



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



14 AUG 2019

FDA ADVISORY
No. 2019-110-A

TO: THE GENERAL PUBLIC

SUBJECT: Lifting the Advisory on the Following Registered Medical Devices under FDA Advisory No. 2019 – 110 “HR™ Lubricating Jelly One Shot”

The Food and Drug Administration (FDA) informs the public that the HR™ Lubricating Jelly One Shot has been registered by the Market Authorization Holder (MAH), Berovan Marketing Inc., with FDA registration number MDR-06020A in accordance to existing FDA rules and regulations.

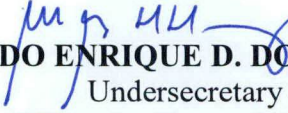
Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2019-110 is hereby lifted.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph, or call **(02) 857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device products, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
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Officer-in-Charge, Director General

DTN 20190311082101

