Food and Drug Administration
PHILIPPINES

• PAMDRAP 22nd GMM 2021

MEDICAL DEVICE REGULATORY UPDATE

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Center for Device Regulation, Radiation Health, and Research
Food and Drug Administration
November 26 2021
10:00 am – 1:30pm
Via Zoom

TOPICS:

- **Update on Implementation of Administrative Order No. 2018-002**
- **Update on Covid-19 Related Products**
- **Update on LTO**
- **What NEW?...**

Implementation of 2018-002

TIMELINE OF IMPLEMENTATION							
Activity	Validity	Timeline					
		2020	**2021**	2022	2023	2024	2025 and beyond
GENERAL MEDICAL DEVICE							
Preparation and approval of Issuance of the Phase implementation (FDA Circular)		September	**FDA Circular 2021-002 is issued on**				
Registration of MD in the List as Per FDA Circular 2020-001	5years	On-going Activity					
Notification of Class A Medical Devices	5years	On-going Activity					
Notification of Other Class B, C, D Medical Devices	2 years		**March**				
Registration of Other Class B, C, D Medical Devices	5years				**March**		

UPDATED TIMELINE OF IMPLEMENTATION							
Activity	Validity	Timeline					
		2021	2022	2023	2024	2025	2026 and beyond
Update of List of Registrable IVDs (FDA Circular)			**2022:** To issue the new list of IVD that will be required to be registered (draft already for internal review				
Registration of IVD in the List	5years	On-going Activity					
Approval of New AO for IVD			**1st Sem**				
Notification of Class A IVD	5years			January			
Notification of Other Class B, C, D IVD	2 years			January			
Registration of Other Class B, C, D IVD Medical Devices	5years					January	

ISSUANCE OF AUTHORIZATIONS FOR (GENERAL) MEDICAL DEVICE PRODUCTS

NOTIFICATION

- Class A
- Class B, C, D not in the list based on FDA Circular 2020-001-A

REGISTRATION

- Class B, C, D indicated in the list based on FDA Circular 2020-001-A

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ISSUANCE OF AUTHORIZATIONS FOR IVD - MEDICAL DEVICE PRODUCTS

FDA Circular 2020-001

5. The list of in-vitro diagnostic (IVD) medical devices that are registrable in Section B of FDA Memorandum Circular No. 2014-005 remains the same; however, the blood collection tube listed in Section A of the said FDA Memorandum Circular shall be added under the list of IVD since it has been re-classified as in-vitro diagnostic (IVD) medical devices based on the definition of IVD in the ASEAN AMDD.

Update on Covid-19 Related Products

COVID-19 TEST KITS

- FDA Memorandum 2020-006 - requirements for special certification
- FDA Memorandum 2021-009 – standard required value for sensitivity and specificity
- FDA Advisory 2021-0684 – process flow

COVID-19 Related Medical Devices

- To still follow the regulatory requirements
- Fast track evaluation
- **upon approval of the pre-assessment, to email cdrrhr@fda.gov.ph of the DTN Number and product name

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Update on License to Operate

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

FDA ADVISORY No. 2021-2634

02 NOV 2021

TO : **RETAILERS OF MEDICAL DEVICES WITHIN THE NATIONAL CAPITAL REGION (NCR) AND THE GENERAL PUBLIC**

SUBJECT : **Pilot Implementation of Food and Drug Administration eServices Portal System for License to Operate Application of Retailers of Medical Devices within the National Capital Region**

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FDA eServices Portal for LTO Application for Retailers of Medical Devices	
Location of Establishment	National Capital Region (Metro Manila)
LTO Establishment Application	Retailers of Medical Devices including; (1) Retail stores for medical devices; (2) Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System; (3) Sellers using online shopping website, social media platforms; (4) TV shopping companies that sell or offer to sell medical device directly to the general public; (5) Optical Shop; and (6) Drug outlets, such as drugstores and retail outlet for non-prescription drugs (RONPD) that also sell or offer to sell medical devices For this pilot run, drug outlets, such as drugstores and RONPDs with multiple outlets/branches within the National Capital Region shall be allowed to apply for a maximum of ten (10) outlets/branches only.

Type of LTO Application	Initial
Fees to be Paid	Based on current issuance on Fees and Charges (Reference: DOH Administrative Order No. 50 s. 2001) Initial: ₱2,000 valid for 2 years Renewal: ₱3,000 valid for 3 years Fee for Variation of LTO: ₱500 + 1% Legal Research Fee
Validity of Initial LTO	Two (2) years
Start of Pilot Implementation	**03 November 2021**
End of Pilot Implementation	**31 January 2022**

Interim Application System for LTO

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2903

18 NOV 2021

SUBJECT : Interim Application System in lieu of the Department of Information and Communication Technology (DICT) System Maintenance of License to Operate (LTO) for FDA eServices

This is in relation to the Department of Information and Communication Technology (DICT) Advisory dated 08 November 2021 on system maintenance entitled "Restoration of Government Common Platform (GCP) and New Cloud". As part of the agency's interim measures, the FDA Information and Communication Technology Management Division (ICTMD) established an interim application system to accept and facilitate applications for License-to-Operate. This system will be accessible on 22 November 2021 through https://eservices.fda.gov.ph.

Medical Device it is still being integrated in this new interim system

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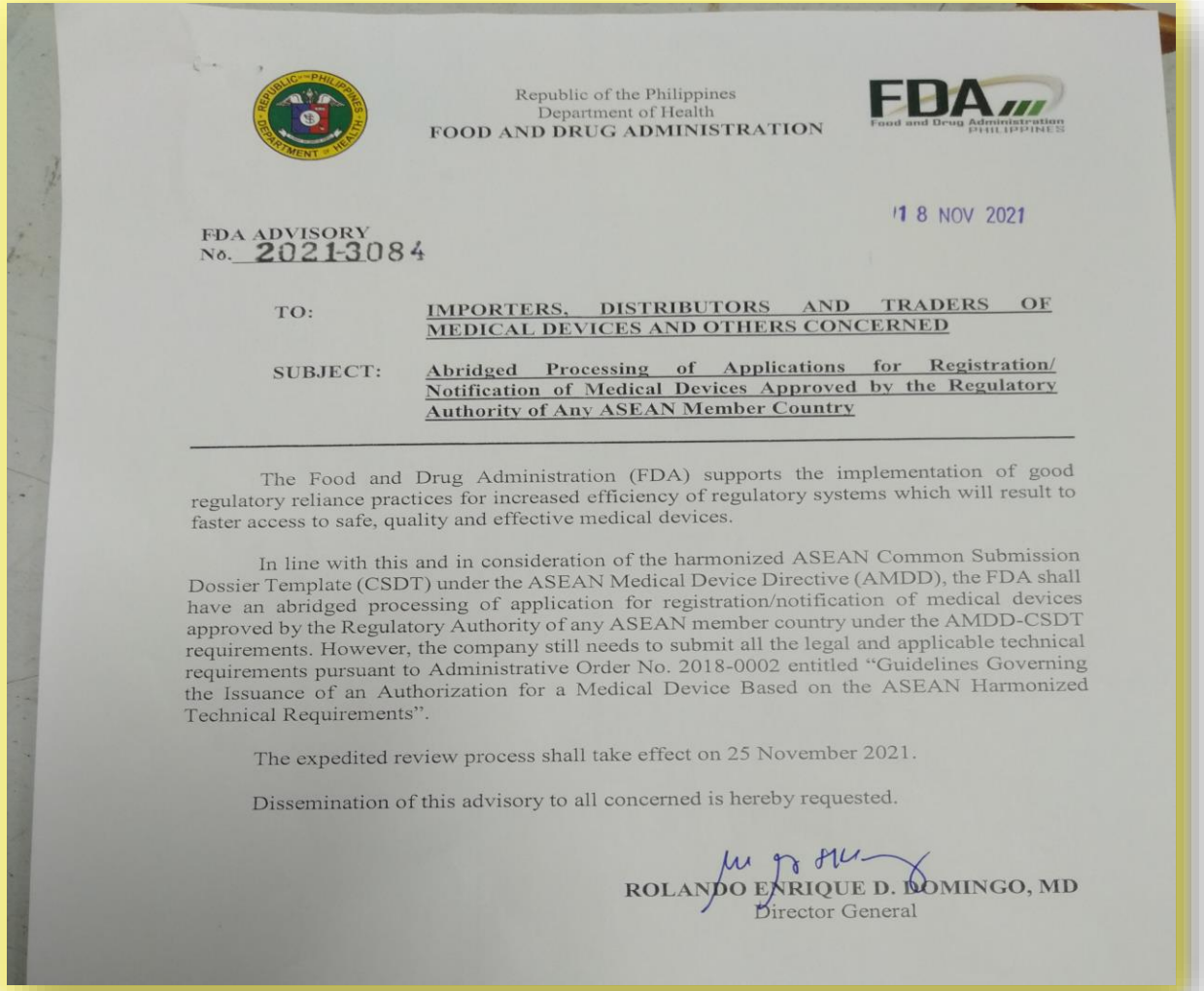
• ON COLLABORATION

Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics

• ON RELIANCE

FDA Advisory 2021-3084

- Applied to all ASEAN Member Countries with issued CPR equivalent following the CSDT Technical Requirements based on AMDD



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 NOV 2021

FDA ADVISORY
No. 2021-3084

TO: IMPORTERS, DISTRIBUTORS AND TRADERS OF MEDICAL DEVICES AND OTHERS CONCERNED

SUBJECT: Abridged Processing of Applications for Registration/ Notification of Medical Devices Approved by the Regulatory Authority of Any ASEAN Member Country

The Food and Drug Administration (FDA) supports the implementation of good regulatory reliance practices for increased efficiency of regulatory systems which will result to faster access to safe, quality and effective medical devices.

In line with this and in consideration of the harmonized ASEAN Common Submission Dossier Template (CSDT) under the ASEAN Medical Device Directive (AMDD), the FDA shall have an abridged processing of application for registration/notification of medical devices approved by the Regulatory Authority of any ASEAN member country under the AMDD-CSDT requirements. However, the company still needs to submit all the legal and applicable technical requirements pursuant to Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements".

The expedited review process shall take effect on 25 November 2021.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Food and Drug Administration
PHILIPPINES

• ON RELIANCE

Draft Policy on this:

1. CPR equivalent is issued by the Regulatory Agency of the **ASEAN** Member Countries only
2. The approval of the CPR is based on the CSDT technical requirements as stated in the ASEAN Medical Device Directive
3. CPRs issued based on abridged approval based on other countries outside the ASEAN are **not qualified**.
4. Applicable only to **Class B, C, and D** medical devices, either for notification or registration.

• ON RELIANCE

Additional Requirements:

Declaration that the submitted CSDT Technical Requirements is the same as the one submitted to our counterpart regulatory agency who issued the CPR equivalent.

• ON RELIANCE

Procedure

1. Company to submit complete requirements based on AO 2018-002 the same procedure as the application

2. CDRRHR to evaluate the compliance of the legal requirements and the completeness of the technical requirements except for the labeling requirements

3. Labelling requirements will be evaluated based on the requirements as stated in AO 2018-002

4. will also be subjected for pre-assessment

• ON FOLLOW-UP on Application without ACTION

Name of Company	Doc Track No.	Product Name	Date Applied	Last Status on DTN (remarkable)
* Indicate in the SUBJECT: APPLICATION with NO ACTION				
** Submit in excel format at cdrrhr@fda.gov.ph				
** November December 2020	** June July 2021			
CMDR, Variation, Renewal				

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OPEN DISCUSSION

Congratulations on your 10th

THANK YOU!