FDA ADVISORY
No. 2024-0748

TO : **DRUG MANUFACTURERS, TRADERS, DISTRIBUTORS AND THE GENERAL PUBLIC**

SUBJECT : **PILOT IMPLEMENTATION OF THE ELECTRONIC CERTIFICATE OF PRODUCT REGISTRATION (E-CPR) INFORMATION SYSTEM FOR THE APPLICATION FOR INITIAL REGISTRATION OF GENERIC PRESCRIPTION DRUGS FOR HUMAN USE FROM 07 MAY 2024 TO 07 AUGUST 2024**

The Food and Drug Administration (FDA) has developed the **Electronic Certificate of Product Registration (e-CPR) Information System**, which shall be included in the FDA eServices Portal System and shall serve as the platform for end-to-end processing of applications for initial registration of generic prescription drugs for human use. It integrates streamlined procedures, automated tracking of application status, and release of electronic communications and authorizations to applicants into one system.

The FDA hereby informs all stakeholders and the general public that the e-CPR Information System is now in its **pilot implementation stage**. All applicants for **Initial Registration of generic prescription drugs for human use** are hereby advised to file their new applications in the FDA eServices Portal System website following below schedule:

Type of Application	:	Initial Registration of Generic Prescription Drugs for Human Use
Pilot Run Period	:	07 May 2024 to 07 August 2024
Submission Day and Time	:	Tuesdays and Wednesdays 7:00 AM to 6:00 PM

During the pilot run, the following shall be observed:

1. Previous applications for initial registration of generic prescription drugs for human use that are (a) pending for submission of documents for pre-assessment to the Food and Drug Action Center (FDAC) and (b) pending for pre-assessment are hereby cancelled. In this regard, the applicant shall be advised to file the application through the FDA eServices Portal System website.
2. Previous applications for initial registration of generic prescription drugs for human use with acceptable pre-assessment result shall proceed to payment and shall still be processed using the manual evaluation procedure.
3. In the event that two (2) applications for initial registration of the same drug product are accepted through FDAC and through the FDA e-Services Portal System, the applicant shall notify the FDA CDRR which application shall be retained. The other duplicate application shall be deemed withdrawn, and the corresponding payment shall be forfeited.
4. The FDA shall observe the right to cancel duplicate applications, whether received through FDAC and/or FDA e-Services Portal System, with forfeiture of payment.

All other drug product applications stated below shall still be filed through FDAC following the existing procedures as indicated in the FDA Citizen's Charter:

1. Monitored Release (MR) applications for New Chemical Entities
2. MR-turned-Initial applications
3. Initial applications for all other types of pharmaceutical products for human use including Vaccines and Biologicals, Reproductive Health Products, Over-the-counter (OTC) Preparations, Household Remedies (HR), Herbal Medicines, Traditionally-used Herbal Products and Medical-Grade Oxygen
4. Initial applications for Animal Health Products
5. Applications for Post-Approval Change (PAC) of Pharmaceutical Products including those requiring application fee equivalent to that of Initial Registration
6. Initial, MR and PAC applications for New and Generic Drugs including Vaccines and Biologicals via Facilitated Registration Pathway (FRP)
7. Initial, MR and PAC applications for World Health Organization (WHO) – Prequalified Products and Vaccines via Collaborative Review Procedure (CRP)

The guidelines and procedures are included in **Annex A and B** of this Advisory.

All marketing authorizations and other documents issued through the e-CPR Information System are deemed valid and considered an official act of the FDA.

For everyone's information and guidance.

DR. SAMUEL A. ZACATE
Director-General

Annexes:

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

Annex B: Procedure on the Use of FDA eServices Portal System Website for the Initial Application for Certificate of Product Registration (CPR) of Generic Prescription Drugs for Human Use