Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 MAY 2016

FDA CIRCULAR
No. 2016-004

TO : **ALL ESTABLISHMENTS REGULATED BY THE THE FOOD AND DRUG ADMINISTRATION SEEKING LICENSE TO OPERATE (LTO)**

SUBJECT : **Procedure on the Use of the New Application Form for License To Operate (LTO) thru the Food and Drug Administration (FDA) Electronic Portal (e-portal)**

In consonance with Section 5 (*Re-engineering of Systems and Procedures*) of Republic Act No. 9485, also known as the Anti-Red Tape Act of 2007, the Food and Drug Administration hereby adopts a new application process and form for License To Operate which are navigable and accessible thru the electronic portal found at the FDA website (www.fda.gov.ph) .

This replaces the current Integrated Application Form (IAF) when applying for a License To Operate as indicated in FDA Circular No. 2014-003, *"Filing and Receiving of Registration, Licensing and Other Authorizations Using the Integrated Application Form"*. The use of the new application form and the corresponding procedures thru the e-portal facilitates application in terms of timeliness and ease of submission especially for applicants outside of the National Capital Region (NCR). Aligning with Republic Act No. 9485, this new process and form will likewise ensure transparency, accountability and greater operational efficiency.

Applicant companies are required to provide true, correct, updated and complete information pertaining to their type of application. Documentary requirements as contained in AO No. 2016-0003, *"Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration"*, should follow the prescribed specifications :

a. All documents for uploading must be in PDF file format, free from bugs, viruses and the like that may jeopardize the system of the FDA ;
b. Before uploading, all documents must be scanned and complied with 100-150 dots-per-inch (dpi) ;
c. Filename of documents for uploading should be less than 40 characters in length and should not contain the following characters \ ? / : * " > < |

Accessing the e-portal to file an LTO application requires the use of an authorized User Account to be provided via email by the Public Assistance, Information and

Receiving (PAIR) Unit upon request. Details on the issuance of the User Account is discussed in **ANNEX A**.

This new application system will be on a pilot run from 01 June 2016 to 31 August 2016. Mandatory use of this web-based application form shall be strictly implemented nationwide starting 01 September 2016, with no exemptions.

Applicant companies, who wish to use the new application form during the pilot run, may start using this medium based on the following schedules per sector :

01 June 2016	-	Drugstores, Retail Outlet for Non-Prescription Drugs (RONPDs), Contract Research Organizations (CROs)/Sponsors
01 June 2016	-	All Distributors
01 August 2016	-	All Manufacturers

By Authority of the Secretary of Health

MARIA LOURDES C. SANTIAGO, MSc., M.M.
OIC, Director General

ANNEX A

Guidance Notes on the Issuance of the User Account

Establishments accessing the FDA e-portal to file for an LTO application, whether initial, renewal or variation/s, shall be required to have an authorized User Account to be provided by the Public Assistance, Information and Receiving (PAIR) Unit via email.

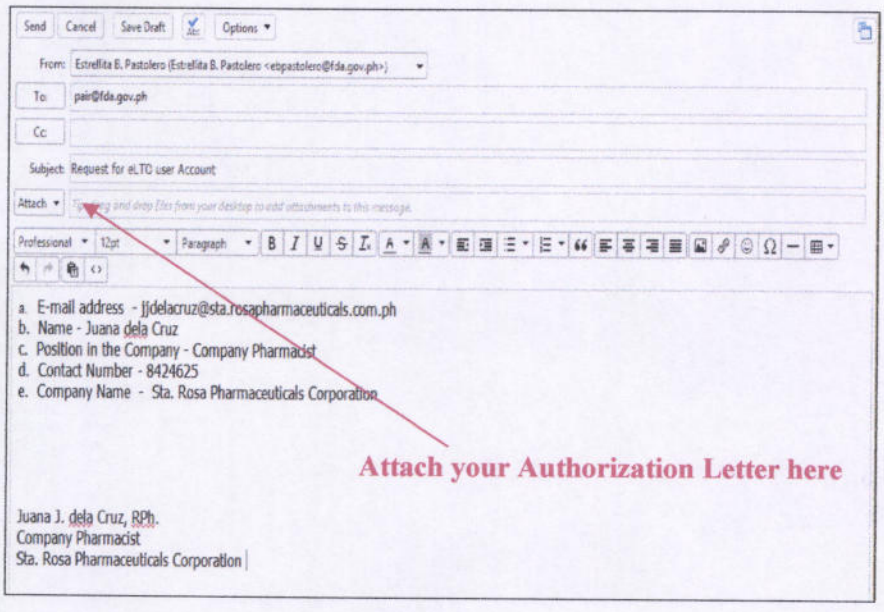
The following are the steps in securing a User Account :

1. Accomplish the Authorization Letter for the eLTO User Account application (please refer to **ANNEX B**).

2. Send a request for a User Account to pair@fda.gov.ph following the format specified below with the signed and notarized Authorization Letter as an attachment. The authorization letter should be scanned and saved in pdf form, and must be free from bugs, viruses and the like that may jeopardize the system of the FDA, before being attached to the email.

   SUBJECT : Request for eLTO User Account
   BODY :
   a. E-mail address (**preferably company e-mail address**)
   b. Name of the authorized company representative (**preferably permanently employed and not merely a consultant**)
   c. Position in the Company
   d. Contact Number
   e. Company Name

   Sample email:



Applicant companies with existing User Account and have previously availed of the cosmetics, toys and childcare articles notification and food electronic registration systems need not file a new request for the issuance of another User Account. However, this is subject to validation by PAIR Unit.

3. Please take note that the User Account will be sent to the **company e-mail address** provided in the body of the request and **not to the sender's e-mail address.** The User Account, including the username and password, is company- specific and valid for one (1) year. The FDA should be duly notified thru pair@fda.gov.ph of any changes concerning the authorized representative or reactivation of the User Account before its expiry date. Reactivation request should be sent to pair@fda.gov.ph within three (3) months before the expiration of the User Account.

4. Issuance of the User Account is within two (2) days upon receipt of the complete and compliant request. Request received beyond 5:00 pm on regular working days and on holidays, Saturdays and Sundays shall be processed on the next working day.

5. The PAIR Unit will accommodate request for User Account starting 16 May 2016.