



06 APR 2020

**FDA ADVISORY
NO. 2020-547**

TO : THE GENERAL PUBLIC

SUBJECT : Updated Procedure for FDA Clearance of Personal Protective Equipment (PPE) Prior to Customs Release

Due to the rapid spread of COVID-19, the following updated measures are adopted for the expedient release of certain protective equipment (PPE) within the jurisdiction of the Bureau of Customs. The PPE include:

1. Face masks including N95 masks
2. Shoe Covers
3. Gloves
4. Head Covers, and
5. Gowns

For the abovementioned PPE intended for entry to the local market for commercial use, the presentation of the copy of the importer's License to Operate (LTO) should be sufficient compliance for customs release.

For foreign donation of the same PPE, clearance from FDA shall not be needed. These include companies, other than medical device establishments, with employees who use face masks in the performance of their jobs and are strictly for company use.

Strict postmarket surveillance will be implemented to all these PPEs. All companies who have imported PPEs under this Advisory and will continue to distribute PPEs for commercial purposes shall apply for Certificate of Medical Device Notification (CMDN) within three (3) months **after** the lifting of Proclamation No. 922 s. 2020 declaring a State of Public Health Emergency throughout the Philippines. Necessary regulatory measures will be implemented to those companies who will not comply with this requirement.

Said procedure for clearance of PPE prior to customs release shall be in effect otherwise lifted.

This advisory supersedes FDA Advisory No. 2020-420 issued on 20 March 2020.

For your guidance.


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