



13 OCT 2021

FDA ADVISORY
No. **2021-2499**

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 Tongbianling Jiaonang**
2. **OTC Northeast Pharm Bacillus Licheniformis Capsule, Live-Diyiyabaoganjun Huojun Jiaonang [as reflected in the package insert]**
3. **OTC Si Ji Gan Mao Pian**

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



整肠生 OTC

地衣芽孢杆菌活菌胶囊

【适应症】用于细菌或真菌引起的急、慢性肠炎、腹泻。也可用于其他原因引起的肠道菌群失调的防治。

每粒含 2.5 亿活菌
6粒/板/盒 每粒0.25克

东北制药
NORTHEAST PHARM

6粒

整肠生 OTC

地衣芽孢杆菌活菌胶囊说明书

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

【药品名称】
通用名称：地衣芽孢杆菌活菌胶囊
商品名称：整肠生
英文名称：Bacillus Licheniformis Capsule, Live
汉语拼音：Diyibaoganjun Huojun Jiaonang

【成份】本品为特选地衣芽孢杆菌经现代生物技术培养不含有害物质，经科学方法处理，制成。

【性状】本品为白色或淡黄色颗粒状。

【作用类别】本品为肠道益生菌类药物。

【适应症】用于细菌或真菌引起的急、慢性肠炎、腹泻。也可用于其他原因引起的肠道菌群失调的防治。

【规格】每粒含2.5亿活菌。

【用法用量】口服。成人：一次2粒，一日3次；儿童：一次1粒，一日3次；首次加倍。对不能咀嚼者，服用时可打碎服用。将药粉加入少量温开水中或凉开水中服用。

【不良反应】个别患者可见便秘。

【禁忌】尚不明确。

【注意事项】
1. 本品为益生菌，服用时及服用后应避免服用抗生素类药物。

OTC Northeast Pharm Bacillus Licheniformis Capsule, Live
Diyiyabaoganjun Huojun Jiaonang [as reflected in the package insert]
by: Northeast Pharmaceutical Group Shenyang No.1 Pharmaceutical Group Co., Ltd.

Figure 2. Unregistered drug product

津舒康[®] 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

国药准字 Z20083397

四季感冒片
SI JI GAN MAO PIAN

【功能主治】
清热解表。用于四季风寒感冒引起的发热头痛，鼻流清涕，咳嗽口干，咽喉疼痛，恶心厌食。

15片 x 2板

长春人民药业集团有限公司
CHANGCHUN PEOPLE PHARMACEUTICAL GROUP CO., LTD.

OTC Si Ji Gan Mao Pian
by: Changchun People Pharmaceutical Group Co., Ltd.

Figure 3. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration 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, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.


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.

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. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <http://verification.fda.gov.ph>.

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 ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Director General

DTN:



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