

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



11 5 OCT 2021

FDA ADVISORY No: 2021-2491

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 15 November 2021 to 15 January 2022 is hereby declared as an Application Holiday. This will enable the CDRR to catch-up with the backlog/pending applications and to conduct test-runs on the proposed systems to be implemented.

For the abovementioned purpose, the CDRR <u>shall not receive</u> the following types of drug product registration application:

- 1. Monitored Release (MR)
- 2. Initial
- 3. Certificate of Listing of Identical Drug Product (CLIDP)
- 4. Principal Certificate of Product Registration (PCPR) conversion
- 5. Post-approval changes (Variation)

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

For information and strict compliance of all concerned.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General



