

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION

## FDA JAMINISTRATION PHILIPPINES

0 3 FEB 2022

FDA ADVISORY No. 2022-0069

TO

: ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of the

Following Unregistered Drug Products:

1. Piracetam Tablets 800 mg. Piratican 800

2. Anastrozole Tablets IP 1 mg Anaridex® 1x10 Tablets

3. Bimatoprost Ophthalmic Solution 0.03% w/v Bimat Eye Drops 3 mL

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



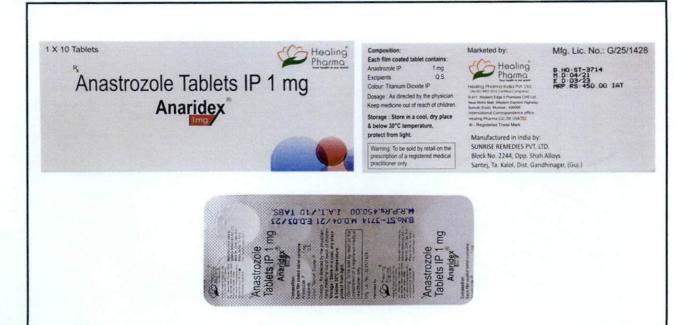
#### Piracetam Tablets 800 mg. Piratican 800

Manufactured by: Elikem Pharmaceutical Private Limited - 816/1, Ta. Kaloi, Dist. Gandhinagar, Guj, 382721

Manufactured for: American Remedies Healthcare Pvt. Ltd. - 307, Gundecha Ind. Complex, Akurli Road, Kandivali East, Mumbai - 400 101, Maharashtra, India

Figure 1. Unregistered drug

Management System ISO 9001:2015



## Anastrozole Tablets IP 1 mg Anaridex® 1x10 Tablets

Manufactured by: Sunrise Remedies Pvt. Ltd. – Block No. 2244, Opp. Shah Alloys Santej, Ta. Kalol, Dist. Gandhinagar, (Guj.)

Marketed by: Healing® Pharma India Pvt. Ltd. - B-411, Eastern Edge II Premises CHS Ltd, Near Metro Mall, Western Express Highway, Borivali (East), Mumbai-400066

Figure 2. Unregistered drug



### Bimatoprost Ophthalmic Solution 0.03% w/v Bimat Eye Drops 3 mL

Manufactured by: Ajanta Pharma Limited - Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128, Regd Office: Ajanta House, Charkop, Kandivli (W), Mumbai 400067

Figure 3. Unregistered drug

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 aboveidentified 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.whoumc.org/Reporting/Reporter?OrganizationID=PH and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. OSCAR & GUTIERREZ, JR. Officer-in-Charge Director General

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