Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

09 AUG 2021

FDA ADVISORY
No. 2021-1678-A

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Lifting of the FDA Advisory No. 2021-1678 entitled "Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product Long Bone Plaster of Paris Bandage (6" x 5y)"**

The Food and Drug Administration (FDA) informs all healthcare professionals and general public that the medical device product **Long Bone Plaster of Paris Bandage (6" x 5y)** has been registered by the Market Authorization Holder (MAH), Skeletal Support Inc., 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. 2021-1678 dated 06 July 2021 is hereby lifted.

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 existing laws, rules, and regulations.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph** or call **(02) 8857-1900 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**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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