

NATIONAL



AUTHORITY

Safe Drugs Save Lives

13th February 2024

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To: Marketing Authorization Holders
Local Technical Representatives

CIRCULAR NO. 002/DPAR/2024

FAST-TRACK ASSESSMENT OF CTD DOSSIER APPLICATIONS.

National Drug Authority wishes to inform you that it will begin receiving CTD dossier applications for fast-track assessment.

As per the National Drug Policy and Authority (Fees) Regulations 2022, under S I No. 5 part one "Fees for Registration of drugs, retention, notification, and amendment," the National Drug Authority (NDA) allows for the fast tracking of CTD (Common Technical Document) dossier applications at a fee of **USD 10,000** per application.

Please note that:

1. The timeline for feedback on a CTD fast track application is 3 months. This period does not include additional information if requested. The timeline for feedback on additional information is 1 month.
2. The Finished Pharmaceutical Product (FPP) manufacturing site(s) must possess a valid NDA Good Manufacturing Practices (GMP) certificate or should have applied for an NDA GMP inspection at the time of submission of the application.
3. The applicant should compile the CTD dossier application as per the NDA guidelines on Submission of Documentation for Registration of a Pharmaceutical Product for Human Use (PAR GDL 004) available on the NDA website.

www.nda.or.ug

Yours faithfully,


David Nahamya
SECRETARY TO THE AUTHORITY



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OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

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