

FDA ADVISORY
No. **2024-0334**

21 FEB 2024

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Himalaya® Koflet® Cough Syrup 100 mL
2. ZANDU Nityam Ayurvedic Vati Castor Oil Shakti Tablet
3. SHETH BROTHERS Ayurvedic Kayam® Tablet
4. INTAS Sildenafil Citrate Tablets I.P. 100 mg Intagra 100

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





Himalaya® Koflet® Cough Syrup 100 mL

Manufactured by: Himalaya Wellness Company

(20) No. 182, Village Gurumajra, Kishanpura, Tehsil Nalagarh 174 101, Dist. Solan (H.P.)

(25) Village Kunja, Rampur Road, Tehsil Paonta Sahib, Dist. Sirmour 173 025, H.P.

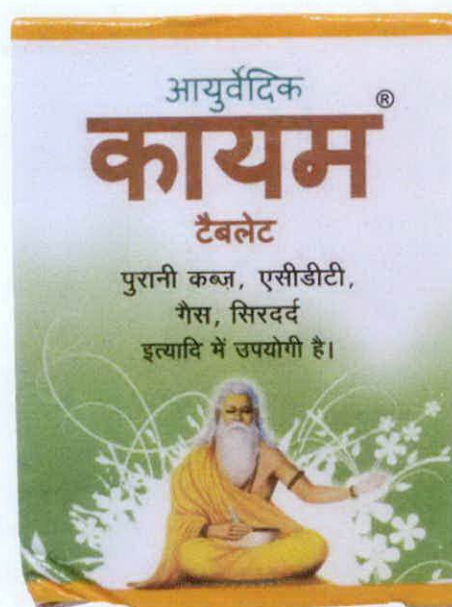
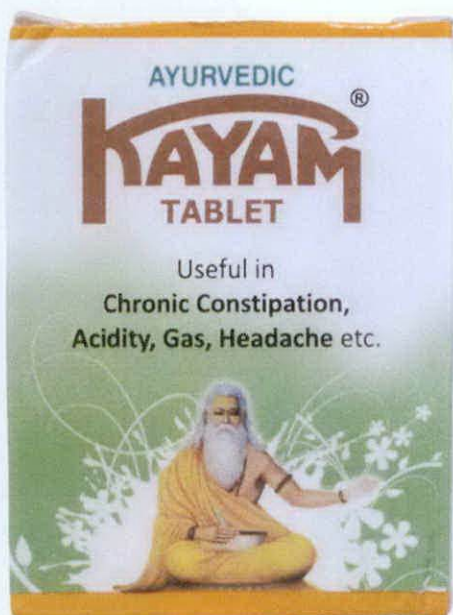
Figure 1. Unregistered drug product



ZANDU Nityam Ayurvedic Vati Castor Oil Shakti Tablet

Manufactured by: Emami Limited - Survey No. 61/2P/1- MASAT, Silvassa, D & NH(U.T.)- 396230.

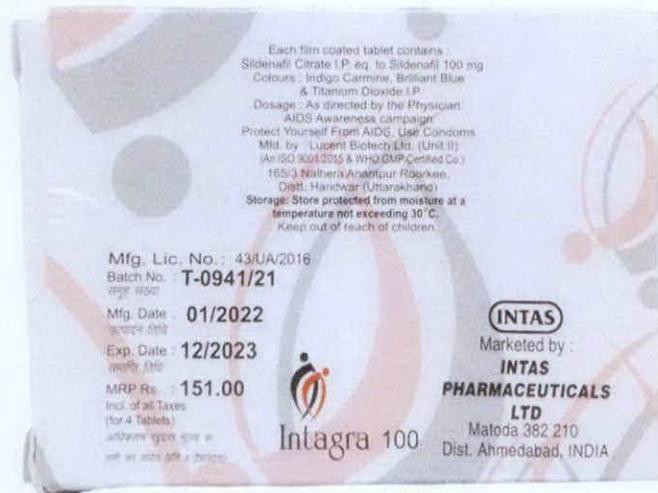
Figure 2. Unregistered drug product



SHETH BROTHERS Ayurvedic Kayam® Tablet

Manufactured by: SHETH BROS. – 30, G.I.D.C. Vithalwadi, Bhavnagar – 364001. Gujarat (India)

Figure 3. Unregistered drug product



INTAS Sildenafil Citrate Tablets I.P. 100 mg Intagra 100

Manufactured by: Lucent Biotech Ltd. (Unit II) – 165/3 Nalhera Anantpur Roorkee, Distt. Haridwar (Uttarakhand)

Figure 4. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product 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 product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is 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 this product is 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.


DR. SAMUEL A. ZACATE
Director General

DTN:



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Keywords	Himalaya® Koflet® Cough Syrup 100 mL, ZANDU Nityam Ayurvedic, Vati Castor Oil Shakti Tablet, SHETH BROTHERS Ayurvedic Kayam® Tablet, INTAS Sildenafil Citrate Tablets I.P. 100 mg Intagra 100.
Related issuances, laws, directives	Republic Act No. 9711 and its Implementing Rules and Regulations