Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20232240

17 OCT 2023

TO : **ALL MARKETING AUTHORIZATION HOLDERS AND APPLICANTS FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF DRUG PRODUCTS FOR HUMAN USE**

SUBJECT : **Application Holiday**

The Center for Drug Regulation and Research (CDRR) of the Food and Drug Administration (FDA) will be conducting an inventory and processing of the pending applications for registration of drug products for human use. As such, the period 01 to 31 December 2023 is hereby declared as an Application Holiday. This will enable the CDRR to catch up with the backlog/pending applications.

For the abovementioned purpose, the FDA **shall not receive** the following types of drug product registration application:

1. Monitored Release (MR)
2. Initial
3. Post-approval changes (Major Variations only)

Notwithstanding the foregoing, the CDRR shall continue to accept renewal and all applications filed through the eService portal.

Moreover, pre-assessment of applications which has already been scheduled by the FDA Action Center (FDAC) may proceed but the payment and endorsement of accepted applications to the CDRR shall resume after the application holiday.

For information and strict compliance of all concerned.

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