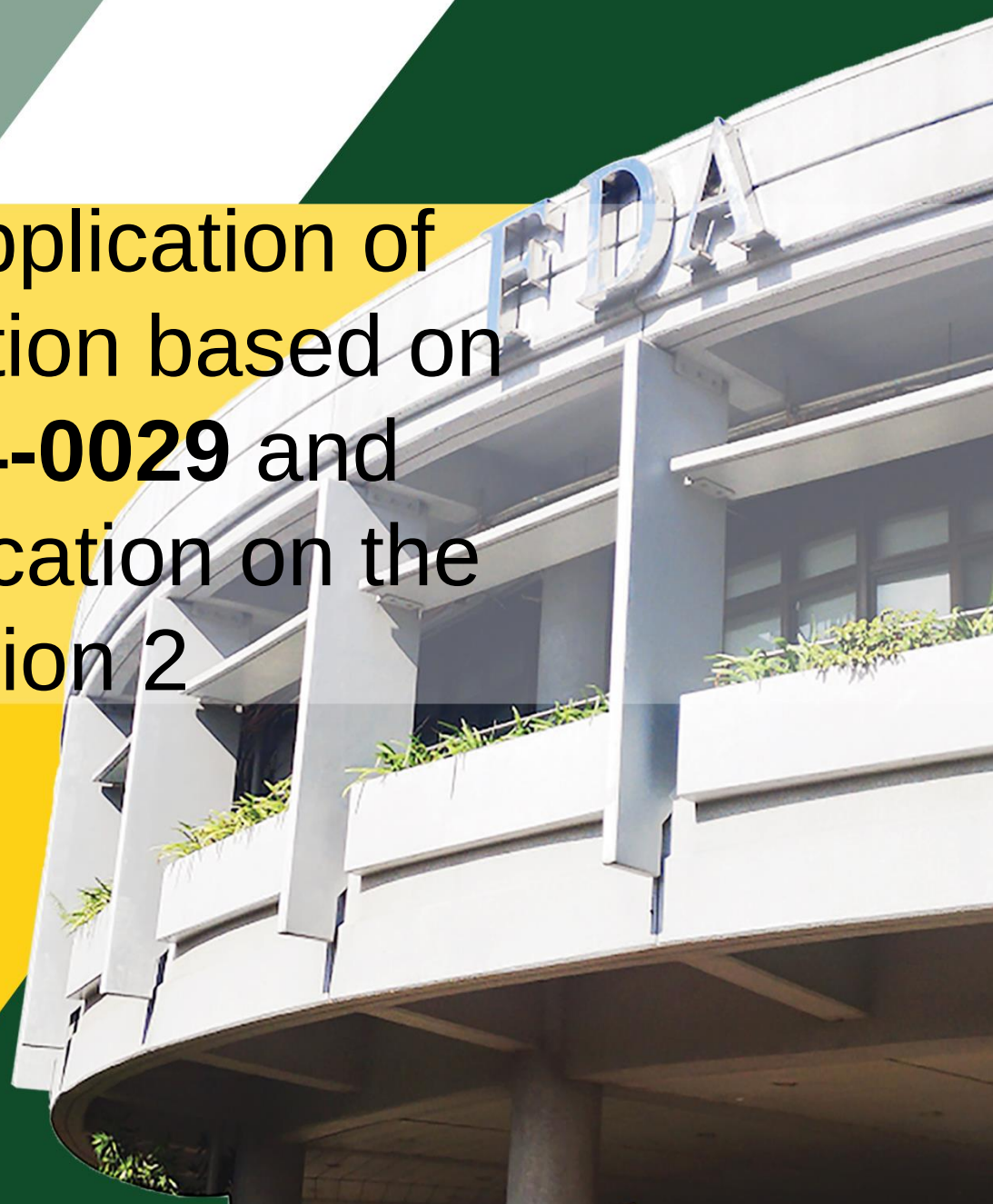
# General Requirements for Application of Certificate of Product Registration based on **Administrative Order 2014-0029** and Procedures for Filing an Application on the Modified E-Portal Version 2




Presented by:

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Center for Food Regulation and Research

# *Presentation outline*

I. Checklist of Requirements
II. General Guidelines
III. Procedure for Filing Initial Application
IV. Process Flow
V. Criteria to Determine Complete Submission of Documents

# Checklist of Requirements

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
|---|---|
| **FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS** | |
| I. General requirements for Application of Certificate of Product Registration based on Administrative Order 2014-0029 | |
| 1. Accomplished Initial Application Form as prescribed by current FDA regulations (e-Registration e-Portal; please refer to FDA Circular No.2020-033, FDA Circular No.2020-033-A or current FDA regulation). | FDA Website (www.fda.gov.ph) |
| 2. Proof of Payment of Fees as prescribed by FDA regulations (e.g. A.O. 50 s. 2001 or current FDA regulation). | FDA Cashier/Other FDA Authorized Payment Portals or Banks |

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# Checklist of Requirements

| | |
|---|---|
| 3. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations (Refer to AO 2014-0030 or current FDA regulation). | Applicant Company/ Manufacturer/Source/Supplier |
| 4. Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable. | Applicant Company/ Manufacturer/Source/Supplier |
| 5. For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted. | Applicant Company/ Manufacturer/Source/Supplier |
| 6. As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labeling regulations. | Applicant Company/ Manufacturer/Source/Supplier<br>For the Certificate of Analysis:<br>a) Manufacturer/Supplier/Source;<br>**OR**<br>b) Laboratory analysis issued/conducted by FDA accredited laboratories. |

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# Checklist of Requirements

| | |
|---|---|
| II. Valid and appropriate FDA License to Operate (required for all types of CPR application) | |
| III. General Requirements based on FDA Circular 2016-007<br>• For Locally Manufactured Products: (in cases when the source is not directly the manufacturer) Distributorship agreement or contract agreement, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR (FDA Circular 2016-007).<br><br>• For Imported Products:<br>a. **ONE** scanned copy of the original copy of **ANY** of the following documents: Distributorship agreement **OR** contract agreement **OR** Sales Invoice or Proforma Invoice **OR** Appointment letter issued by the supplier/manufacturer appointing the applicant company to distribute the product being applied in the local market, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR (FDA Circular 2016-007). | Manufacturer/Source/Supplier |

# Checklist of Requirements

| | |
|---|---|
| b. **ONE** scanned Certified true copy or certified photocopy of **ANY** of the following original documents issued to the source by the regulatory or health authority from the country of origin per source:<br>✓ Valid manufacturer's certificate of registration with GMP compliance or its equivalent; **OR**<br>✓ Valid Phytosanitary Certificate/ Health Certificate; **OR**<br>✓ Valid ISO 22000 Certification; **OR**<br>✓ Valid HACCP Certificate; **OR**<br>✓ Certificate of Free Sale (CFS issued by a regulatory agency or duly authenticated by the Philippine consulate from the country of origin) | Manufacturer/Source/Supplier |

# Checklist of Requirements

## IV. **ADDITIONAL** REQUIREMENTS PER FOOD CATEGORY

MRF1Aii. CURED (INCLUDING SALTED) DRIED NON-HEAT TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS

- Certificate of Analysis for Microbiological parameters for PACKAGED COOKED, CURED/SALTED MEAT: S. aureus (coagulase +) cfu/g, Salmonella/25g & Listeria monocytogenes/25g based on FDA Circular 2013-010.

HRG1a./HRG2a. HEAT-TREATED PROCESSED MEAT, POULTRY AND GAME PRODUCTS (CANNED)

- Certificate of Analysis for Microbiological parameters for MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS: Commercial Sterility based on FDA Circular 2013-010.

1) For the Certificate of Analysis:
a) Applicant Company/ Manufacturer/Source/Supplier; **OR**

HRG2b. FROZEN PROCESSED MEAT, POULTRY AND GAME PRODUCTS (NUGGETS, PATTIES, DUMPLINGS, SALAMI, MEAT LOAF, HOTDOG)

- Certificate of Analysis for Microbiological parameters for COLD CUTS, FROZEN & CHILLED HOTDOGS: E. coli MPN/g, Salmonella/25g, S. aureus (coagulase +) cfu/g & SPC/APC cfu/g based on FDA Circular 2013-010.

- Certificate of Analysis for Nitrate and Nitrite Content (if utilized) based on Administrative Order No. 154 s. 1971 and Bureau Circular 2006-016.

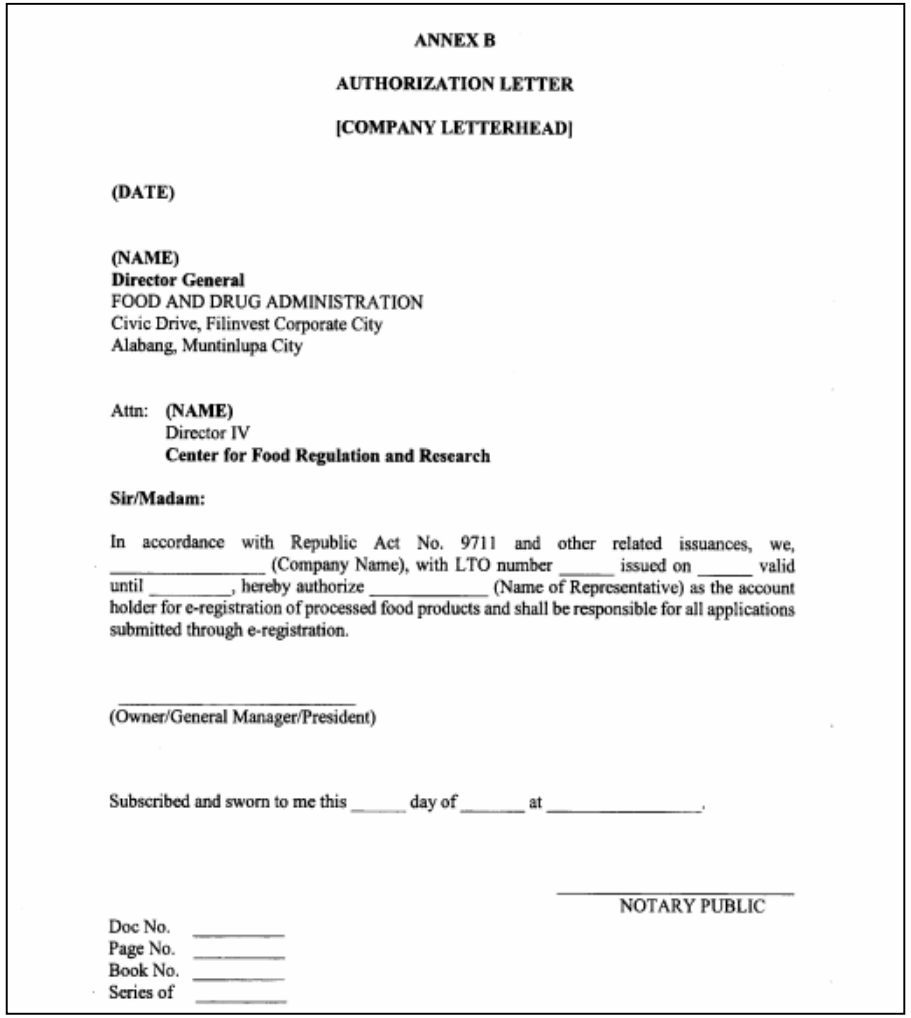
# General Guidelines

1. Submit ONE (1) scanned copy of the required document in the e-Registration Portal
2. Product labels and pictures of the product in commercial presentation for upload should be scanned in 200-dpi setting and 150-dpi setting for documents.
3. Limit the total size of attachments to 25 MB with a limit of 2 MB per file using the format ".png" or ".pdf"
4. Provide an appropriate file name for each scanned copy of documents to be uploaded in the E-registration system. For product labels, follow the format: "Label_(Case Number)" e.g. Label_12345.png or Label_12345.pdf
5. The validity and contents of the Certificate of Analysis to be uploaded/attached must conform to FDA Circular 2020-033 and/or current FDA regulation (e.g. for Assessment of Microbiological Quality of Processed Food, the COA must indicate the methodology/ies used to verify test result/s for each parameter. The methodologies may be obtained from internationally recognized references as stated in FDA Circular 2013- 010).
6. 20 working days processing time (Day 1 starts with date of posting of payment by FDA Cashier)
7. All CPR remarks shall be complied within validity of CPR prior to renewal

# PROCEDURE FOR FILING INITIAL APPLICATION

## *Issuance of CFRR E-Portal User Account*

- The CFRR E-Portal User Account and Password is company-specific
- The User Account issued and revalidated by CFRR thru the old portal does not need to request for new User Account



**ANNEX B**

**AUTHORIZATION LETTER**

**[COMPANY LETTERHEAD]**

**(DATE)**

**(NAME)**
**Director General**
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attn: **(NAME)**
Director IV
**Center for Food Regulation and Research**

**Sir/Madam:**

In accordance with Republic Act No. 9711 and other related issuances, we, _____ (Company Name), with LTO number _____ issued on _____ valid until _____, hereby authorize _____ (Name of Representative) as the account holder for e-registration of processed food products and shall be responsible for all applications submitted through e-registration.

_____
(Owner/General Manager/President)

Subscribed and sworn to me this _____ day of _____ at _____.

_____
NOTARY PUBLIC

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Book No. _____
Series of _____

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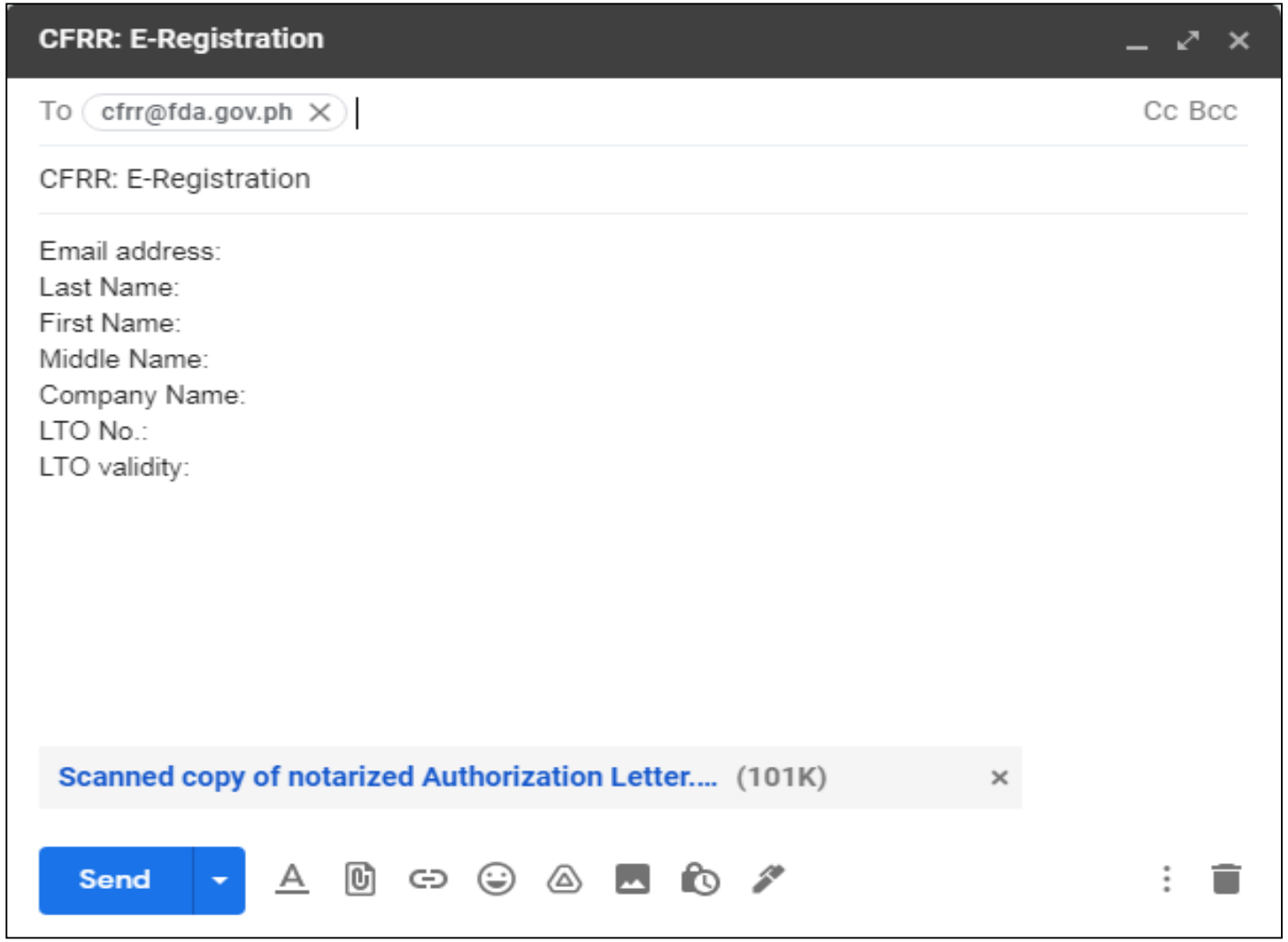
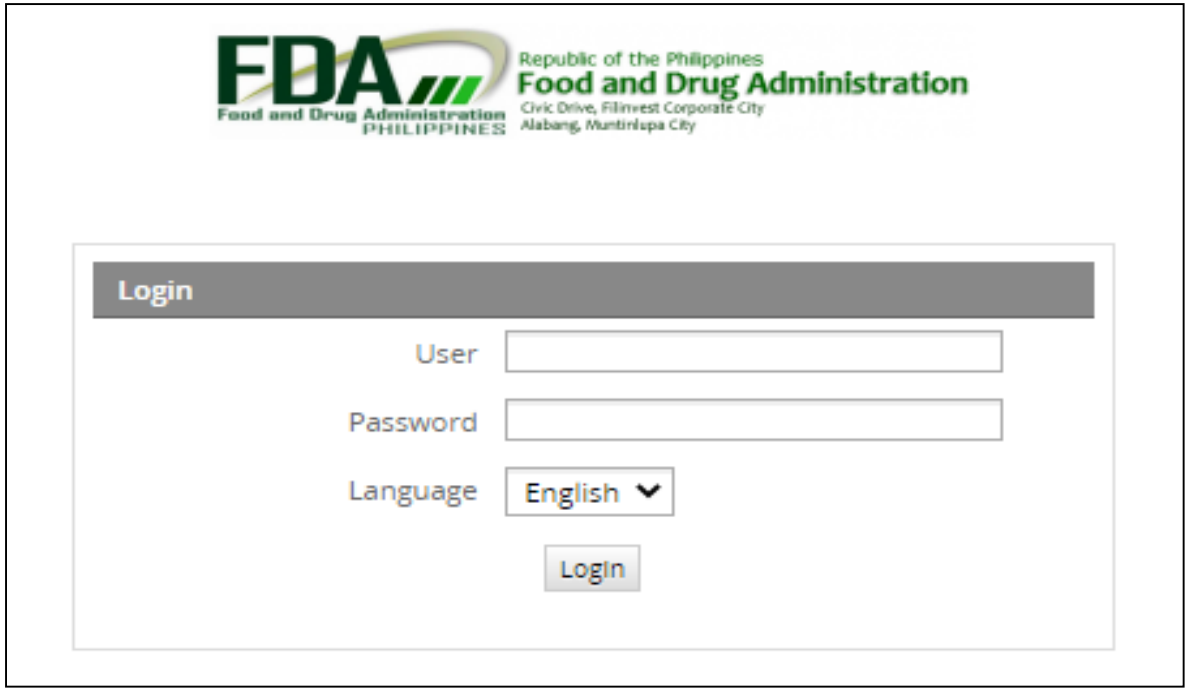
# Request for E-Portal User Account

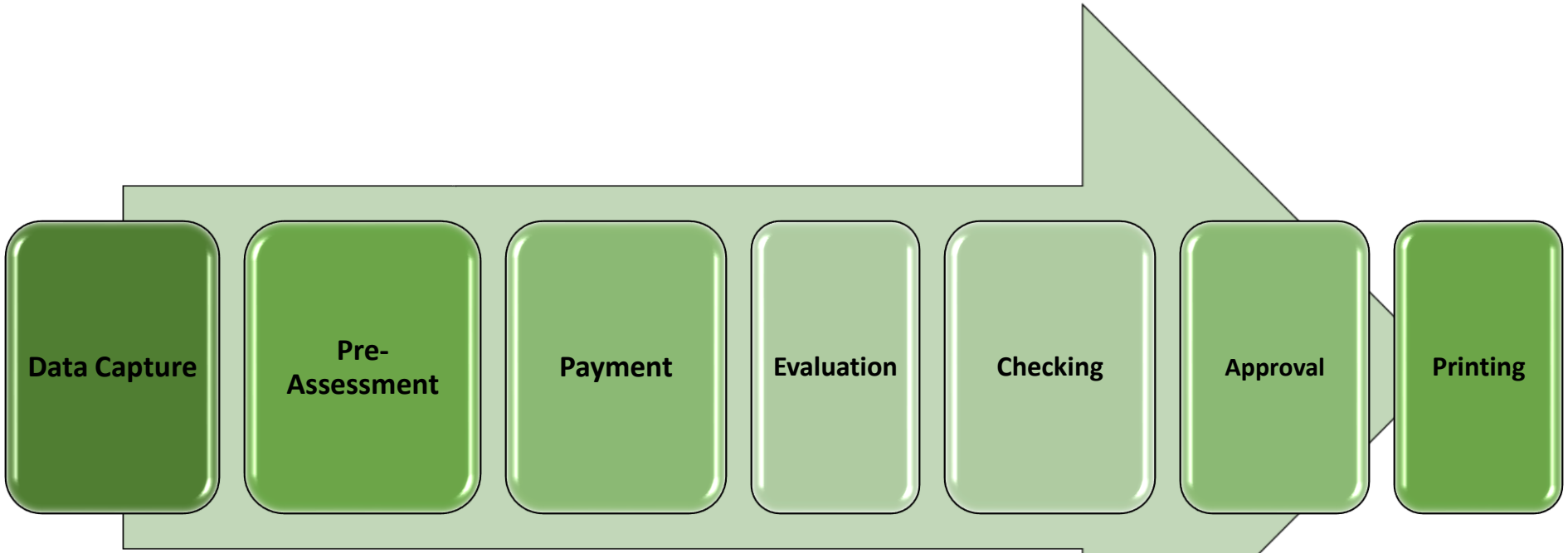


# Login to E-portal User Account

Go to: https://eportal.fda.gov.ph



# Process Flow – Certificate of Product Registration



# Criteria to Determine COMPLETE Submission of Documents

- An approved pre-assessment does not automatically mean that the product will be issued a CPR

- A pre-assessed food product application for registration could be approved only if it conforms to **ALL** of the following requirements:

1. Correct E-portal account consistent with the applicant company
2. Valid License to Operate (LTO).
3. Clear, valid and readable uploaded documents with integrity
   - For reapplications, completeness and accuracy of uploaded documents for compliance to mentioned deficiencies in LOD are assessed during pre-assessment
4. Accurate and complete data entry declaration consistent with uploaded documents.
5. Compliance of the product being applied with requirements as stipulated in the new CFRR Citizen's Charter based on:
   - FC 2020-033; AO 2014-0029, FC 2013-010, AO 2014-0030, AO 88-a s. 1984, BC 2006-016, BC 2007-002), standards of identity based on FDA regulations, and all other applicable existing regulations
   - Refer to Annex D of FDA Circular 2020-033

# THANK YOU!

www.fda.gov.ph

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