



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2020-2184-A

21 JAN 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting the Advisory of the Products under FDA Advisory No. 2020-2184 entitled Public Health Warning Against the Purchase and Use of the following Unnotified Medical Device Products:

- 1. Hisamitsu® Bye-Bye Fever (For Adults)**
- 2. Hisamitsu® Bye-Bye Fever (For Babies)**

The Food and Drug Administration (FDA) informs all healthcare professionals and the public that the medical device products mentioned above has Certificate of Exemption (CoE) issued to Hisamitsu Pharmaceutical Co., Inc., Marketing Authorization Holder. Based on FDA Circular No. 2020-001 all Certificate of Exemption for Class A medical devices issued from 25 February 2014 shall remain valid until 03 November 2021 or within 2 years from date of effectivity of this Circular whichever is earlier.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2020-2184 is hereby lifted.

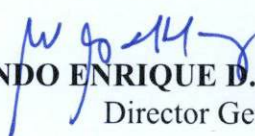
Furthermore, all medical device with risk classification A whether or not included in FDA Memorandum Circular No. 2014-005 and 2014-055-A shall apply for a Certificate of Medical Device Notification (CMDN).

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) 8857-1900 loc. 8301.**

To report any sale or distribution of unnotified 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
Director General

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