

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



2 4 NOV 2022

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 December 2022 to 31 January 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)
- 3. Post-approval changes (Major Variations only)

Notwithstanding the foregoing, the CDRR shall continue to accept COVID-19-related applications, renewal, and all applications filed through the eService portal.

Moreover, pre-assessment of applications that have 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.

DR. SAMUEL A. ZACATE Director General



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