



**FDA CIRCULAR**

No. 2021-021-A

26 MAR 2024

**SUBJECT :** Extension of the Transitory Provision of FDA Circular No. 2021-021 Entitled “Guidelines on the Licensing of Retailers of Medical Devices in the Philippines” for FDA Licensed Manufacturers, Traders or Distributor (Importers, Exporters and/or Wholesalers) of Medical Devices that Also Sell or Intend to Sell Medical Devices to the General Public

**I. RATIONALE**

On 8 May 2020, Administrative Order No. 2020-0017<sup>1</sup> was issued to simplify the requirements and processes for initial, renewal, and variation of LTO applications for health product establishments including retailers of medical devices. Following the issuance of the said AO, FDA Circular (FC) No. 2021-021 was issued on 7 October 2021 to provide specific guidelines on the licensing of retailers of medical devices and to supplement the provisions of the AO. The said Circular took effect on 18 December 2021 after its publication in a newspaper of general circulation on 3 December 2021.

Section IX of the said Circular stipulates that “*All existing retailers of medical devices prior to the issuance of this Circular shall be given a period of two (2) years from the effectivity of this Circular to comply with the provisions thereof.*” Based on this provision, the transitory period for the said establishments shall end on 18 December 2023.

As of this date, the Food and Drug Administration (FDA) is updating its processes through migration of the online licensing application process from the ePortal System to the eServices Portal System for manufacturers of medical devices. In view of this, Section IX. Transitory Provision of FDA Circular No. 2021-021 is hereby amended.

**II. AMENDMENT OF TRANSITORY PROVISION**

Section IX of FC No. 2021-021 is amended to include the following provisions:

1. The filing of LTO variation application of FDA-licensed manufacturers that sell or intend to sell medical devices directly to the general public pursuant to FC No. 2021-021 is hereby extended until the migration of the online licensing application process from the ePortal System to the eServices Portal System has been completed for the said establishments.

<sup>1</sup> Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003





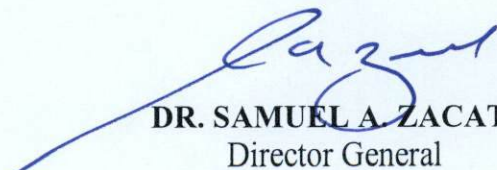
2. Whereas, FDA-licensed traders or distributors of medical devices that sell or intend to sell directly to the general public may apply for variation (additional activity) of their existing LTO through the eServices Portal System (<https://eservices.fda.gov.ph/>) following the provisions of AO No. 2020-0017, FC No. 2021-021, and FC No. 2021-014<sup>2</sup>. FDA-licensed traders or distributors are given until June 30, 2024 to secure the approval of the said LTO variation; after which selling of medical devices directly to the general public by the said establishments without securing the amended LTO shall be prohibited.

### III. SEPARABILITY CLAUSE

All other provisions of FC NO. 2021-021 not affected by this amendment shall remain in effect. In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

### IV. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center of the National Administrative Register.



**DR. SAMUEL A. ZACATE**  
Director General

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<sup>2</sup> Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Water Treatment Devices/Systems