Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-012-A

27 JUL 2020

SUBJECT: **Amendment to FDA Circular No. 2020-012 entitled Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)**

Relative to the recent updates of the Philippine Society for Microbiology and Infectious Diseases (PSMID) Clinical Practice Guideline (CPG) on the Interim Management Guidelines for Coronavirus Disease 2019 (COVID-19) Version 3.1 issued on 20 July 2020, the list of Drug Product under Emergency Use (DEU) is hereby amended.

The drug product eligible for registration under DEU is as follows:

Generic Name	Dosage Form and Strength
Tocilizumab	400 mg/ 20 mL Concentrate Solution for I.V. Infusion 200 mg/ 10 mL Concentrate Solution for I.V. Infusion 80 mg/ 4 mL Concentrate Solution for I.V. Infusion 162 mg/ 0.9 mL Solution for Injection (S.C.)

New applications for the registration of Chloroquine, Hydroxychloroquine, and Lopinavir + Ritonavir under DEU registration shall no longer be accepted.

Current stocks at the manufacturing level of those issued with Certificate of Product Registration (CPR) shall be exhausted for their approved indications within the given validity. No further extension shall be granted. Furthermore, the inventory of stocks on hand shall be submitted as required under FDA Circular No. 2020-013.

This Circular shall take effect immediately.

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Director General