F. CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCTS (CLIDP) OF PHARMACEUTICAL PRODUCTS (ELECTRONIC CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCTS) [E-CLIDP]

The CLIDP is granted to identical drug products as proof that its pharmaceutical product has been officially listed by FDA as identical, in terms of its manufacturer and formulation, to the pharmaceutical product already covered by the Principal CPR

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	AO 50 s. 2001 and AO 2005-0031 Branded: Php 3,000.00/year* + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year* + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Certificate of Listing of Identical Product (CLIDP)	
1. Proof of payment (based on AO 50 s. 2001 and AO 2005-0031)	Applicant
2. Copy of the current and valid LTO of the PCPR and Identical Drug Applicant	Applicant
3. Copy of current and valid PCPR	Applicant
4. Authenticated copy of the duly notarized Distributorship Agreement, license Agreement, or other written contract between the principal CPR holder and the identical Drug Applicant	Applicant
5. Facsimile of Labeling Materials	Applicant
6. Additional Requirement for Imported Products: Foreign GMP Clearance	Applicant

References:	
1. Republic Act 9711 – Food and Drug Administration Act of 2009 2. Administrative Order No. 2005-31 - Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation 3. Bureau Circular No. 11 s. 2006 - Specific Operational Instructions Implementing Administrative Order No. 2005-0031 dated December 7, 2005, Subject: Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation 4. FDA Advisory No. 2021-1791 – Pilot Implementation of the Food and Drug Administration (FDA) eService Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications 5. FDA Advisory No.2022-0418 - Implementation of The Food and Drug Administration (FDA) Eservices Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications 6. FDA Advisory No.2022-0907 - Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) “Applications“		None	0	
2. Select “Certificate of Product Registration” and select “Drug”. Select the classification of the product to be registered then select “Certificate of Listing of Identical Drug Products (CLIDP) Of Pharmaceutical Products”.		None	0	

3. Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None	0	
4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None	0	
5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1. Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None	0	CDRR Pre-assessor
6. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail		None	0	

7. Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	2. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Branded: Php 3,000.00/year + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF *per year – depending on the remaining validity of the Principal Certificate of Product Registration (PCPR)	0	FDA Cashier
	3. Post payment in eServices for confirmed payments. Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None	0	FDA Cashier
	4. This will prompt automatic decking of application to respective Center	None	0	ICTMD (eService)

8. Receives acknowledgement receipt through email Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator.	5. The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance (QA). Note: (1) For applications with proposed brand names, request approval from the Brand Name Clearance (BNC) evaluator. (2) Any minor deficiencies/ clarifications will be communicated through electronic communication. The Client is given 5 working days to comply. If the client complies or when there is no deficiency found, the CDRR evaluator will resume its evaluation.	None	Day 1-20 20 working days	FDRO I/II (CDRR Evaluator)
	6. QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	Day 21-25 5 working days	FDRO IV (CDRR Supervisor)

	7. Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	Day 26-30 5 working days	Director IV
9. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	
	TOTAL:		**30 Working days**	