



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<p>1. Notifying Member: <u>PHILIPPINES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):</p>
<p>2. Agency responsible: Dr. Charmaine Ann M. Rabago Officer-in-Charge, Director IV Center for Drug Regulation and Research Food and Drug Administration DEPARTMENT OF HEALTH Email: cdr@fda.gov.ph, cdr.sds@fda.gov.ph www.fda.gov.ph</p>
<p>3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:</p>
<p>4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Pharmaceuticals (ICS code(s): 11.120)</p>
<p>5. Details of notified document(s) (title, number of pages and languages, means of access): Content of License to Operate (LTO) issued by the Food and Drug Administration for Pharmaceutical Establishments; (4 page(s), in English) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2026/TBT/PHL/26_01947_00_e.pdf https://www.fda.gov.ph/draft-for-comments-content-of-license-to-operate-lto-issued-by-the-food-and-drug-administration-for-pharmaceutical-establishments/</p>
<p>6. Description of content: Pursuant to Administrative Order (A.O.) No. 2024-0015, "Prescribing the Rules, Requirements, and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration, Repealing A.O. No. 2020-0017," and as part of its commitment to continuous quality improvement, the Food and Drug Administration (FDA) continues to strengthen institutional efficiency through the implementation of a robust Quality Management System (QMS). This initiative supports the FDA's ongoing efforts to accede to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and be a World Health Organization (WHO) Listed Authority (WLA). These international standards strongly recommend having a standardized format and content for authorizations on pharmaceutical manufacturing. By aligning as well the authorization issued for other regulated pharmaceutical establishments, the FDA ensures consistency, transparency, and proper monitoring across all issued licenses. This also facilitates compliance with internationally accepted practices and promotes ease of verification by both local and foreign regulatory bodies.</p>

<p>In line with these initiatives, the FDA issues this Circular to establish the contents of License to Operate (LTO) issued by the FDA for pharmaceutical establishments.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: This Circular aims to establish a standardized and updated contents of License to Operate (LTO) of pharmaceutical establishments that reflects current regulatory requirements, improves the clarity and transparency of information indicated therein, and ensures compliance with A.O. No. 2024-0015 and related issuances.</p>
<p>8. Relevant documents: Administrative Order (A.O.) No. 2024-0015</p>
<p>9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined</p>
<p>10. Provision of comments Final date for comments: 24 April 2026 [] 60 days from notification Contact details of agency or authority designated to handle comments regarding the notification: Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines 1200 Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph</p>