

ANNEX E

LICENSE TO OPERATE APPLICATIONS EXEMPTED FROM AUTOMATIC RENEWAL

The automatic renewal applications shall not be applicable in the following instances:

1. Those with critical findings of inspection during the validity of the LTO immediately preceding the renewal application, even if with accepted Corrective and Preventive Action (CAPA);
2. Those establishments were not inspected at all during the validity of the LTO immediately preceding the renewal application;
3. Those renewal application with pending variation or expired LTO at the time of application;
4. Those with written directive from the Office of the Director General for deferment of action for renewal applications or with penalty of fine not yet settled or whose license has been suspended or revoked ; and
5. Such other analogous instances as determined by the FDA.