

FDA ADVISORY
No. **2024-0640**

18 APR 2024

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 Shumi Jiaonang [as reflected in package insert]
2. OTC LN Bromhexine Hydrochloride Tablets
3. Nin Jiom Pei Pa Koa [Label in foreign language]
4. Echeng Qianbai Biyan Pian Tablet

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

The image displays the packaging and insert for OTC Shumi Jiaonang (Constipation-relief Capsule). The top left shows the product box with the brand name '舒秘胶囊' (Shumi Jiaonang) and 'OTC' marking. The box text includes: '批准文号: 国药准字B20040016', '功能主治: 清热通便', '用于功能性便秘属热秘者', '包装: 铝塑, 10粒/盒', and '福州辰星药业有限公司 FUZHOU CHENXING PHARMACEUTICAL CO., LTD.'. The top right shows a blister pack of capsules and a small packet of capsules. The bottom left shows the back of the box with detailed information: '成份: 芦荟, 辅料为硬脂酸镁。', '性状: 本品为胶囊剂, 内容物为暗褐色或深褐色的粉末或颗粒; 味极苦。', '功能主治: 清热通便, 用于功能性便秘属热秘者。', '用法用量: 口服, 每晚睡前2粒。', '规格: 每粒装0.3克', '贮藏: 密封。', '包装: 铝塑, 10粒/盒。', '注意事项: 忌服辛辣刺激性食物等详见说明书。', '不良反应、禁忌: 尚不明确。', '生产日期: 2023/07/05', '产品批号: 20230705', '有效期至: 2024/07/04'. The bottom right shows the product insert with the title '舒秘胶囊说明书' and 'OTC 甲类' marking. The insert text includes: '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】: 舒秘胶囊', '通用名称: 舒秘胶囊', '汉语拼音: Shumi Jiaonang', '【成 份】: 芦荟, 辅料为硬脂酸镁。', '【性 状】: 本品为胶囊剂, 内容物为暗褐色或深褐色的粉末或颗粒, 味极苦。', '【功能主治】: 清热通便, 用于功能性便秘属热秘者。', '【规 格】: 每粒装0.3克', '【用法用量】: 口服, 每晚睡前2粒。', '【不良反应】: 尚不明确。'

OTC Shumi Jiaonang [as reflected in package insert]
Manufactured by: Fuzhou Chenxing Pharmaceutical Co.,Ltd





OTC LN Bromhexine Hydrochloride Tablet

Figure 2. Unregistered drug product



Nin Jiom Pei Pa Koa [Label in foreign language]

Manufactured by: Nin Jiom Medicine Manufactory (Hong Kong) Ltd.

Note: The registered Nin Jiom Pei Pa Koa has Registration no. THPR-35.

Manufactured by: Nin Jiom Medicine Manufactory (Hong Kong) Ltd.

Imported by: Jelma Philippines, Inc.

Figure 4. Unregistered drug product



Echeng Qianbai Biyan Pian Tablet

Figure 4. 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 <https://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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