



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. **2021-0697**

06 APR 2021

**TO : ALL STAKEHOLDERS AND THE GENERAL PUBLIC**

**SUBJECT : Pilot Implementation of the Food and Drug Administration (FDA) eServices Portal System for Automatic Renewal Applications for Drug Products**

The FDA, in its commitment to provide stakeholders with streamlined and improved government services, is developing the **FDA eServices Portal System** – an online platform for FDA marketing authorization applications.

The FDA wishes to invite stakeholders to use the FDA eServices Portal System through <https://eservices.fda.gov.ph> for Automatic Renewal applications. The eServices Portal is in its Pilot Implementation; hence, the scope of the application is limited for the time being:

<b>FDA eServices Portal Pilot Implementation for Automatic Renewal Applications</b>	
Transactions	Automatic Renewal Registration for Regular Certificate of Product Registration (CPR) and Principal Certificate of Product Registration (PCPR)
	Automatic Renewal Registration for Certificate of Listing of Identical Drug Product (CLIDP)
Fees to be Paid	Based on Current Issuance on Fees and Charges (DOH Administrative Order No. 50, s. 2001)
Start of Pilot Implementation	05 April 2021
End of Pilot Implementation	05 May 2021

Please follow **Annex A** of this Advisory for the Guidelines on Automatic Renewal Applications Using eServices Portal System and **Annex B** for Procedure on the Use of the FDA eServices Portal System for Automatic Renewal Application.

For comments and suggestions on the FDA eServices Portal, please send them to [cdr.od@fda.gov.ph](mailto:cdr.od@fda.gov.ph).

  
**ROLANDO ENRIQUE D. DOMINGO, MD.**  
Director General



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## ANNEX A

### Guidelines on Automatic Renewal Applications Using eServices Portal System

#### I. Guidelines

1. All Automatic Renewal Applications shall be accomplished using the online application form through the eServices Portal System (<http://eservices.fda.gov.ph>). Creation of account and password is no longer a requirement to obtain access to the-online portal.
2. The declared e-mail address under the Contact Information is **unalterable**. The applicant shall make sure that the e-mail address is within the scope and access of the Authorized Person/s and/or Qualified Personnel handling the transaction. Thus, FDA shall not be held liable in any way for loss of access to the declared e-mail address.
3. All fields on the online application form have written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of information provided.
4. The result of the application will be sent to the e-mail address of the applicant.
5. Documentary requirements shall be in pdf with 5 MB maximum file size.
6. All information filled-out by the applicant during the process shall be reflected in the final output based on the consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filling out all the required information.

#### II. Pre-assessment

1. An FDA evaluator/assessor shall conduct pre-assessment on the submitted application and documentary requirements with regard to their completeness and correctness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. The pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. The FDA shall inform the applicant of the result of the pre-assessment through the registered e-mail address of the applicant. If the application passes the pre-assessment step, the applicant shall receive the Order of Payment (OP) with Reference Number through e-mail indicating the fees to be paid. If the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance (e.g., deficiency/ies found) and prompt the applicant to apply again through the eServices Portal.

### **III. Payment of Fees**

1. Payment of the total application fee as indicated in the OP may be done through Over-the-Counter (OTC) payment at FDAC, On-Coll payment at Land Bank of the Philippines (LBP) branches, or online payment through BancNet (including LBP bills payment) based on existing FDA issuances. Always indicate the Reference Number reflected in the OP. Clients will be informed of other available channels of payment through an FDA issuance.
2. Once the payment is made, the payment channel (LBP or BancNet, except for OTC payment at FDAC) will send a transaction report to the FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
3. Incomplete payment (amount paid is less than that of the OP amount) will not be posted until the full amount as indicated in the OP is settled. This also means that the application will not proceed to the next step of the process.
4. Applications will receive a system-generated message through the registered e-mail address on the status of the payment made once posted or needs further settlement. If full payment is made, e-mail will contain an Acknowledgement Receipt, otherwise, a notification on payment deficiency.

### **IV. Evaluation**

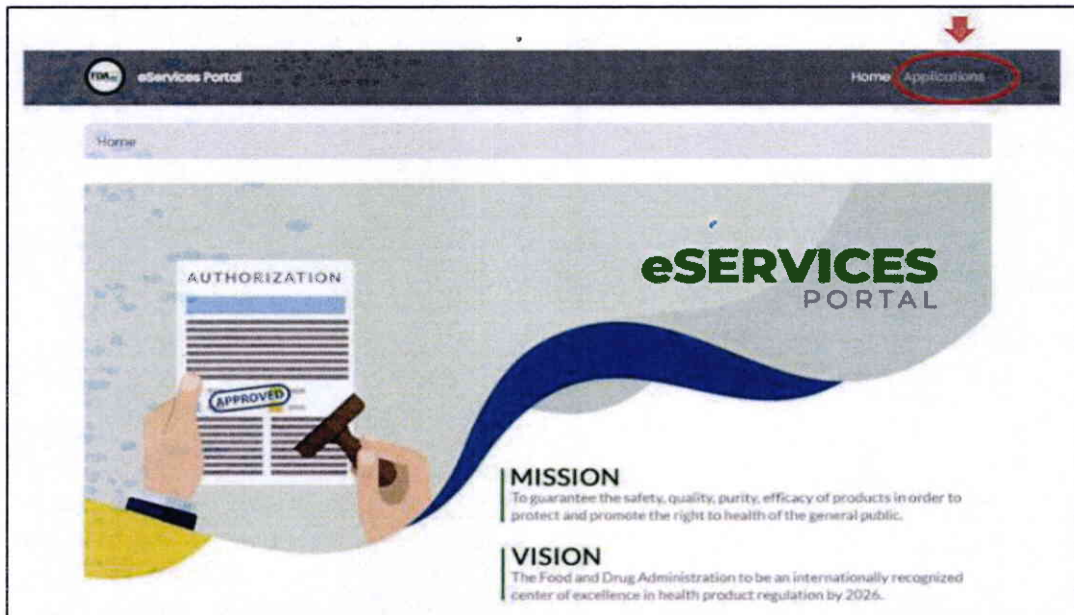
1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.
2. The action on the application shall be Approval or Disapproval pursuant to Republic Act (RA) No. 11032, otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act.
3. Evaluation shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.



## ANNEX B

### Procedure on the Use of the FDA eServices Portal System for Automatic Renewal Applications

1. Access the online portal through <https://eservices.fda.gov.ph> and click **Applications** found at the upper right corner of the landing dashboard.



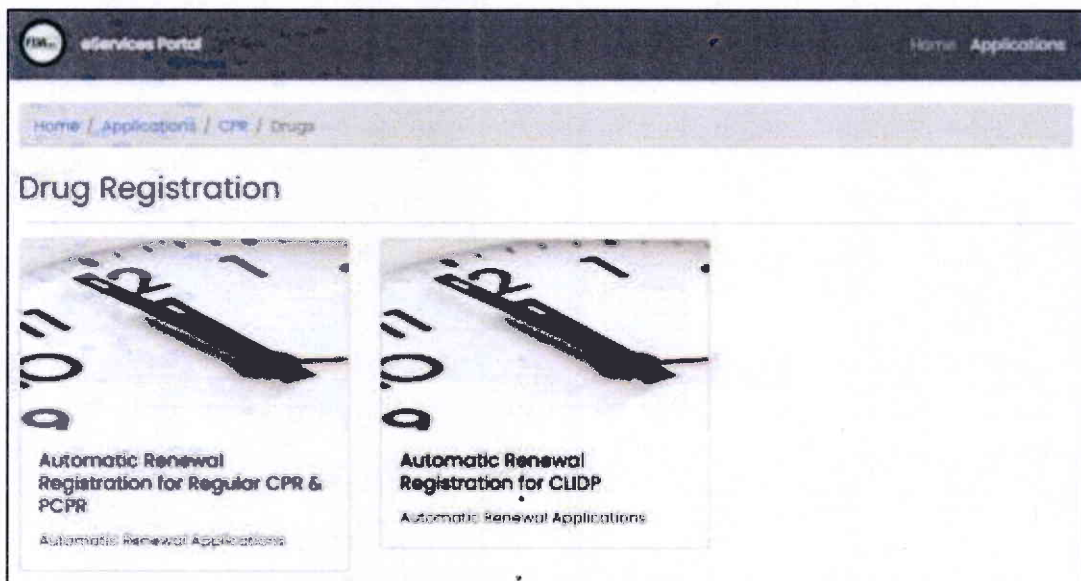
2. Click on the **Certificate of Product Registration**.



3. Click on the **Drug**.



4. Select the Application Type.



5. Read carefully the **Declaration & Undertaking**. Once done, check the box if you agree with all the conditions stated. Click on the **Start Application**.

**Drug Product Renewal**

1 Declaration & Undertaking **Declaration & Undertaking**

2 Applicant Information

3 Contact Information

4 Contact Person

5 Product Information

6 Packaging Description

7 Establishment Information

8 Uploading of Documents

9 Self-Assessment Review

We assume primary responsibility and/or stewardship over the product in case of liability, adverse events, or other public health & safety issues arising from its use. We agree to have in good faith exerted due diligence in ensuring & that third-party intellectual property rights are not infringed. We further agree and bind ourselves that the label of the product shall at all times conform to the labeling regulations, and shall not be presented including any advertisement of the product in a manner that is false, deceptive, "s" misleading, or contrary to public morals/ public policy. Non-observance of any of the undertakings in this declaration is deemed a misrepresentation which is a ground for disapproval of this application or, if approved, the suspension or cancellation of the product registration.

We, categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available. We certify that we have examined the following statements and we attest to their accuracy and truthfulness. We ensure that the submitted documentary requirements are complete and correct as prescribed to our application:

I agree to the declaration and undertaking

**Start Application**

6. From the **Applicant Information** page, choose the Establishment Type. Fill out the required fields such as LTO Number, Company Name, and Address. Please take note that all fields marked with asterisk (\*) are required to be filled out.

**Drug Product Renewal**

1 Declaration & Undertaking

2 Applicant information **Applicant information**

3 Contact Information

4 Contact Person

5 Product Information

6 Packaging Description

7 Establishment Information

8 Uploading of Documents

9 Self-Assessment Review

\* Entity

\* LTO Number

\* Company Name

\* Address

Form Select

- Drug Distributor - Importer
- Drug Distributor - Importer/Wholesaler
- Drug Distributor - Importer/Exporter/Wholesaler
- Drug Distributor - Exporter/Wholesaler
- Drug Distributor - Importer/Exporter
- Drug Distributor - Exporter
- Drug Distributor - Wholesaler
- Drug Trader
- Drug Manufacturer

7. Click on Next.

**Drug Product Renewal**

1 Declaration & Undertaking  
2 Applicant Information  
3 Contact Information  
4 Contact Person  
5 Product Information  
6 Packaging Description  
7 Licensure Information  
8 Uploading of Documents

**Applicant Information**

\* Entity: Drug Distributor - Importer  
select entity

\* LTO Number: 300000234567

\* Company Name: Par Pharmaceutical

\* Address: Unit 31A, 20th Floor, Yander Bldg, Merlin Road, Brgy. 123, Taguig City, Metro Manila

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8. Provide a valid and working e-mail address and mobile number in the **Contact Information** page. Click on Next.

**Drug Product Renewal**

1 Declaration & Undertaking  
2 Applicant Information  
3 Contact Information  
4 Contact Person  
5 Product Information  
6 Packaging Description

**Contact Information**

\* Email Address: abcd1234@gmail.com

\* Mobile Number: 09170000123

\* Licensure Number: (02) 8-467-0001

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9. In the **Contact Person** page, supply the information of the company pharmacist or the person in charge of the regulatory affairs. Click on **Next**.

**Drug Product Renewal**

1. **Details of the Contact Person**

2. **Government issued Identification Document**

Must be the company pharmacist or personnel in charge of regulatory affairs

1 Applicant Information: \* First Name: Wendy

2 Contact Information: \* Middle Name: N.

3 Contact Person: \* Last Name: Park

4 Contact Person: \* Designation or Profession: Company Pharmacist

5 Product Information: \* ID Type: PNC ID

6 Packaging Description: \* ID Number: 0012345

7 Establishment Information: \* Expiry Date: 15 December 2023

8 Uploading of Documents

9 Self-Assessment Review

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10. Fill out all the required fields in the **Product Information** page.

**Drug Product Renewal**

1. **Product Information**

\* Registration Number: SRP-0245

\* Proposed Date of Validity: 31 May 2025

\* Expiry: 31 May 2025

\* Generic Name: Clonidine propionate

\* Brand Name: Dem

\* Dosage Form and Strength: 100 mg/150 mg/180 mg Cream

\* Pharmacologic Category: Cardiovascular

\* Product Classification: Prescription Drug (Rx)

\* Product Category: Human Drug - Prescription

\* Marketing Condition: Not Applicable

\* Shelf Life: 24 months

\* Storage Condition: Store at temperatures not exceeding 30°C

Formulation (as reflected in the current CFR)

\* Add Formulation

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2 (only if applicable, e.g., Multivitamins, etc.)

3



11. In the Formulation, provide all the formulations reflected in your current Certificate of Product Registration (CPR). Click on Next.

**Formulation (as reflected in the current CPR)**

**Formulation**

\* Ingredient

\* Dosage Strength

12. In the **Packaging Description** page, provide the details of all approved pack sizes. Click on Next.

**Drug Product Renewal**

1 Declaration & Undertaking 1 **Packaging Description**

2 Applicant Information

3 Contact Information

4 Contact Person

5 Product Information

6 **Packaging Description**

7 Establishment Information

**Packaging Description**

\* Description   
Ex. 10g-100-1000 pack x 10's

\* Pack Size   
Ex: Single Dose Unit

GPI / GTN (if any)

Suggested Retail Price (SRP) in Php

**2 (only if applicable)**

**3**

13. Provide the required details of all the establishments reflected in the CPR. Click on Next.

### Drug Product Renewal

1 Indicate all Establishments reflected in the CPR

2 Applicant Information **1** Establishment Information

3 Contact Information

4 Contact Person

5 Product Information

6 Packaging Description

**7** Establishment Information

8 Uploading of Documents

9 Self-Assessment Review

\* Establishment: Manufacturer

select Establishment Type

\* LTO Number: N/A

For Foreign entities, type N/A

LTO Expiry: Date of Expiry

FcGMP Clearance Number: CDRR-CGMP-123

If applicable

FcGMP Expiry: 11 April 2023

Proof of Renewal: Case Number or DTN

For expired LTO or Foreign GMP Clearance but with renewal application filed in the FDA and for those applicants whose initial PDMF Clearance are still on-going, please indicate the QRN of the PDMF Clearance application/Case number of the LTO renewal application (whichever is applicable)

\* Company Name: Morley Serum Pharmaceuticals

\* Address: Shiganshina, Wall Maria

Click to add more Establishments (as applicable).

**2** Add Establishment

Back **3** Next

14. Upload all the necessary documents for verification purposes. Click on Next.

## Drug Product Renewal

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Information
- 4 Contact Person
- 5 Product Information
- 6 Packaging Description
- 7 Establishment Information
- 8 Uploading of Documents**
- 9 Self-Assessment Review

**Uploading of Documents**

Indicate or upload the following documents for verification of compliance to existing local and international standards, and post-approval commitments:

**Do you have any post-approval commitments to be submitted prior to the renewal of your CPR?**

* Submission of Equivalent Evidence?	Please Select	File Upload
* GMP Compliance of Foreign Drug Manufacturer(s)	Please Select	File Upload
Old CPR	Copy of previously issued CPR (front and back)	File Upload
Approved Labeling	Currently approved labeling materials <small>in compliance to A.D. 2018-0008</small>	File Upload
Post Approval	Copy of approved post-approval changes <small>for reflection of CPR to be issued</small>	File Upload
Risk Management Plan	Risk Management Plan <small>for Vaccines and Biologics</small>	File Upload
Periodic Safety Update Report	Periodic Safety Update Report <small>for Vaccines and Biologics</small>	File Upload
Other File	copy of LTO, FGMP clearance etc. <small>All Other Files must be merged into one (1) pdf file</small>	File Upload

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15. The Applicant shall review if all the details are correct in the **Self-Assessment Review**.

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## Drug Product Renewal

**1 Declaration & Undertaking**

**2 Applicant Information**

**3 Contact Information**

**4 Contact Person**

**5 Product Information**

**6 Packaging Description**

**7 Establishment Information**

**8 Uploading of Documents**

**9 Self-Assessment Review**

### Self-Assessment Review

#### Applicant Information

\* Entity  select entity

\* LTO Number

\* Company Name

\* Address

#### Contact Information

\* Email Address

\* Mobile Number

Landline Number

**1** Must be the company pharmacist or personnel in charge of regulatory affairs

#### Details of the Contact Person

\* First Name



Middle Name

\* Last Name

\* Designation or Profession



16. Once reviewed, the Applicant shall confirm the correctness of the data given and click on **Confirm** to submit the application.

 I'm not a robot   
reCAPTCHA  
Privacy - Terms

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

[Back](#) [Confirm](#)