

NATIONAL



AUTHORITY

Safe Drugs Save Lives

09th September 2024

Ref: 1983G/DR/NDA-09/2024

To: Marketing Authorization Holders
Local Technical Representatives

CIRCULAR NO. 003/DPAR/2024

FAST-TRACK ASSESSMENT OF VARIATIONS (AMMENDMENTS) AND CTD DOSSIER APPLICATIONS.

National Drug Authority wishes to inform you that it commenced receipt of variations (amendments) and 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: -

1. Variations (Amendments) Applications

Please note that:

- i. Fee per application.
 - a. Major amendment - **USD 2,100.**
 - b. Minor amendment - **USD 1,200.**
- ii. The timeline for feedback on:
 - a. Major amendment - **12** working days.
 - b. Minor amendment - **10** working days.
- iii. The applicant should compile the variations (amendments) application as per the NDA guidelines available on the NDA website. www.nda.or.ug.
 - a. Guidelines on variations to registered pharmaceutical products.
 - b. Guidelines on variation of registered Biotherapeutic products.
 - c. Guidelines for Variation of Registered Vaccines.

HEAD OFFICE

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OUR MISSION

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

REGIONAL OFFICES

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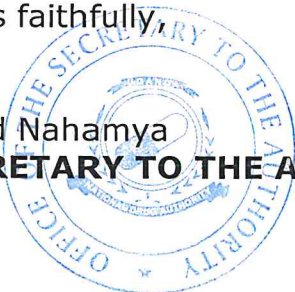
2. Common Technical Document (CTD) dossier applications

Please note that:

- i. Fee is **USD 10,000** per application.
- ii. 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.
- iii. 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.
- iv. 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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