

04 APR 2024

FDA ADVISORY

No. 2022-1544 -A

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting of the FDA Advisory No. 2022-1544 entitled Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product "Mr. DIY Reading Glasses"

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, Unnotified Mr. DIY Reading Glass, has been issued an FDA Certificate of Medical Device Notification (CMDN) to the Market Authorization Holder (MAH), Bricolage Philippines Inc., in accordance with existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2022-1544 dated 12 September 2022 is hereby lifted.

The public health warning imposed on the remaining product listed in FDA Advisory No. 2022-1544 shall remain to be upheld and shall not be affected by the issuance of this advisory. Furthermore, 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.


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Director General

DTN 20240117134953 / 20220713102018

