



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



FDA ADVISORY  
No. 2022-0418

03 MAR 2022

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

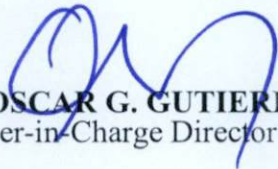
**SUBJECT : IMPLEMENTATION OF THE FOOD AND DRUG ADMINISTRATION (FDA) ESERVICES PORTAL SYSTEM FOR CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCT (CLIDP) APPLICATIONS**

The FDA, in its commitment to provide stakeholders with streamlined and improved government services, developed the **FDA eServices Portal System** for Certificate of Listing of Identical Drug Product (CLIDP) applications.

The FDA advises and encourages all stakeholders to utilize the eServices Portal System for CLIDP 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 CLIDP Applications Using eServices Portal System and **Annex B** for Procedure on the Use of the FDA eServices Portal System for CLIDP Applications.

For any feedback and comments for the FDA eServices Portal, please send them to [cdrr.od@fda.gov.ph](mailto:cdrr.od@fda.gov.ph).

  
**DR. OSCAR G. GUTIERREZ, JR.**  
Officer-in-Charge Director General



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## ANNEX A

### Guidelines on Certificate of Listing of Identical Drug Product Applications Using eServices Portal System

#### I. Guidelines

1. All Certificate of Listing of Identical Drug Product 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 Certificate of Listing of Identical Drug Product 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, 'eServices Portal', and 'Home Applications'. 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 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
- 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 **Certificate of Listing of Identical Drug Product (CLIDP)**.

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 application tiles: 'Automatic Renewal Registration for Regular CPR & PCPR', 'Automatic Renewal Registration for CLIDP', and 'Principal Certificate of Product Registration (PCPR) Conversion'. A fourth tile, 'Certificate of Listing of Identical Drug Product (CLIDP)', is highlighted with a red border. This tile includes an image of a hand holding a pill in front of a chalkboard with 'UPDATE' written on it, and the text 'CLIDP Applications'.

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 'Certificate of Listing of Identical Drug Product (CLIDP)' application page. On the left is a vertical navigation menu with steps 1 through 8. Step 1, 'Declaration & Undertaking', is selected. A blue information box states: 'All products under Monitored Release (MR) and Monitored Release Extension (MRE) are not eligible to apply for CLIDP Conversion.' The main content area is titled 'Declaration & Undertaking' and contains a text box with the following text: '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:'. Below this text are three bullet points: 'I. The current Good Manufacturing Practice Guidelines is applied in full in the manufacture of this product;', 'II. The formulation per dosage form is in agreement with the master formula and with the batch manufacturing record forms;', and 'III. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing records;'. At the bottom, there is a checkbox labeled 'I agree to the declaration and undertaking' which is checked and circled in red. Below the checkbox is a blue 'Start Application' button 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**.

**eServices Portal** Home Applications

Home / Applications / CPR / Drugs / Biovac / Clidp conversion

### Certificate of Listing of Identical Drug Product (CLIDP)

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

**Applicant Information 1**

\* Company Name Pan Pharmaceuticals

\* Address Unit 31A, 20th floor, Yander Bldg., Merlin road, Brgy. 123, Taguig City, Metro

\* Establishment Type Drug Distributor - Importer

select entity

\* LTO Number 12345678910

**Contact Information 2**

\* Email Address abcd123@gmail.com

\* Mobile Number 0917000123

Landline Number Landline Number of MAH

**Details of the Contact Person 3**

\* Must be the company pharmacist or personnel in charge of regulatory affairs

\* First Name Wendy

Middle Name N.

\* Last Name Park

\* Designation or Profession Company Pharmacist

Government Issued Identification Document

\* ID Type PRC ID

\* ID Number 00123456

Expiry Date 15 December 2023

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

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### Certificate of Listing of Identical Drug Product (CLIDP)

- 1 Declaration & Undertaking **Product Information** 1
- 2 Applicant Information
  - \* PCR Registration Number: DRP-123456
  - \* PCR Date of Validity: 18 June 2026
- 3 Product Information
  - \* Generic Name: Sample Generic Name
- 4 Special Conditions
  - Proposed Brand Name: Sample Brand Name  
Leave Blank if Unbranded
- 5 Packaging Description
  - \* Dosage Form and Strength: 500 mcg/g
- 6 Establishment Information
  - \* Pharmacologic Category: Vaccine
- 7 Uploading of Document
  - \* Product Classification: Prescription Drug (Rx)
- 8 Self-Assessment Review
  - \* Product Category: Biologics - Vaccine
  - Marketing Condition: Please Select
  - \* Shelf Life: 36  
in months
  - \* Storage Condition: Store at temperatures between 30°C  
For accurate storage information

**Formulation (as reflected in the current CPR's back page, where applicable)**

Formulation Remarks: **2 (only if applicable, e.g. Multivitamins, etc.)**  
Remarks, e.g., Each 5 ml Contains:

[Add Formulation](#)

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

9. In the Formulation, provide all the formulations reflected in the current valid PCPR. Click on **Next**.

**Formulation (as reflected in the current CPR)** 1

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

**Formulation**

Ingredient:

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 the current valid PCPR.

FDA eServices Portal Home Applications

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## Certificate of Listing of Identical Drug Product (CLIDP)

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

**CPR Special Conditions/Remarks/Post-Approval Commitment** 1

**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.
- 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.

Has the product fulfilled the requirements of product interchangeability/equivalence with the submission of a satisfactory (if applicable):

- Bioequivalence (BE) Study Report
- Biowaiver based on Dose Proportionality
- Biopharmaceutics Classification System (BCS)

**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 PCPR 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**.

FDA eServices Portal Home Applications

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### Certificate of Listing of Identical Drug Product (CLIDP)

1 Declaration & Undertaking **Packaging Description 1**

2 Applicant Information

3 Product Information

4 Special Conditions

5 Packaging Description

6 Establishment information **2 (only if applicable)**

7 Uploading of Documents

8 Self-Assessment Review

Package Description

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

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

GPIN / GTIN (if any) 11111111

Suggested Retail Price (SRP) in Php Price per unit

[Add Packaging Description](#)

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13. Provide the required details of all establishments to be reflected in the CLIDP. Click on **Next**.

FDA eServices Portal Home Applications

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### Certificate of Listing of Identical Drug Product (CLIDP)

- 1 Declaration & Undertaking **1** Indicate all Establishments reflected in the CPR
- 2 Applicant Information **1** Establishment Information  
\* Company Name A Pharmaceuticals  
\* Address Civic Drive, Alabang, Muntinlupa City  
\* 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 18 June 2023
- 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**

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

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### Certificate of Listing of Identical Drug Product (CLIDP)

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Product Information
- 4 Special Conditions
- 5 Packaging Description
- 6 Establishment Information
- 7 Uploading of Documents **1** Uploading of Documents  
LTO of the Distributor File Upload  
Copy of the current and valid LTO of the Identical Drug Applicant  
LTO of the PCPR Holder File Upload  
Copy of the current and valid LTO of the PCPR Holder  
Valid PCPR File Upload  
Copy of current and valid PCPR  
Agreement File Upload  
Authenticated copy of the duly notarized Distributorship Agreement, license Agreement, or other written contract between the principal CPR holder and the identical Drug Applicant  
Labelling Materials File Upload  
All Other Files must be merged into one (1) pdf file  
Foreign GMP Clearance (For Imported products) File Upload  
Copy of current and valid Foreign GMP Clearance
- 8 Self-Assessment Review

**2**

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

Home / Applications / CPR / Drugs / Biovac / Clidp conversion

### Certificate of Listing of Identical Drug Product (CLIDP)

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

**Applicant Information**

\* Company Name: Pan Pharmaceuticals

\* Address: Unit 31A, 20th floor, Yander Bldg., Merlin road, Brgy. 123, Taguig City, M

\* Establishment Type: Drug Distributor - Importer  
select entity

\* LTO Number: 12345678910


**Contact Information**

\* Email Address: abcd123@gmail.com

\* Mobile Number: 09170000123

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.

1  I'm not a robot 

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.

2