DRUG

NATIONAL AUTHORITY

Safe Drugs Save Lives

6th December 2018

1150/NDA/DPS/12/2018

CIRCULAR NO. 26

Dear Investigator

INCOMPLETE CLINICAL TRIAL APPLICATION SUBMISSIONS

The National Drug Authority (NDA) is mandated under section 40 of the National Drug Policy and Authority Act, Cap 206 to regulate drug-related clinical trials. The National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014 provide the regulatory framework for submission, consideration, authorization and oversight of clinical trials in Uganda.

The Authority has noted that some investigators have continued to submit incomplete clinical trial applications and this hinders the Authority's ability to efficiently process your applications and offer a timely service.

This therefore serves to notify all investigators that incomplete submissions shall not be received at the NDA registry with ***immediate effect***. All submissions that are deemed incomplete will be returned through the bearer of the application documents to the respective applicant with a checklist indicating the missing regulatory requirements.

Thank you for your continued cooperation and your efforts in developing safe, efficacious and quality medicines.

Yours sincerely,

Helen Byomire Ndagije
DIRECTOR PRODUCT SAFETY

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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