Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

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

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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 cdrr.od@fda.gov.ph.

ROLANDO ENRIQUE D. DOMINGO, MD
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.

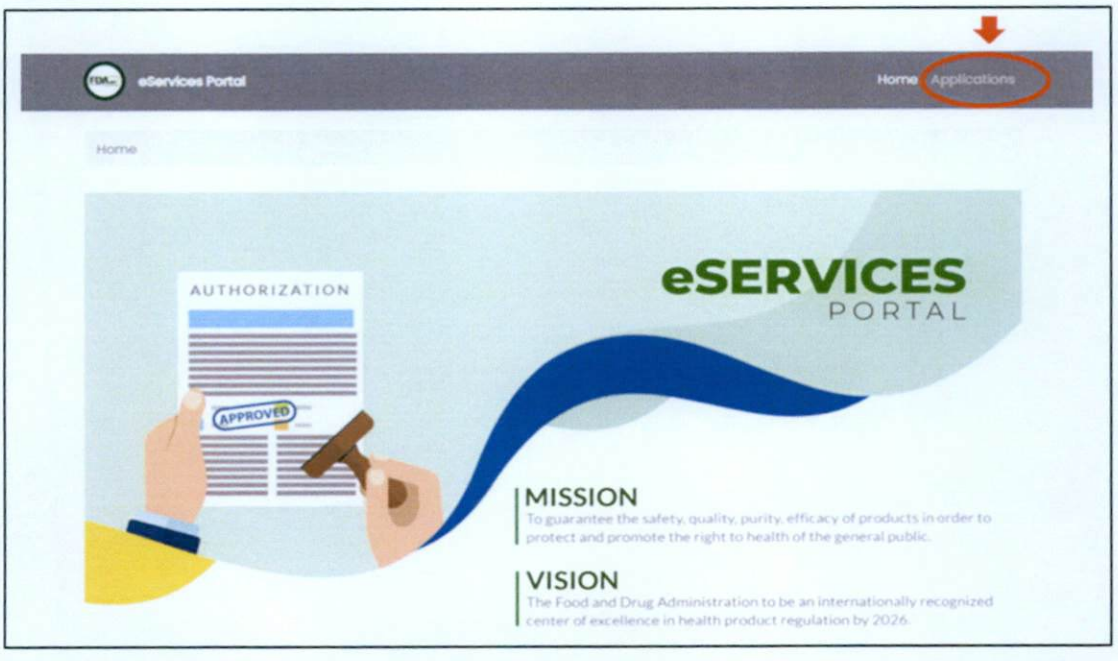
2. The action on the application shall be Approval or Disapproval pursuant to Republic Act (RA) No. 11032, otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act.

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

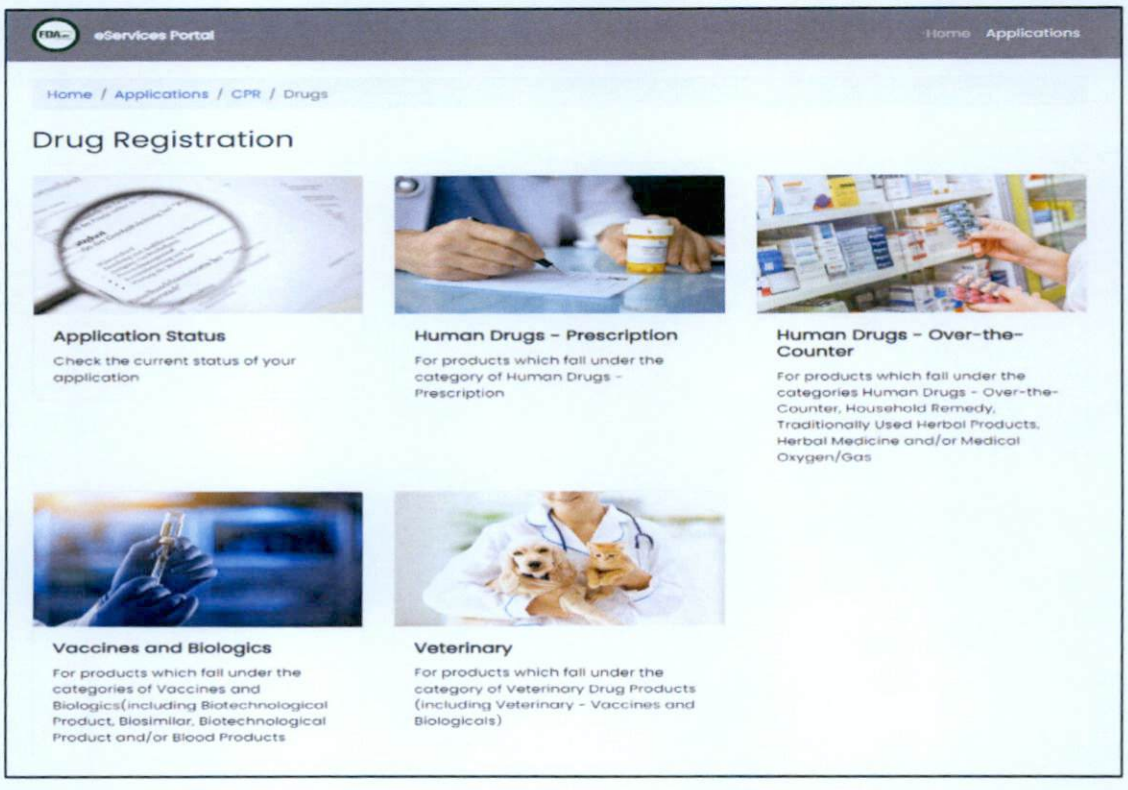
1. Access the online portal through https://eservices.fda.gov.ph and click **Applications** found at the upper right corner of the landing dashboard.



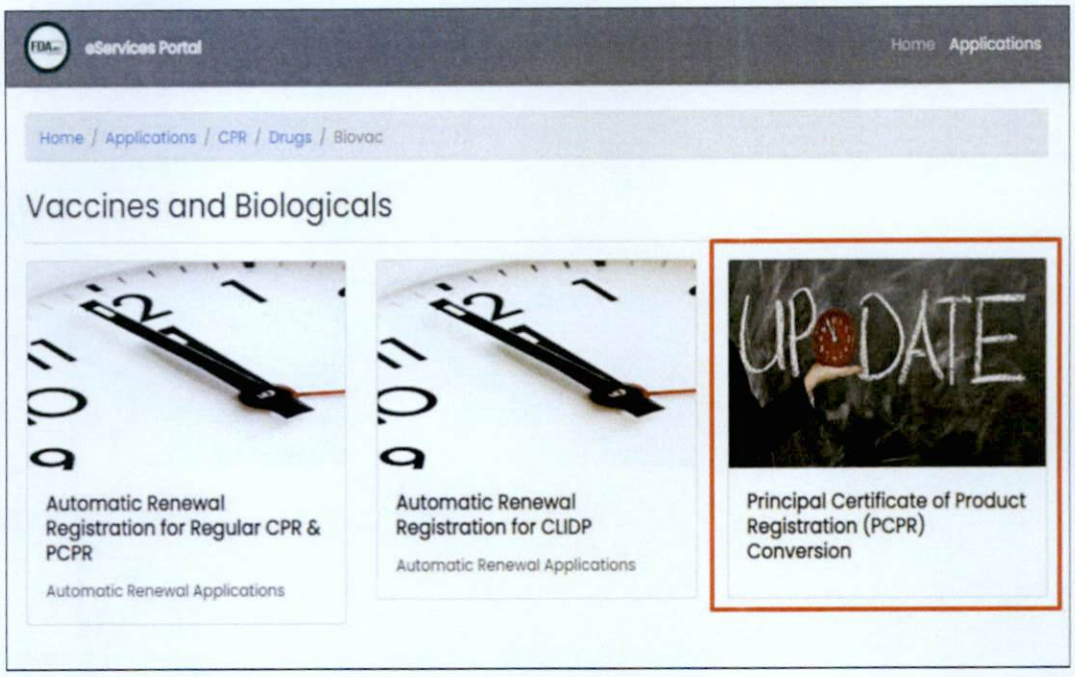
2. Click on the **Certificate of Product Registration.**

3. Click on the **Drug.**

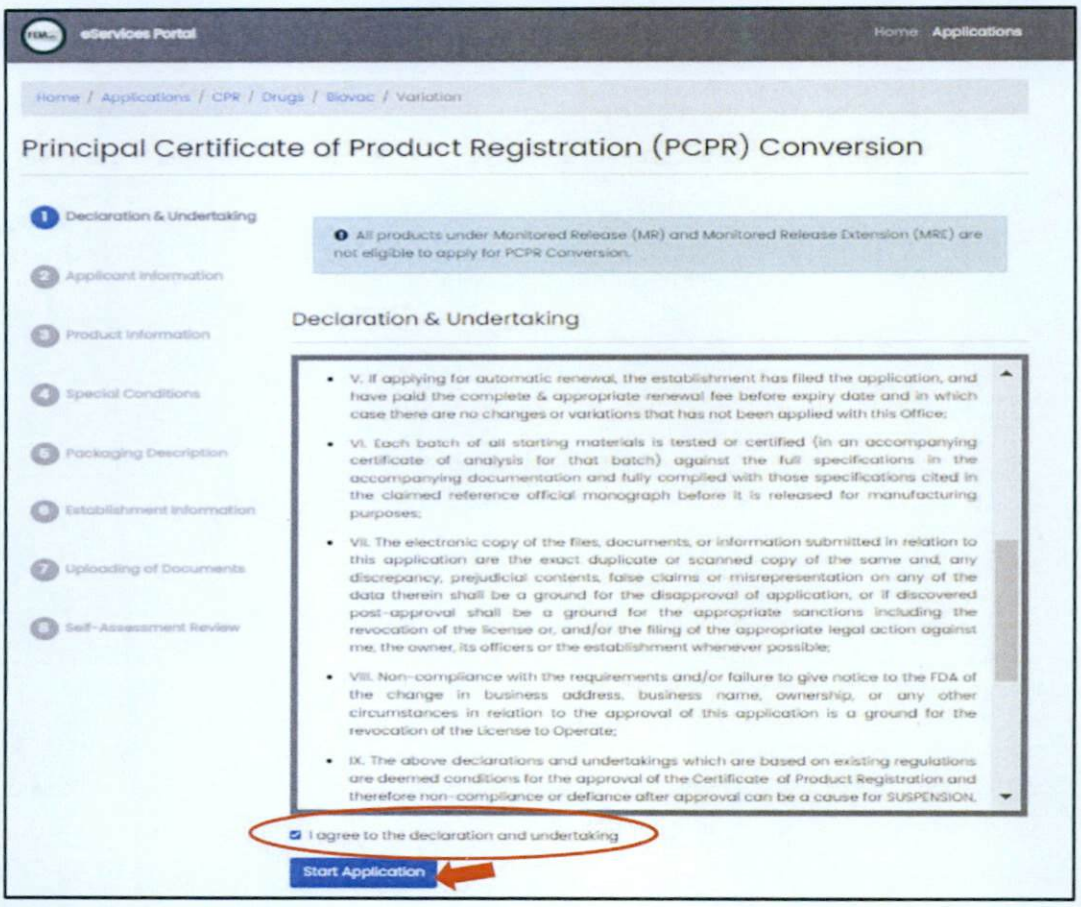
4. Select the Product Category.



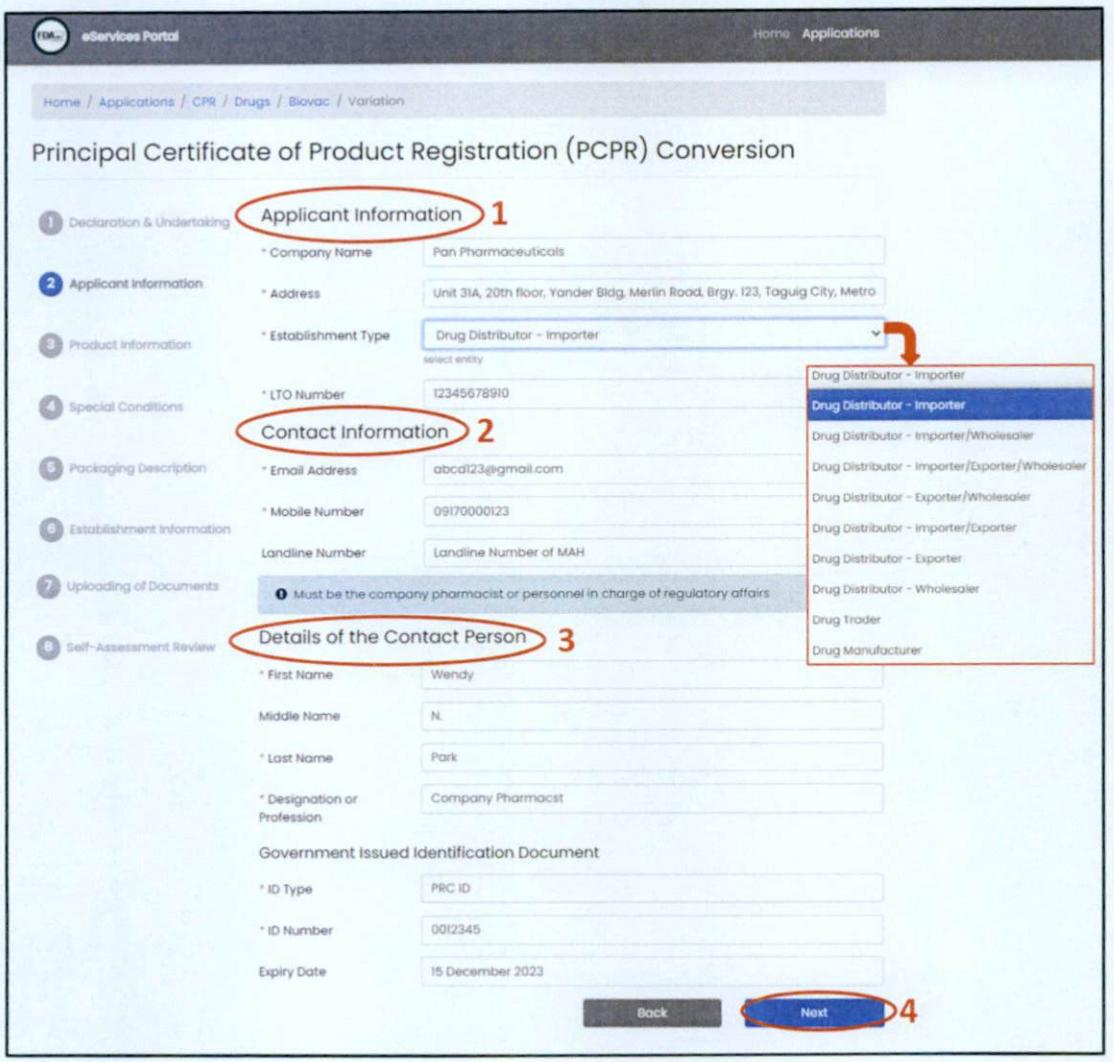
5. Click on the **Principal Certificate of Product Registration (PCPR) Conversion.**



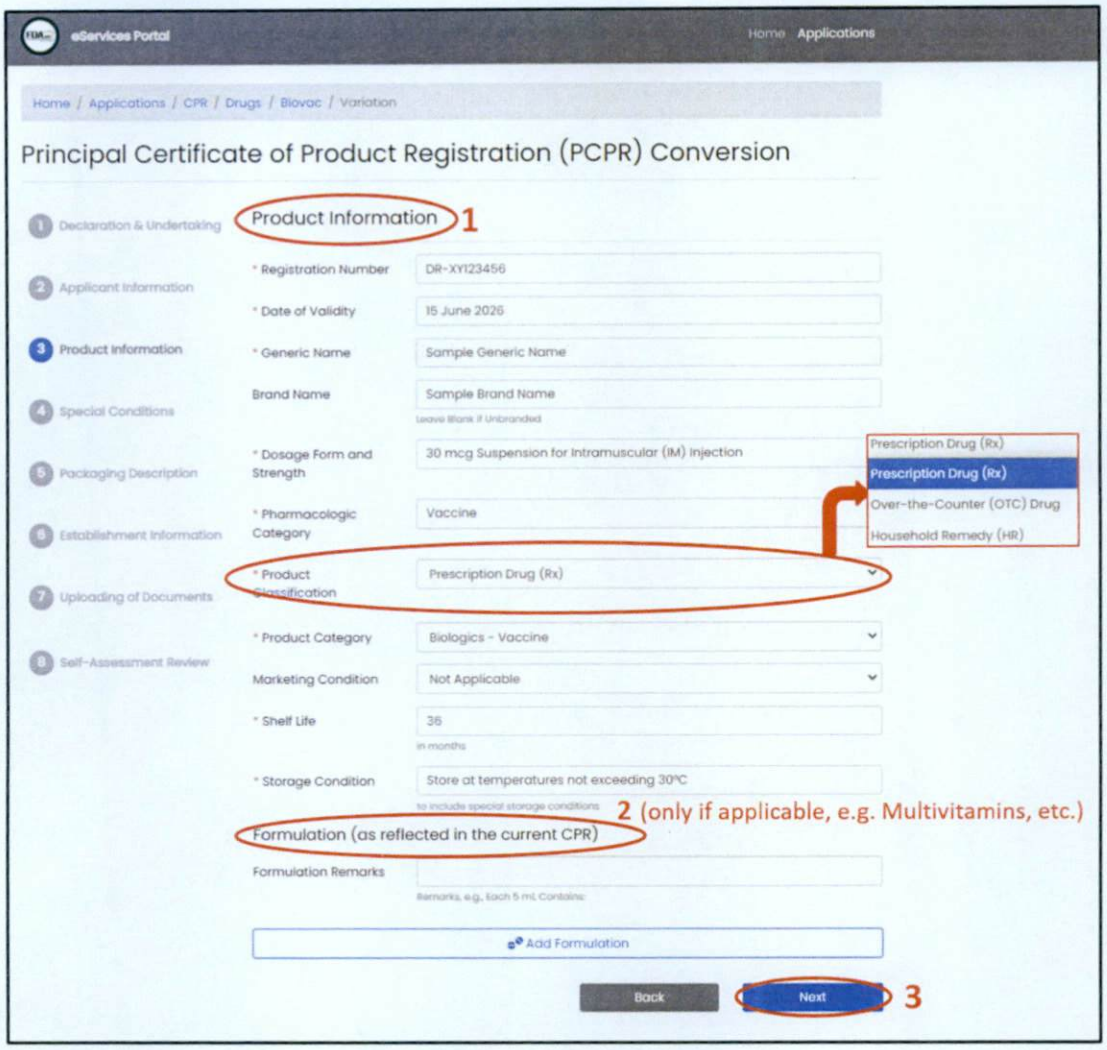
6. Read carefully the **Declaration & Undertaking.** Once done, check the box if you agree with all the conditions stated. Click on the **Start Application.**



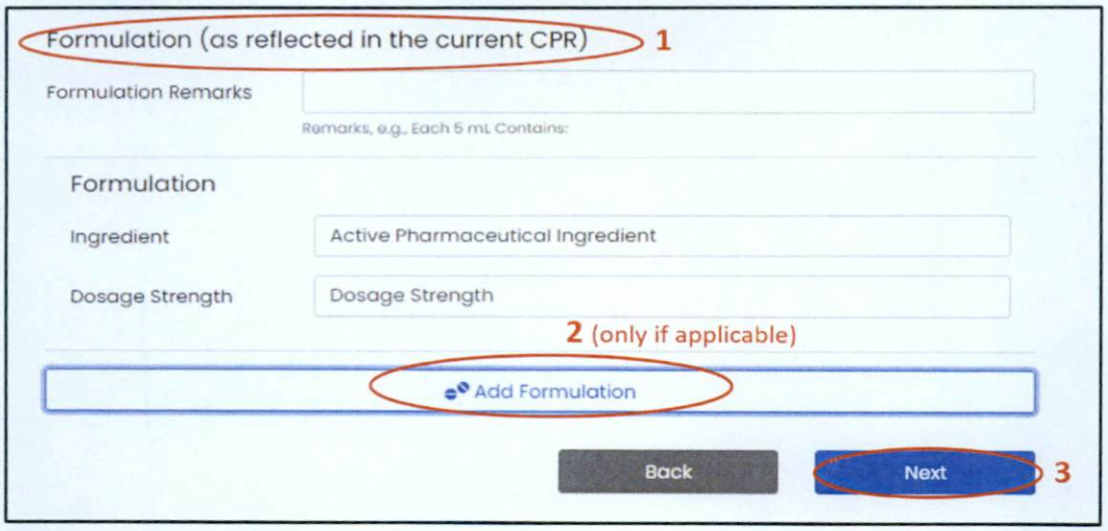
7. In the **Applicant Information** page, fill out all the required fields which are marked with asterisk (*). Provide a valid and working e-mail address and mobile number in the Contact Information, and the company pharmacist or the person in charge of the regulatory affairs in the Details of the Contact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



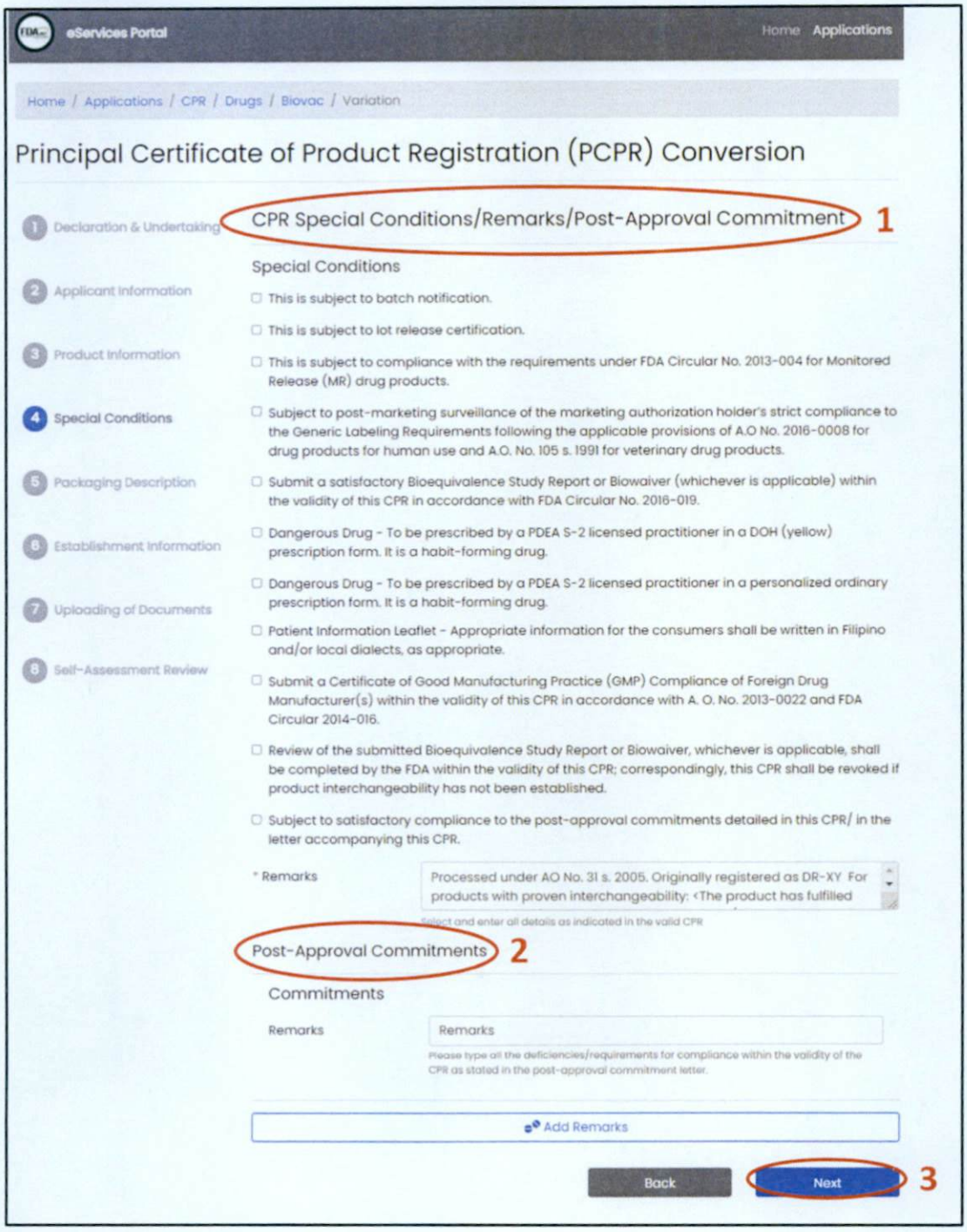
8. Fill out all the required fields in the **Product Information** page.



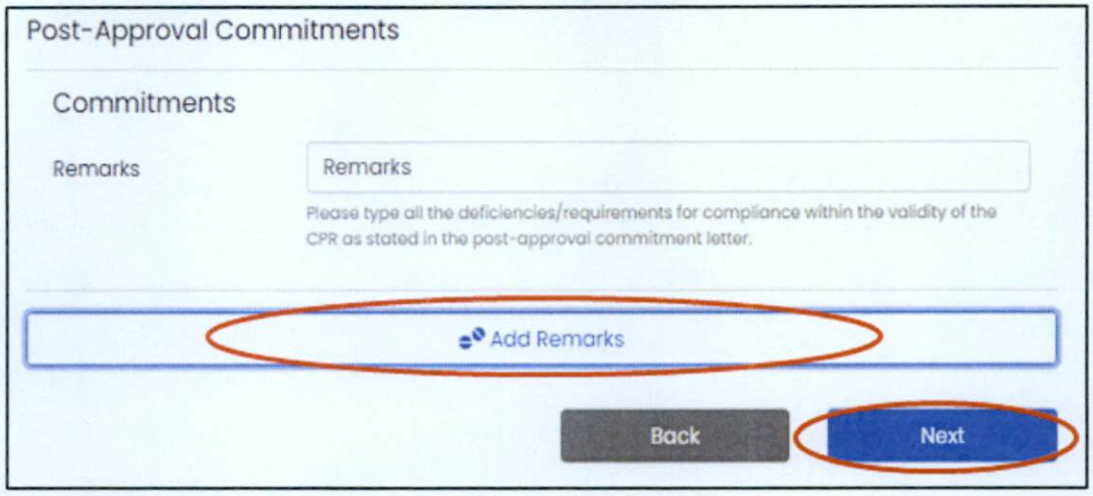
9. In the Formulation, provide all the formulations reflected in your current Certificate of Product Registration (CPR). Click on **Next**.



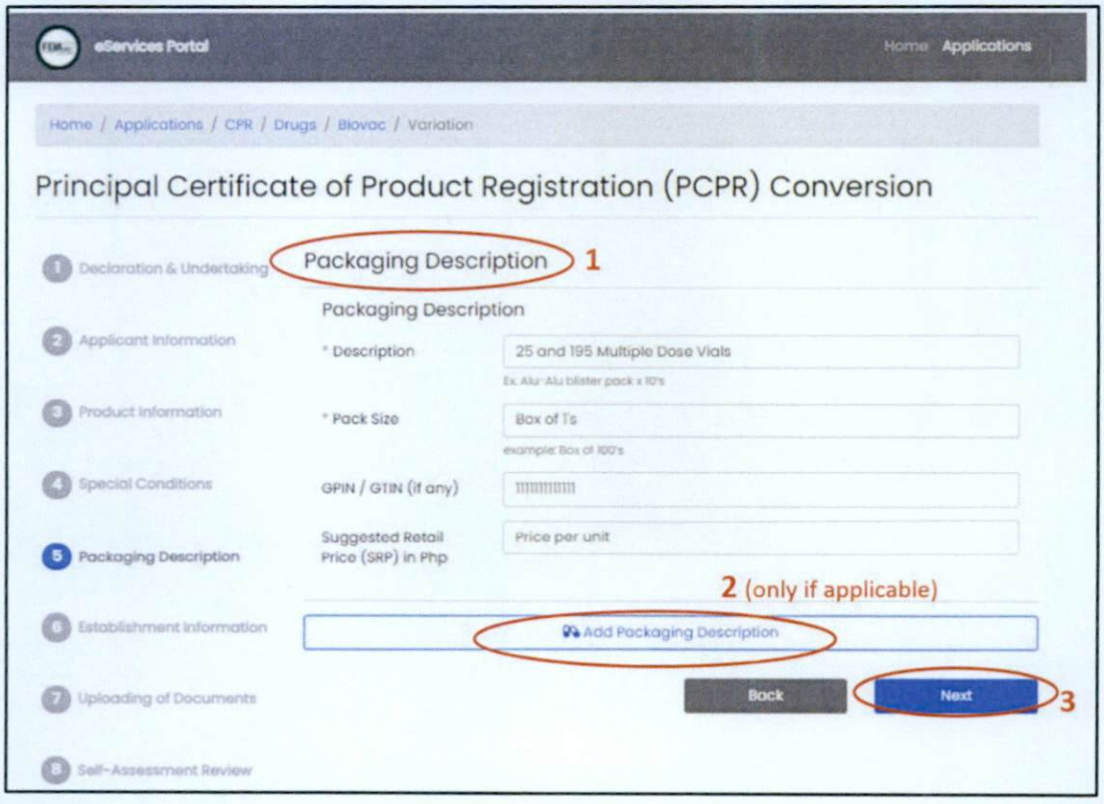
10. In the **Special Conditions** page, tick all the special conditions/remarks/post-approval commitment as reflected in your current valid CPR.



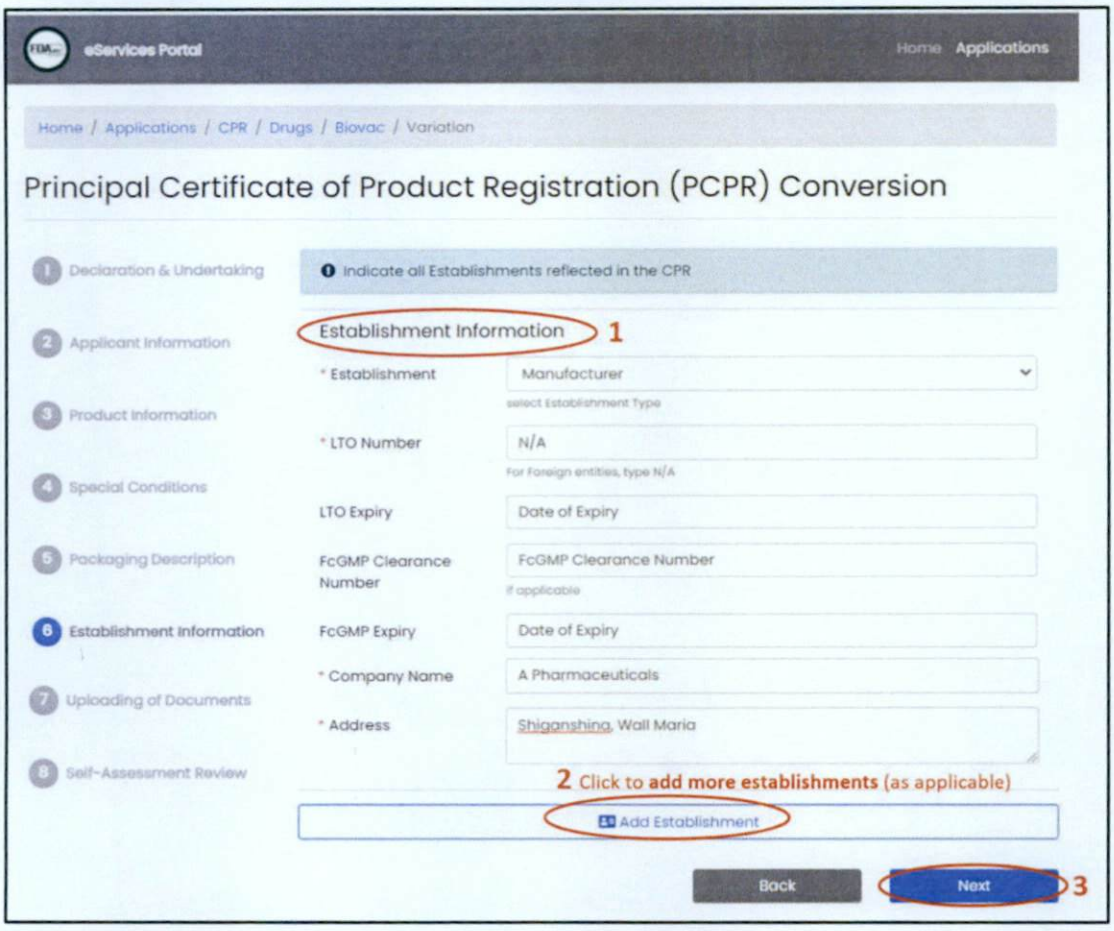
11. In the Post-Approval Commitment, provide all the deficiencies/requirements for compliance within the validity of the CPR as stated in the post-approval letter. Click on **Next**.



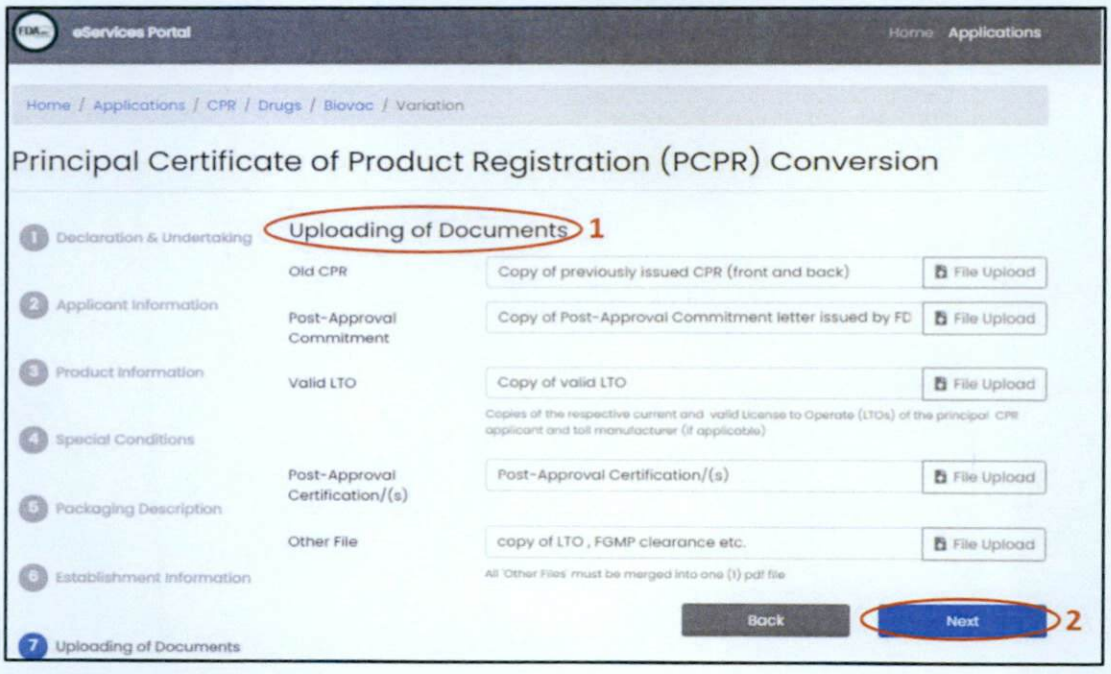
12. In the **Packaging Description** page, provide the details of all approved pack sizes. Click on **Next.**



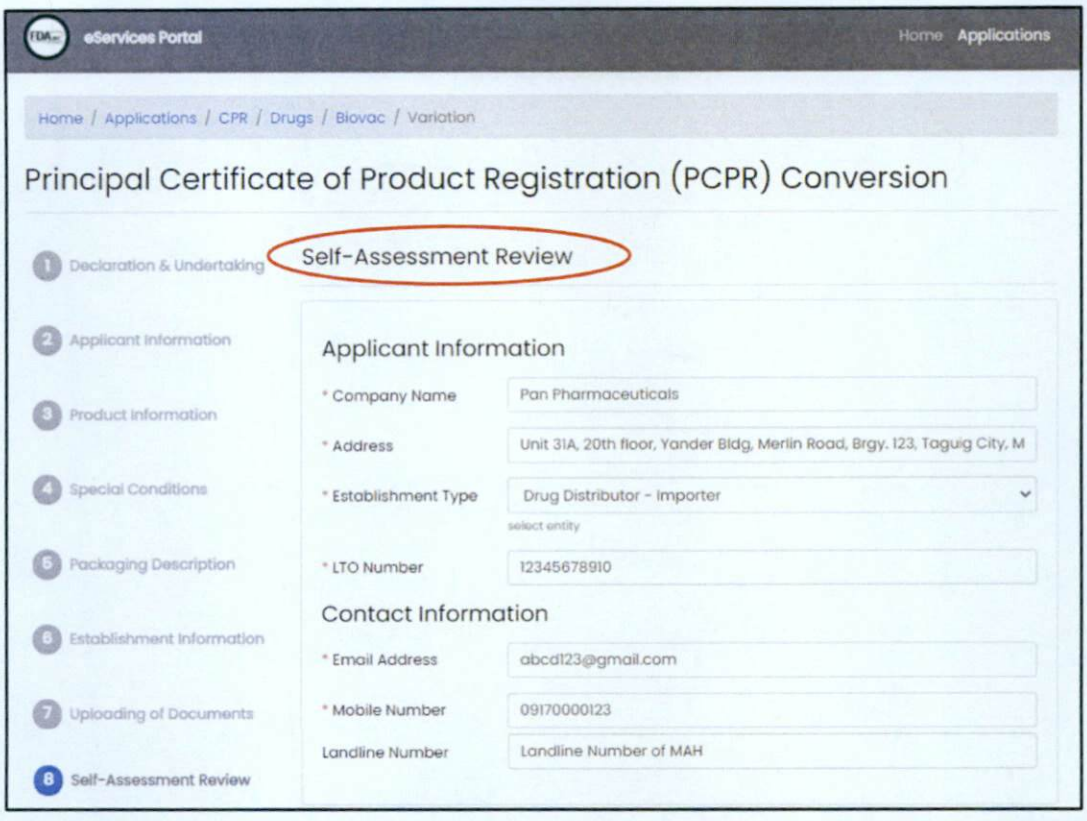
13. Provide the required details of all the establishments reflected in the CPR. Click on **Next.**



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



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



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