



FDA ADVISORY
No. **2018-084**

16 MAR 2018

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. HEALING EYE DROPS
2. HEALING GALING EC Healing Oil
3. NUMOTIZINE CATAPLASM
4. HEALING GALING LIQUID CALCIUM

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



HEALING EYE DROPS

Figure 1. Unregistered drug product





HEALING GALING EC Healing Oil

Figure 2. Unregistered drug product

<p>NUMOTIZINE[®] CATAPLASM</p> <p>安樂大仙消炎膏</p> <p> For External Use Only</p> <p>H Numotizine Cataplastm aids in relieving pain and soreness of minor chest colds, sprains, muscular aches, skin irritations, insect bites, external pain of a sore throat and related conditions.</p> <p>Numotizine Cataplastm provides sustained comfort, permitting uninterrupted rest for a prolonged period.</p> <p>Keep this and all medications out of the reach of children</p> <p><small>HOBART LABORATORIES, INC., BEMIDJI, MN 56601 U.S.A.</small></p>	<p>NUMOTIZINE[®] CATAPLASM</p> <p>安樂大仙消炎膏</p> <p> 家庭工廠 必備良藥 (外用藥膏)</p> <p>主治： 跌打扭傷 肌肉酸痛 昆蟲咬傷 喉嚨疼痛 消炎止痛</p> <p>美國 HOBART 藥廠製造</p>
<p>NUMOTIZINE[®] CATAPLASM</p> <p>安樂大仙消炎膏</p> <p> NET WT. 3.5 OZS. (99 GRAMS)</p> <p>H APPLICATION - Spread 1/8" to 1/4" thick on cloth and apply in contact with the skin. Bandage to keep in place. Numotizine Cataplastm can also be applied directly to the skin and then bandaged. Remove before it becomes totally dry (usually 8 to 12 hours). Repeat applications as desired.</p> <p>CAUTION Apply according to directions and in no case to large areas of the body. In all cases of excessive temperature or persistent swellings consult your physician. Discontinue use if excessive irritation of the skin develops. Avoid contact with eyes or mucous membranes.</p>	<p>NUMOTIZINE[®] CATAPLASM</p> <p>安樂大仙消炎膏</p> <p> NET WT. 3.5 OZS. (99 GRAMS)</p> <p>H 使用方法： 安樂大仙使用時不宜擇於過大範圍，宜先調勻在厚布上，再敷在患處，用繃帶包紮，防止脫落，每天一至二次</p> <p>注意： 如患者有發高燒及持續腫痛，應速由醫生診治 請將此藥物放置於兒童不能取得的地方</p> <p><small>NUMOTIZINE[®] Trade Mark Reg. Printed and Mfd. in USA</small></p>

NUMOTIZINE CATAPLASM

Manufactured by – HOBART LABORATORIES, INC. BEMIDJI, MN 56601. U.S.A.
Agent & Importer – TIN CHUN TRADING CO. – FLAT/RM F, BLK 4, 6/F
GOLDEN DRAGON IND CTR 182-190 TAI LIN PAI RD KWAI CHUN NEW TERRITORIES

Figure 3. Unregistered drug product



HEALING GALING LIQUID CALCIUM

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 Certificates of Product Registration.

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.

Accordingly, since these unregistered drug products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee their quality and safety. The consumption of such violative products may pose potential danger or injury if administered.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. 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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Director General



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