



FDA ADVISORY
No. 2021-1790

23 JUL 2021

TO : ALL STAKEHOLDERS AND THE GENERAL PUBLIC

SUBJECT : Pilot Implementation of the Food and Drug Administration (FDA) eServices Portal System for Principal Certificate of Product Registration (PCPR) Conversion 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 PCPR Conversion applications. The eServices Portal is in its Pilot Implementation; hence, the scope of the application is limited for the time being:

FDA eServices Portal Pilot Implementation for PCPR Conversion Applications	
Transactions	PCPR Conversion
Fees to be Paid	Based on Current Issuance on Fees and Charges (DOH Administrative Order No. 50, s. 2001)
Start of Pilot Implementation	26 July 2021
End of Pilot Implementation	26 August 2021

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

For comments and suggestions on the FDA eServices Portal, please send them to cdr.od@fda.gov.ph.


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Director General



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ANNEX A

Guidelines on Principal Certificate of Product Registration Conversion Applications Using eServices Portal System

I. Guidelines

1. All PCPR Conversion 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.

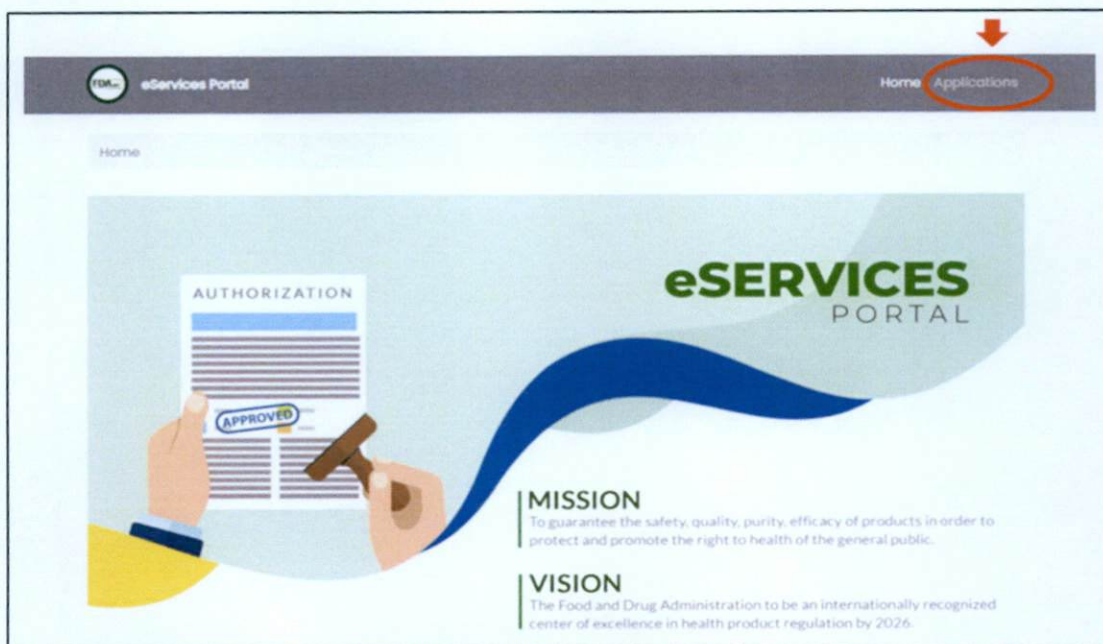
IV. Evaluation

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 Principal Certificate of Product Registration (PCPR) Conversion 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**.

The screenshot shows the FDA eServices Portal interface. At the top, there is a navigation bar with the FDA logo and 'eServices Portal' on the left, and 'Home Applications' on the right. Below the navigation bar, a breadcrumb trail reads 'Home / Applications / CPR'. The main heading is 'Certificate of Product Registration'. A large image of various pills is shown, with a red arrow pointing to it from the right. Below the image, the word 'Drug' is displayed in bold, followed by the text: 'For drug products, including Biologicals, Vaccines and Veterinary Products'. The entire 'Drug' section is enclosed in a red rectangular border.

4. Select the Product Category.

The screenshot shows the FDA eServices Portal interface for 'Drug Registration'. The breadcrumb trail is 'Home / Applications / CPR / Drugs'. The main heading is 'Drug Registration'. There are five product category options, each with an image and a description:

- Application Status**: Check the current status of your application. Image: A magnifying glass over a document.
- Human Drugs - Prescription**: For products which fall under the category of Human Drugs - Prescription. Image: A person's hands writing on a prescription form next to a pill bottle.
- Human Drugs - Over-the-Counter**: For products which fall under the categories Human Drugs - Over-the-Counter, Household Remedy, Traditionally Used Herbal Products, Herbal Medicine and/or Medical Oxygen/Gas. Image: A person's hands selecting a product from a pharmacy shelf.
- Vaccines and Biologics**: For products which fall under the categories of Vaccines and Biologics (including Biotechnological Product, Biosimilar, Biotechnological Product and/or Blood Products). Image: A person's hands holding a vial.
- Veterinary**: For products which fall under the category of Veterinary Drug Products (including Veterinary - Vaccines and Biologics). Image: A veterinarian holding two small dogs.

5. Click on the **Principal Certificate of Product Registration (PCPR) Conversion**.

The screenshot shows the FDA eServices Portal interface. The breadcrumb trail is: Home / Applications / CPR / Drugs / Biovac. The main heading is 'Vaccines and Biologicals'. There are three cards displayed:

- Card 1: Automatic Renewal Registration for Regular CPR & PCPR. Subtext: Automatic Renewal Applications.
- Card 2: Automatic Renewal Registration for CLIDP. Subtext: Automatic Renewal Applications.
- Card 3: Principal Certificate of Product Registration (PCPR) Conversion. This card is highlighted with a red border.

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

The screenshot shows the 'Principal Certificate of Product Registration (PCPR) Conversion' page. The breadcrumb trail is: Home / Applications / CPR / Drugs / Biovac / Variation. The page has a sidebar with steps 1 through 8, with step 1 'Declaration & Undertaking' selected. A warning box states: 'All products under Monitored Release (MR) and Monitored Release Extension (MRE) are not eligible to apply for PCPR Conversion.'

Declaration & Undertaking

- V. If applying for automatic renewal, the establishment has filed the application, and have paid the complete & appropriate renewal fee before expiry date and in which case there are no changes or variations that has not been applied with this Office;
- VI. Each batch of all starting materials is tested or certified (in an accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and fully complied with those specifications cited in the claimed reference official monograph before it is released for manufacturing purposes;
- VII. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible;
- VIII. Non-compliance with the requirements and/or failure to give notice to the FDA of the change in business address, business name, ownership, or any other circumstances in relation to the approval of this application is a ground for the revocation of the License to Operate;
- IX. The above declarations and undertakings which are based on existing regulations are deemed conditions for the approval of the Certificate of Product Registration and therefore non-compliance or defiance after approval can be a cause for SUSPENSION.

I agree to the declaration and undertaking

Start Application (indicated by a red arrow)

7. In the **Applicant Information** page, fill out all the required fields which are marked with asterisk (*). Provide a valid and working e-mail address and mobile number in the Contact Information, and the company pharmacist or the person in charge of the regulatory affairs in the Details of the Contact Person. Please take note that all fields marked with asterisk (*) in the succeeding steps are also required to be filled out. Click on **Next**.

The screenshot displays the 'Principal Certificate of Product Registration (PCPR) Conversion' form on the eServices Portal. The form is organized into a vertical list of steps on the left and corresponding input fields on the right. Red circles and arrows highlight specific areas: 'Applicant Information' (Step 1), 'Contact Information' (Step 2), 'Details of the Contact Person' (Step 3), and the 'Next' button (Step 4). A dropdown menu for 'Establishment Type' is open, showing a list of roles such as 'Drug Distributor - Importer' and 'Drug Distributor - Importer/Wholesaler'. The 'Next' button is highlighted in blue.

Step	Section	Field	Value
1	Applicant Information	* Company Name	Pan Pharmaceuticals
2	Applicant Information	* Address	Unit 31A, 20th floor, Yander Bldg, Merlin Road, Brgy. I23, Taguig City, Metro
3	Product Information	* Establishment Type	Drug Distributor - Importer
4	Special Conditions	* LTO Number	I2345678910
5	Contact Information	* Email Address	abcd123@gmail.com
6	Contact Information	* Mobile Number	09170000123
7	Contact Information	Landline Number	Landline Number of MAH
8	Details of the Contact Person	* First Name	Wendy
8	Details of the Contact Person	Middle Name	N.
8	Details of the Contact Person	* Last Name	Park
8	Details of the Contact Person	* Designation or Profession	Company Pharmacist
8	Details of the Contact Person	Government Issued Identification Document	
8	Details of the Contact Person	* ID Type	PRC ID
8	Details of the Contact Person	* ID Number	0012345
8	Details of the Contact Person	Expiry Date	15 December 2023

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

Home / Applications / CPR / Drugs / Biovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

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

* Registration Number: DR-XY123456

* Date of Validity: 15 June 2025

* Generic Name: Sample Generic Name

Brand Name: Sample Brand Name
Leave Blank if Unbranded

* Dosage Form and Strength: 30 mcg Suspension for Intramuscular (IM) Injection

* Pharmacologic Category: Vaccine

* Product Classification: Prescription Drug (Rx)

* Product Category: Biologics - Vaccine

Marketing Condition: Not Applicable

* Shelf Life: 36
in months

* Storage Condition: Store at temperatures not exceeding 30°C
to include special storage conditions

Formulation (as reflected in the current CPR) **2 (only if applicable, e.g. Multivitamins, etc.)**

Formulation Remarks:
Remarks, e.g., Each 5 mL Contains:

[Add Formulation](#)

Back **Next** **3**

9. 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) **1**

Formulation Remarks:
Remarks, e.g., Each 5 mL Contains:

Formulation

Ingredient: Active Pharmaceutical Ingredient

Dosage Strength: Dosage Strength

2 (only if applicable)

[Add Formulation](#)

Back **Next** **3**

10. In the **Special Conditions** page, tick all the special conditions/remarks/post-approval commitment as reflected in your current valid CPR.

FDA eServices Portal Home Applications

Home / Applications / CPR / Drugs / Biovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

- 1 Declaration & Undertaking** **CPR Special Conditions/Remarks/Post-Approval Commitment** **1**
- 2 Applicant Information
- 3 Product Information
- 4 Special Conditions
- 5 Packaging Description
- 6 Establishment Information
- 7 Uploading of Documents
- 8 Self-Assessment Review

Special Conditions

- This is subject to batch notification.
- This is subject to lot release certification.
- This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
- Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.
- Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.
- Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
- Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a personalized ordinary prescription form. It is a habit-forming drug.
- Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
- Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular 2014-016.
- Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.
- Subject to satisfactory compliance to the post-approval commitments detailed in this CPR/ in the letter accompanying this CPR.

* Remarks

Select and enter all details as indicated in the valid CPR

Post-Approval Commitments **2**

Commitments

Remarks

Please type all the deficiencies/requirements for compliance within the validity of the CPR as stated in the post-approval commitment letter.

3

11. In the Post-Approval Commitment, provide all the deficiencies/requirements for compliance within the validity of the CPR as stated in the post-approval letter. Click on **Next**.

Post-Approval Commitments

Commitments

Remarks

Please type all the deficiencies/requirements for compliance within the validity of the CPR as stated in the post-approval commitment letter.

[Add Remarks](#)

[Back](#) [Next](#)

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

eServices Portal Home Applications

Home / Applications / CPR / Drugs / Blovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

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

Packaging Description

* Description
Ex. Alu/Alu blister pack x 10's

* Pack Size
example: Box of 100's

GPIN / GTIN (if any)

Suggested Retail Price (SRP) in Php

2 (only if applicable)

[Add Packaging Description](#)

[Back](#) [Next 3](#)

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

eServices Portal Home Applications

Home / Applications / CPR / Drugs / Biovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

1 Declaration & Undertaking **Indicate all Establishments reflected in the CPR**

2 Applicant Information **Establishment Information 1**

3 Product Information

4 Special Conditions

5 Packaging Description

6 **Establishment Information**

7 Uploading of Documents

8 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: FcGMP Clearance Number
if applicable

FcGMP Expiry: Date of Expiry

* Company Name: A Pharmaceuticals

* Address: Shiganshing, Wall Maria

2 Click to add more establishments (as applicable)

Add Establishment

Back **Next 3**

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

eServices Portal Home Applications

Home / Applications / CPR / Drugs / Biovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

1 Declaration & Undertaking **Uploading of Documents 1**

2 Applicant Information

3 Product Information

4 Special Conditions

5 Packaging Description

6 Establishment Information

7 **Uploading of Documents**

Old CPR: Copy of previously issued CPR (front and back) **File Upload**

Post-Approval Commitment: Copy of Post-Approval Commitment letter issued by FD **File Upload**

Valid LTO: Copy of valid LTO **File Upload**
Copies of the respective current and valid License to Operate (LTOs) of the principal CPR applicant and toll manufacturer (if applicable)

Post-Approval Certification/(s): Post-Approval Certification/(s) **File Upload**

Other File: copy of LTO, FGMP clearance etc. **File Upload**
All 'Other Files' must be merged into one (1) pdf file

Back **Next 2**

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

The screenshot shows the 'eServices Portal' interface. At the top, there are navigation links for 'Home' and 'Applications'. Below that, a breadcrumb trail reads 'Home / Applications / CPR / Drugs / Blovac / Variation'. The main heading is 'Principal Certificate of Product Registration (PCPR) Conversion'. On the left, a vertical list of steps is shown, with 'Self-Assessment Review' (step 8) circled in red. The main content area is titled 'Applicant Information' and contains several input fields: 'Company Name' (Pan Pharmaceuticals), 'Address' (Unit 31A, 20th floor, Yander Bldg, Merlin Road, Brgy. 123, Taguig City, M), 'Establishment Type' (Drug Distributor - Importer), 'LTO Number' (12345678910), 'Email Address' (abcd123@gmail.com), 'Mobile Number' (09170000123), and 'Landline Number' (Landline Number of MAH). The 'Self-Assessment Review' step is also circled in red.

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

The screenshot shows a confirmation page. At the top left, there is a '1' next to a CAPTCHA box containing a checkmark, the text 'I'm not a robot', and the reCAPTCHA logo. Below this, there is a large text box containing the following text: '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.', and '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.' At the bottom of the page, there are two buttons: 'Back' and 'Confirm'. The 'Confirm' button is circled in red and has a '2' next to it.