

ANNOUNCEMENT

TO : ALL CONCERNED HEALTH PRODUCT ESTABLISHMENTS
AND THE GENERAL PUBLIC

SUBJECT : **DRAFT FOR COMMENTS | Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017**

Date : 27 February 2024

The Food and Drug Administration through the Policy and Planning Service is hereby posting the attached proposed Administrative Order entitled, “Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017” for comments.

The proposed Administrative Order aims:

1. To further reengineer the FDA’s processes and automate its system for initial, renewal, and variation applications for License to Operate (LTO) through the FDA eServices Portal System, affirming the integration of information and communication technologies to maximize a focus on risks, promote coordination and information-sharing and ensure an optimal use of FDA resources;
2. To update the list of documentary and other technical requirements for LTO applications, including the procedures that shall be complied with by FDA-covered establishments promoting transparency and alignment with internationally acceptable standards; and
3. To institutionalize a longer validity period of licenses to operate, as well as the appeal mechanism in the regulatory authorization processes.

It is in this view that the FDA respectfully seeks for the comments of all covered health product establishments including Manufacturers, Distributors, Retailers, Pharmaceutical Outlets and other covered establishments to the proposed Administrative Order using the “Comment Form Template” attached herein.

All comments are requested to be submitted in MS Word Format via e-mail to pfpid@fda.gov.ph on or before 12 March 2024.

Thank you very much.



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DR. SAMUEL A. ZACATE
Director General

