ANNEX A

Guidelines on the Initial Application for Certificate of Product Registration (CPR) of Generic Prescription Drugs for Human Use using the FDA eServices Portal System Website

I. Application Schedule

During the pilot implementation of the e-CPR Information System, applicants shall apply for Initial CPR of human prescription generic drugs using the FDA eServices Portal System website (URL: https://eservices.fda.gov.ph) following below schedule:

Pilot Run Period	:	07 May 2024 to 07 August 2024
Submission Day and Time	:	Tuesdays and Wednesdays 7:00 AM to 6:00 PM

II. Registration Requirements and Application Processing Timeline

The documentary requirements for registration and the turn-around time for application processing shall be based on existing rules and regulations as posted in the FDA Citizen's Charter.

III. Application Fee

The application fee shall be based on the current fees and charges as per Department of Health (DOH) Administrative Order No. 50 s. 2001.

IV. Overview of Application and Review Process Steps

1. Online Submission of Application Form

Applicant Action	Decision and Outcome
Fill up the Application Form using the FDA eServices Portal System website (Refer to Annex B).	If complete information: The applicant can proceed to submit the Application Form. Then two (2) email notifications are sent to the applicant. The first email includes the Application Summary. The second email includes the link to the designated SharePoint folder where the applicant should upload the application documents. If incomplete information: The applicant cannot proceed to submit the Application Form.

2. Uploading of Documents

Applicant Action	Timeframe	Outcome
Upload the documentary requirements in the SharePoint folder within the given timeframe.	Within 2 working days from the receipt of the email instructions to submit documents	After the given timeframe, the uploaded documents shall be forwarded for pre-assessment, and the applicant shall lose access to edit the SharePoint folder.

3. Pre-assessment

Agency Action	Person Responsible	Decision and Outcome
Pre-assess the completeness of the documentary requirements.	CDRR Pre-assessor	If the submission is Acceptable: The pre-assessor forwards the application for payment, and the applicant receives an Order of Payment through email. If the submission is Not Acceptable: The pre-assessor triggers the termination of the registration process, and the applicant receives the Pre-assessment Result.

4. Payment

Applicant Action	Timeframe	Outcome
Pay the corresponding fee to Landbank via Landbank Link.Biz Portal payment and Landbank Oncoll Deposit.	Within 7 working days after receipt of the Order of Payment	The applicant receives a Debit Confirmation Slip of LANDBANK Link.BizPortal and/or email confirmation for every successful transaction.

5. Payment Validation

Agency Action	Person Responsible	Decision and Outcome	Timeframe
Validation of payment and posting of payment details	FDA Cashier	If the payment is Sufficient: The FDA Cashier forwards the application to CDRR for evaluation, and the applicant receives the Acknowledgment Receipt and application status notification through email. If the payment is Insufficient: The applicant receives a notice of insufficient payment through email and is instructed to settle the payment balance.	Within 5 working days after receipt of payment notification from Landbank

6. Evaluation

Agency Action	Person Responsible	Decision and Outcome	Timeframe
Evaluate the application according to requirements and prescribed standards, issue Notice of Deficiencies (NOD) and draft the recommendations, i.e. Certificate of Product Registration and	CDRR Evaluation Team composed of the Junior Evaluator/Food Drug Regulation Officer (FDRO) I/II, Senior Evaluator/FDRO III and Supervisor/FDRO IV	If the application is satisfactory: The evaluation team forwards the recommendations for quality assurance, and the applicant receives an application status notification through email.	Within 120 working days from the date of receipt of the application forwarded by FDA Cashier

attachments, Post-Approval Commitment Letter (if applicable), or Letter of Disapproval		If the application has deficiencies: The evaluation team sends an email Notice of Deficiencies (e-NOD) to the applicant to require compliance within a given timeframe. Upon receipt of the applicant's response or after the given timeframe, the team reviews the submitted documents, and forwards the recommendations for quality assurance. The applicant receives an application status notification through email.	

7. Quality Assurance Check

Agency Action	Person Responsible	Outcome	Timeframe
Check and endorse the recommendations for final decision.	CDRR Licensing and Registration Division Chief	After quality assurance check, the applicant receives an application status notification through email.	Within 120 working days from the date of receipt of the application forwarded by FDA Cashier

8. Final Decision and Release of Results

Agency Action	Person Responsible	Outcome	Timeframe
Review, approve and sign the recommendations, then trigger the release of FDA issued authorization or documents to the applicant.	CDRR Director	After the final decision is done, the applicant receives the electronic marketing authorizations and other documents issued by FDA through email for record keeping.	Within 120 working days from the date of receipt of the application forwarded by FDA Cashier

V. Responsibilities of the Applicant

1. Enter accurate, correct and complete information in the online application form.
2. Ensure that the Authorized Person/s and/or Qualified Personnel handling the application has access to the declared e-mail address in the online application form.
3. Pay the prescribed fee and upload correct documentary requirements in the designated SharePoint folder within the given timeframe.
4. Attend to requests for compliance within the given timeframe as per email Notice of Deficiencies (e-NOD) from FDA.

VI. Collection of Feedback

Applicants who have filed for Initial Application for CPR of Human Prescription Generic Drugs using the FDA eServices Portal System during the pilot implementation of the e-CPR Information System are advised to accomplish the feedback form through this link: https://forms.office.com/r/qpit3m14Zd