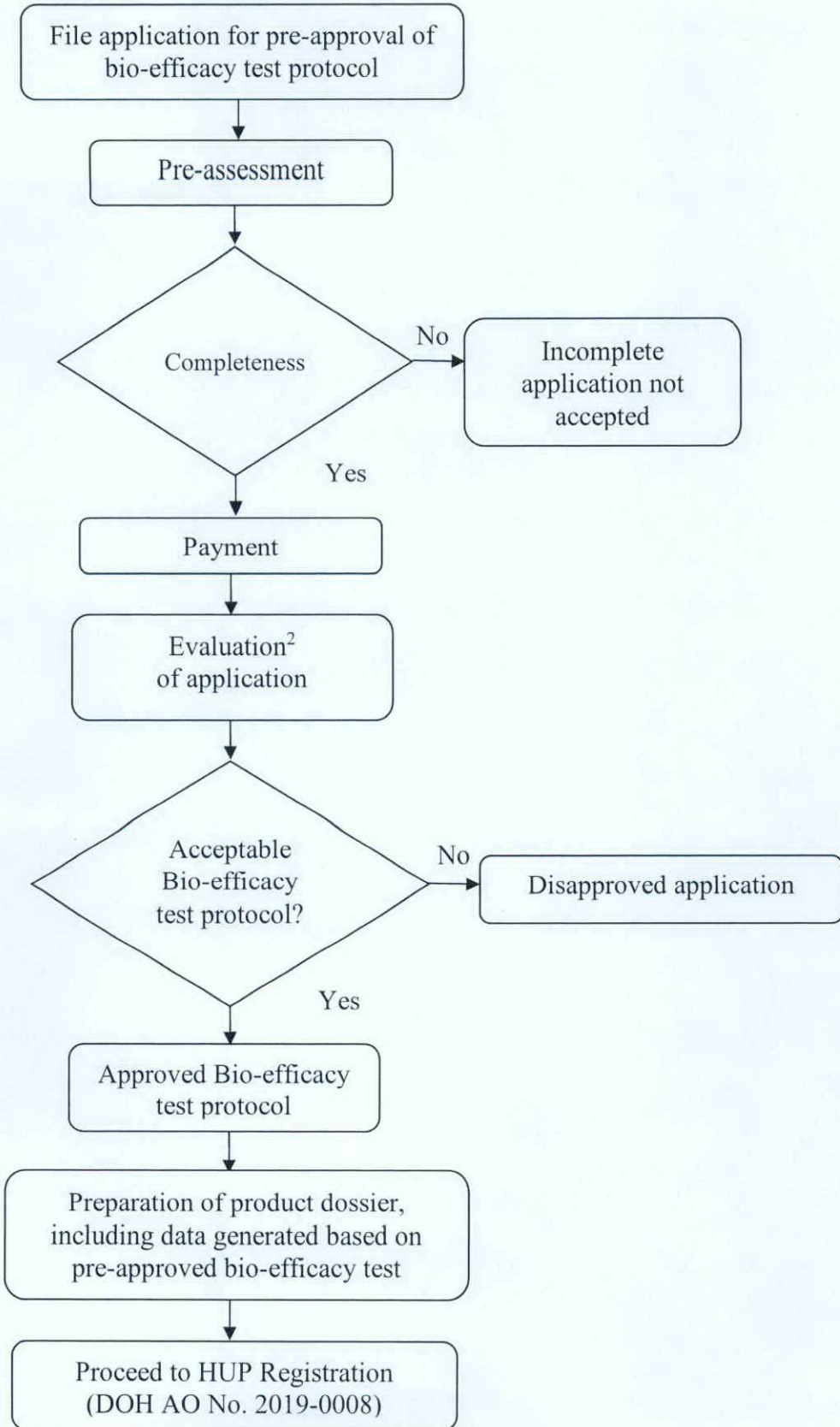


UPDATED ANNEX B
Step-by-step Application Procedure

1. Pathway for pre-approval of Modified/Non-standard Bio-efficacy test protocols



2. Application procedure for the review and pre-approval of test protocols:

- 2.1 Applicant sends a request for schedule of submission of application requirements to FDAC **with email subject “Request for schedule for HUP Bio-efficacy Protocol (Product name) “to (fdac@fda.gov.ph) or the latest nominated FDAC e-mail addresses as stipulated in the latest guidelines.** Requests for schedule may be submitted from Monday to Friday. **Applications received after the end of the business hours of the Agency shall be deemed to have been received the next immediate working day.** The schedule of the applications for pre-assessment is on Thursdays, except for Holidays, from 8AM to 12NN **or in accordance with the latest schedule announced by FDAC and the Center.**
- 2.2 Applicant submits the application requirements **with email subject “Submission of HUP Bio-efficacy Protocol (Product name) DTN”** for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from 8AM to 12NN. Only applications with complete requirements pre-assessed by the Center shall proceed to payment.
- 2.3 Applicant pays for the corresponding fee.
- 2.4 Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph) **together with the proof of payment.**
- 2.5 The FDAC forwards the application to the Center.
- 2.6 The Center **conducts an evaluation² of the received application and renders the decision. The disapproved application will provide the reasons of disapproval and advise the applicant to file a new application compliant with the standards and legal requirements on this FDA Circular.**
- 2.8 Releasing of the final issued document **via electronic mailing to the applicant’s declared email address.**

² The flow chart is hereby updated to reflect the general evaluation procedure which may include the review of a Bio-efficacy expert/consultant.