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ANNEX A

Procedure for the Submission of Requests for HUHS LTO Renewal

The following procedure shall apply for the submission of requests for HUHS LTO Renewal pursuant to this FDA Circular:

1. On or before the expiry of the previously issued LTO, the HUHS establishment shall submit a notarized letter request for LTO renewal to the Food and Drug Action Center (FDAC). Refer to Annex B for the template on the letter for request for HUHS LTO renewal.
2. FDAC shall assign a document tracking number (DTN) to the letter and endorse it to the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR).
3. CCHUHSRR shall check the information and make appropriate updates in the DTN on the result of the request:
 - a. **Acknowledgement** - Note of acknowledgement for submitted correct and complete notarized letter and declaration statement; or
 - b. **Needs clarification** - Information or instruction for requests with concerns or needing clarifications; or
 - c. **Disapproved** - Reasons for disapproval of disapproved requests.
4. The status and/or decision of their request shall be posted through the DTN as uploaded in the FDA Kiosk accessible at <https://www.fda.gov.ph/kiosk/>.

HUHS establishments shall check the FDA website and platforms for any updates or issuances on the availability, implementation, guidelines and procedure for the on-boarding of the HUHS licensing process to the FDA eServices Portal System.