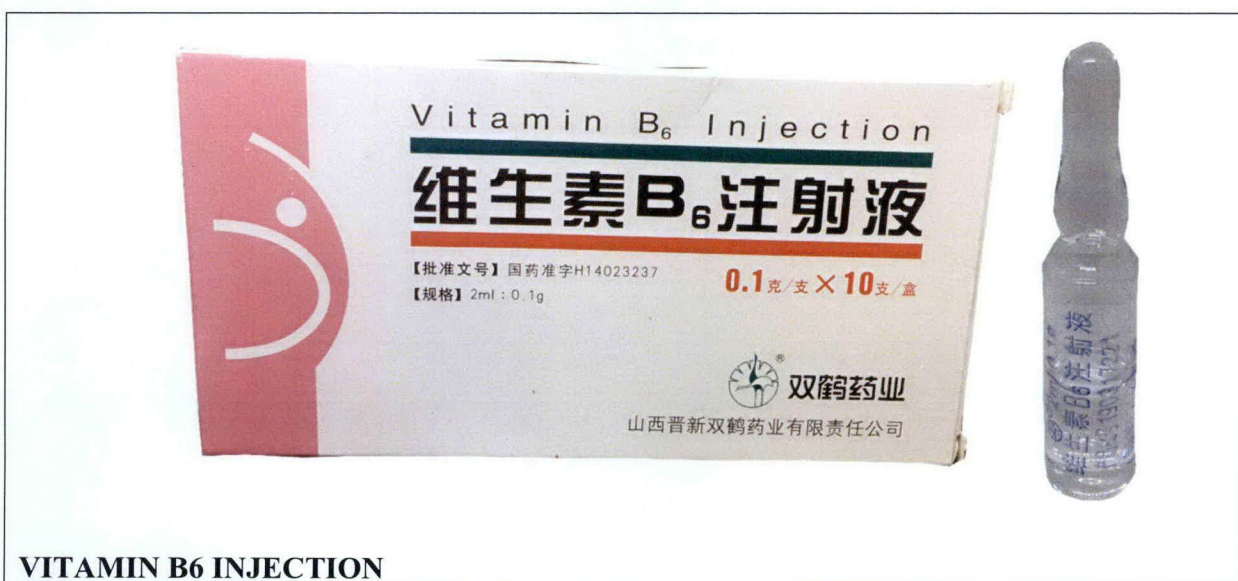


Figure 46. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration and testing process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality and safety. The consumption of such violative products may pose potential danger or injury if administered.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

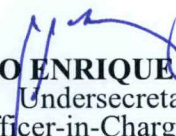
In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against it. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number (02)809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Undersecretary of Health
Officer-in-Charge, Director General

DTN: 
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