

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2021 - 2034 - A 2 1 MAR 2022

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Lifting of the FDA Advisory No. 2021-2034 entitled "Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product RC SERIES RC-98

RM"

The Food and Drug Administration (FDA) informs all healthcare professionals and general public that the medical device product **RC Series RC-98 RM** has been notified 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. 2021-2034 dated 10 August 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 unnotified medical device, contact the online reporting facility, **eReport**, through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

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

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