



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



**FDA ADVISORY**  
No. **2021-0999**

11 MAY 2021

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


**SUBJECT : IMPLEMENTATION OF THE FOOD AND DRUG ADMINISTRATION (FDA) ESERVICES PORTAL SYSTEM FOR AUTOMATIC RENEWAL (AR) APPLICATIONS FOR DRUG PRODUCTS**

The FDA, in its commitment to provide stakeholders with streamlined and improved government services, developed the **FDA eServices Portal System** for AR applications for Drug Products.

The FDA advises and encourages all stakeholders to utilize the eServices Portal System for AR applications. All applicant companies are hereby advised to apply through the FDA eServices Portal starting **01 June 2021**.

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

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 (<https://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 2 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

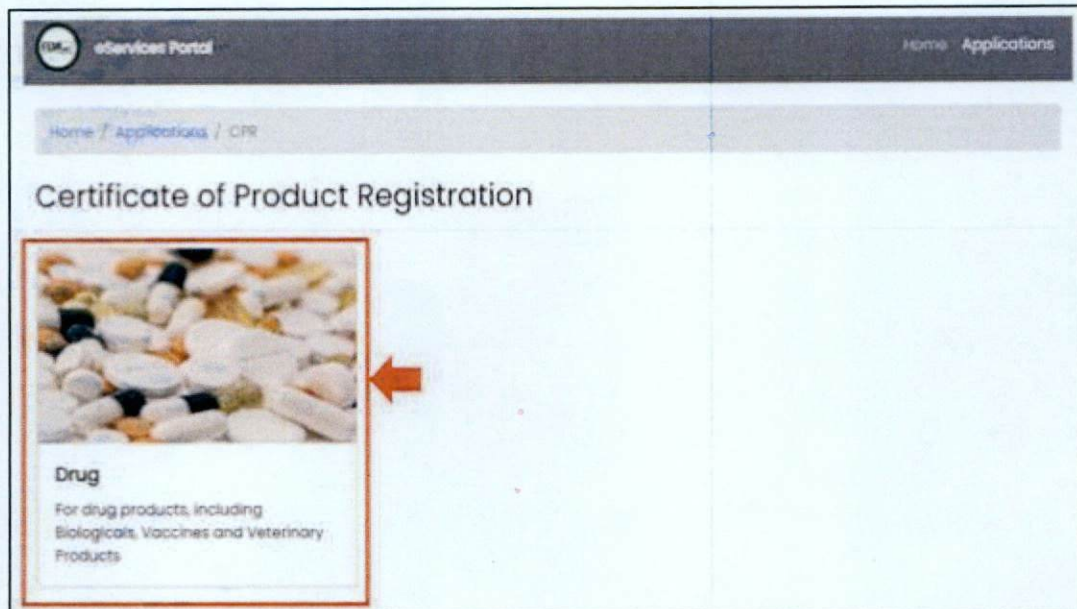
1. Access the online portal through <https://eservices.fda.gov.ph> and click **Applications** found at the upper right corner of the landing dashboard.



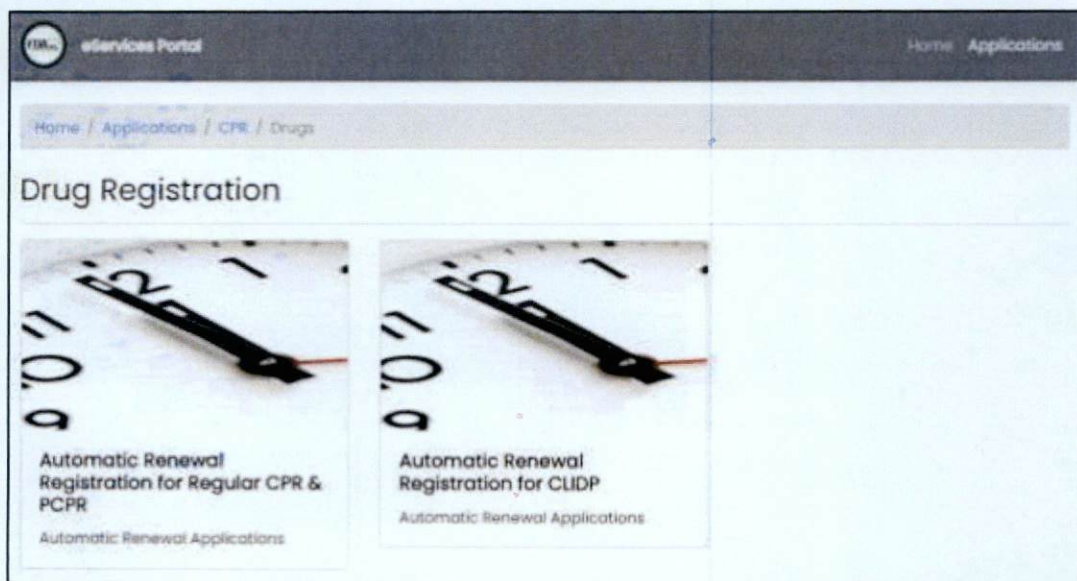
2. Click on the **Certificate of Product Registration**.



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, & 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    Applicant Information

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

\* Entity

\* LTO Number

\* Company Name

\* Address

Please 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 Establishment Information  
8 Uploading of Documents

**Applicant Information**

\* Entity: Drug Distributor - Importer  
select entity

\* LTD Number: 3000001234567

\* Company Name: Pan Pharmaceuticals

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

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

**eservices Portal** Home Applications

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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

\* Email Address: abc@1234@gmail.com

\* Mobile Number: 09170000123

Landline 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 Declaration & Undertaking **Must be the company pharmacist or personal in charge of regulatory affairs**

2 Applicant Information **1 Details of the Contact Person**

3 Contact Information

4 Contact Person

5 Product Information **2 Government issued identification Document**

6 Packaging Description

7 Establishment Information

8 Uploading of Documents

9 Self-Assessment Review

\* First Name: Wendy

\* Middle Name: N

\* Last Name: Park

\* Designation or Profession: Company Pharmacist

\* ID Type: PRC ID

\* ID Number: 0012345

\* Expiry Date: 15 December 2023

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

**Drug Product Renewal**

1 Declaration & Undertaking

2 Applicant Information

3 Contact Information

4 Contact Person

5 Product Information **1 Product Information**

6 Packaging Description

7 Establishment Information

8 Uploading of Documents

9 Self-Assessment Review

\* Registration Number: SPP-12345

\* Registered Date of Validity: 15 May 2020

\* Expiry: 15 May 2025

\* Generic Name: Carbamazepine

\* Brand Name: Dem

\* Storage Form and Strength: 300 mg/g (525 % w/w) Cream

\* Pharmacologic Category: Carbamazepine

\* Product Classification: Prescription Drug (Rx)

\* Product Category: Prescription Drug (Rx)

\* Product Category: Human Drug - Prescription

\* Marketing Condition: Not Applicable

\* Shelf Life: 24 months

\* Storage Condition: Store at temperatures not exceeding 20°C

Formulation (as reflected in the current CPR)

+ 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. Alu-Alu blister pack x 10's

\* Pack Size   
example Size of 100's

GPI / GTN (if any)

Suggested Retail Price (SRP) in Php

**2 (only if applicable)**

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

### Drug Product Renewal

1 Declaration & Undertaking **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  select Establishment Type

\* LTO Number  For Foreign entities, type N/A

LTO Expiry

FcGMP Clearance Number  If applicable

FcGMP Expiry

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

\* Company Name

\* Address

**2** [Click to add more Establishments \(as applicable\).](#)

**3**

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?	<input type="text" value="Please Select"/>	▼
* GMP Compliance of Foreign Drug Manufacturer(s)	<input type="text" value="Please Select"/>	▼
Old CPR	<input type="text" value="Copy of previously issued CPR (front and back)"/>	<input type="button" value="File Upload"/>
Approved Labeling	<input type="text" value="Currently approved labeling materials"/>	<input type="button" value="File Upload"/>
	<small>In compliance to A.O. 2019-0008</small>	
Post Approval	<input type="text" value="Copy of approved post-approval changes"/>	<input type="button" value="File Upload"/>
	<small>for reflection of CPR to be issued</small>	
Risk Management Plan	<input type="text" value="Risk Management Plan"/>	<input type="button" value="File Upload"/>
	<small>for Vaccines and Biologics</small>	
Periodic Safety Update Report	<input type="text" value="Periodic Safety Update Report"/>	<input type="button" value="File Upload"/>
	<small>for Vaccines and Biologics</small>	
Other File	<input type="text" value="copy of LTO, FGMP clearance etc."/>	<input type="button" value="File Upload"/>
	<small>All 'Other Files' must be merged into one (1) pdf file</small>	



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
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- 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

**!** 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.