



FDA ADVISORY

No. ~~2022-0417~~

03 MAR 2022

TO : ALL STAKEHOLDERS AND THE GENERAL PUBLIC

SUBJECT : 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, developed the **FDA eServices Portal System** for Principal Certificate of Product Registration (PCPR) applications for Drug Products.

The FDA advises and encourages all stakeholders to utilize the eServices Portal System for PCPR applications. All applicant companies are hereby advised to apply through the FDA eServices Portal starting **15 March 2022**.

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

For any feedback and comments for the FDA eServices Portal, please send them to cdr.od@fda.gov.ph.


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Officer-in-Charge 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.

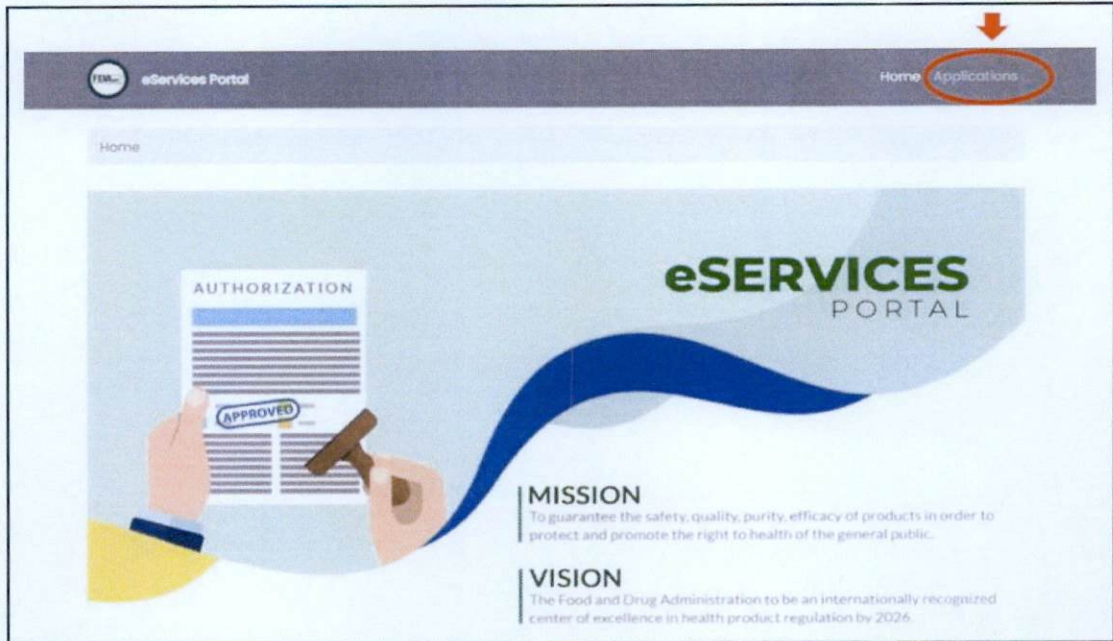
IV. Evaluation

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 this is a breadcrumb trail: '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 is a box with the following text:

Drug
For drug products, including
Biologicals, Vaccines and Veterinary
Products

4. Select the Product Category.

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 this is a breadcrumb trail: '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
- Human Drugs - Prescription**
For products which fall under the category of Human Drugs - Prescription
- 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
- Vaccines and Biologics**
For products which fall under the categories of Vaccines and Biologics (including Biotechnological Product, Biosimilar, Biotechnological Product and/or Blood Products)
- Veterinary**
For products which fall under the category of Veterinary Drug Products (including Veterinary - Vaccines and Biologics)

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

The screenshot shows the FDA eServices Portal interface. At the top, there is a navigation bar with 'Home' and 'Applications'. Below it, a breadcrumb trail reads 'Home / Applications / CPR / Drugs / Biovac'. The main heading is 'Vaccines and Biologicals'. There are three main cards displayed, each with a clock icon. The first card is 'Automatic Renewal Registration for Regular CPR & PCPR'. The second card is 'Automatic Renewal Registration for CLIDP Automatic Renewal Applications'. The third card, which is highlighted with a red border, is 'Principal Certificate of Product Registration (PCPR) Conversion'.

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. On the left, there is a vertical navigation menu with steps 1 through 8. Step 1, 'Declaration & Undertaking', is selected. A blue box contains a warning: 'All products under Monitored Release (MR) and Monitored Release Extension (MRE) are not eligible to apply for PCPR Conversion.' The main content area is titled 'Declaration & Undertaking' and contains a list of conditions (V, VI, VII, VIII, IX). Below the list, there is a checkbox labeled 'I agree to the declaration and undertaking' which is checked and circled in red. At the bottom, there is a blue button labeled 'Start Application' with a red arrow pointing to it.

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 in the eServices Portal. The form is divided into several sections, with three sections circled in red and numbered 1, 2, and 3. A dropdown menu is open for the 'Establishment Type' field, with a red arrow pointing to it from the 'Applicant Information' section. The 'Next' button at the bottom right is also circled in red and numbered 4.

Applicant Information 1

* Company Name: Pan Pharmaceuticals

* Address: Unit 21A, 20th floor, Yander Bldg, Merlin Road, Brgy. 123, Taguig City, Metro

* Establishment Type: Drug Distributor - Importer

* ITO Number: I2345678910

Contact Information 2

* Email Address: abcd123@gmail.com

* Mobile Number: 09170000123

Landline Number: Landline Number of MAH

Details of the Contact Person 3

* First Name: Wendy

Middle Name: N.

* Last Name: Park

* Designation or Profession: Company Pharmacist

Government Issued Identification Document

* ID Type: PRC ID

* ID Number: 0012345

Expiry Date: 15 December 2023

Back Next 4

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

- Product Information** 1
- Applicant Information
- Product Information
- Special Conditions
- Packaging Description
- Establishment Information
- Uploading of Documents
- Self-Assessment Review

* Registration Number: DR-XY123456

* Date of Validity: 15 June 2026

* 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

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

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 25 and 195 Multiple Dose Vials
Ex. Alu-Alu blister pack x 10's

* Pack Size Box of 1's
example: box of 100's

GPIN / GTIN (if any) 1111111111

Suggested Retail Price (SRP) in Php Price per unit

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**.

FDA eServices Portal Home Applications

Home / Applications / CPR / Drugs / Biovac / Variation

Principal Certificate of Product Registration (PCPR) Conversion

- 1 Declaration & Undertaking **1** Indicate all Establishments reflected in the CPR
- 2 Applicant Information **Establishment Information 1**
 - * 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
- 3 Product Information
- 4 Special Conditions
- 5 Packaging Description
- 6 Establishment Information
- 7 Uploading of Documents
- 8 Self-Assessment Review

2 Click to add more establishments (as applicable)

3 Add Establishment

Back Next

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

FDA 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 **2**

Old CPR	Copy of previously issued CPR (front and back)	File Upload
Post-Approval Commitment	Copy of Post-Approval Commitment letter issued by FDA	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

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 / Biovac / 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' highlighted in a red oval. 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).

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

The screenshot shows the confirmation step. At the top left, there is a CAPTCHA box with a checkmark and the text 'I'm not a robot', which is circled in red. 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 right, there are two buttons: 'Back' and 'Confirm', with the 'Confirm' button circled in red and labeled with a '2'.