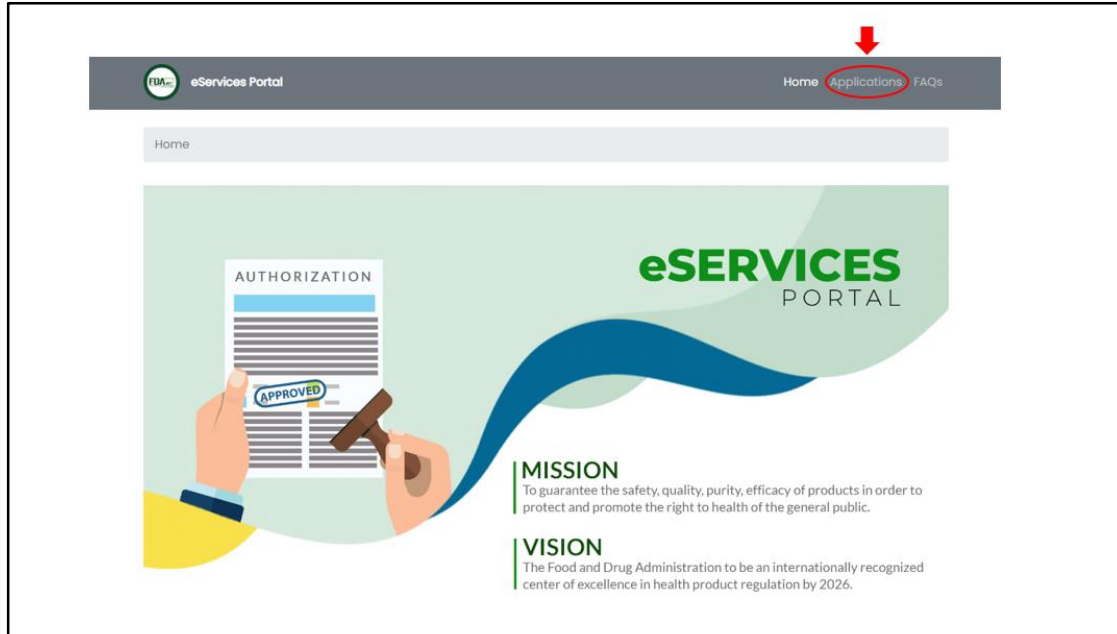


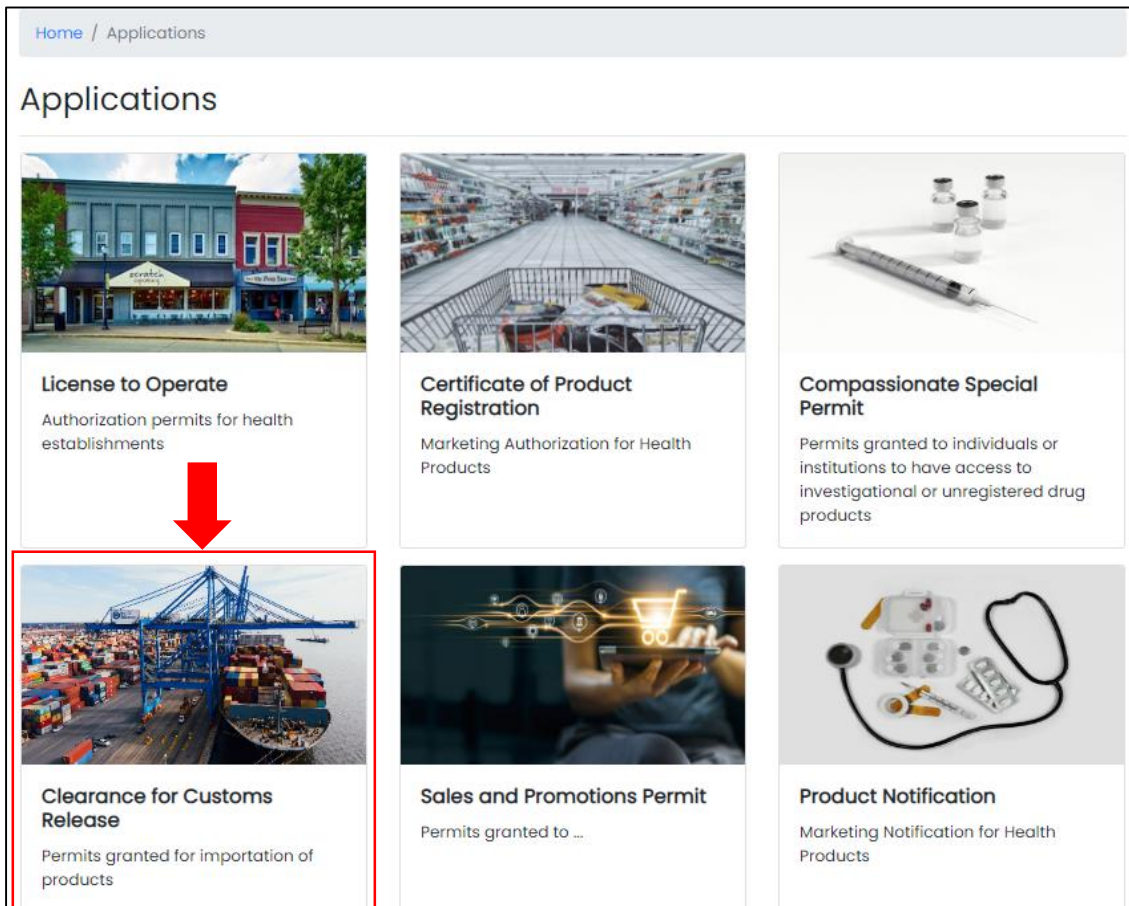
## ANNEX C

### Procedure on the Use of the FDA eServices Portal System for Clearance for Customs Release Applications

1. Access the online portal through <https://eservices.fda.gov.ph> and click **Applications** found at the upper right corner of the landing dashboard.



2. Click on the **Clearance for Customs Release**.



### 3. Click on the **Drug**.

Home / Applications / Clearance for Customs Release

## Clearance for Customs Release

**Drug**  
Importation of Drug Products

**Xray**  
Clearance for Customs Release for Radiation Emitting Devices

### 4. Read carefully the **Declaration & Undertaking**. Once done, check the box if you agree with all the conditions stated. Click on the **Start Application**.

Home / Applications / Clearance for Customs Release / Drugs

## Clearance for Customs Release

**1 Declaration & Undertaking** Declaration & Undertaking

2 Applicant Information

3 Contact Person

4 Product Details

5 Uploading of Documents

6 Self-Assessment Review

We assume primary responsibility and/or stewardship over the product in case of liability, adverse events, or other public health & safety issues arising from its use. We agree to have in good faith exerted due diligence in ensuring & that third-party intellectual property rights are not infringed. We further agree and bind ourselves that the label of the product shall at all times conform to the labeling regulations, and shall not be presented including any advertisement of the product in a manner that is false, deceptive, & misleading, or contrary to public morals/ public policy. Non-observance of any of the undertakings in this declaration is deemed a misrepresentation which is a ground for disapproval of this application or, if approved, the suspension or cancellation of the product registration.

We, categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available. We certify that we have examined the following statements and we attest to their accuracy and truthfulness. We ensure that the submitted documentary requirements are complete and correct as prescribed to our application:

- I. The current Good Manufacturing Practice Guidelines is applied in full in the manufacture of this product;
- II. Each batch of all finished product is tested or certified and fully compliant (in an accompanying certificate of analysis for that batch) with the specifications cited in the claimed reference official monograph prior to importation;
- III. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and are

I agree to the declaration and undertaking

**Start Application**

- In the **Applicant Information** page, fill out all the required fields which are marked with asterisk (\*). Provide a valid and working e-mail address and mobile number in the Contact Information, and the company pharmacist or the person in charge of the regulatory affairs in the Details of the Contact Person. Please take note that all fields marked with asterisk (\*) in the succeeding steps are also required to be filled out. Click on **Next**.

The screenshot shows the 'Clearance for Customs Release' form at Step 2, 'Applicant Information'. The left sidebar shows steps 1 through 6, with 'Applicant Information' highlighted. The main form area contains several sections:

- Applicant Information:** Fields for \* Entity (Please Select), \* LTO Number, \* Company Name, \* Address, \* Email Address (Email Address of MAH), \* Mobile Number (Mobile Number of MAH), and Landline Number (Landline Number of MAH).
- Details of the Contact Person:** Fields for \* First Name, Middle Name, \* Last Name, \* Designation or Profession, Government Issued Identification Document (ID Type, ID Number, Expiry Date).

At the bottom, there are 'Back' and 'Next' buttons. The 'Next' button is circled in red.

- Fill out all the required fields in the **Product Details** page.

The screenshot shows the 'Clearance for Customs Release' form at Step 4, 'Product Details'. The left sidebar shows steps 1 through 6, with 'Product Details' highlighted. The main form area contains several sections:

- Product #1:** Fields for \* Invoice Number, \* Bill of Lading No., \* Port of Entry, \* Registration Number, \* Date of Expiry, \* Product Type (Please Select dropdown menu with options: Raw Materials, Drug Product), \* Generic Name, \* Dosage Strength and Form, Brand Name (leave blank if unbranded), \* Packaging, \* Manufacturer, \* Lot/Batch No., and \* Quantity.

At the bottom, there is an 'Add Product' button and 'Back' and 'Next' buttons. The 'Next' button is circled in red.

7. Upload all the necessary documents for verification purposes. Click on **Next**.

The screenshot shows the 'Clearance for Customs Release' page in the eServices Portal. The breadcrumb trail is 'Home / Applications / Clearance for Customs Release / Drugs'. The page title is 'Clearance for Customs Release'. A progress indicator on the left shows six steps: 1. Declaration & Undertaking, 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents (highlighted with a red circle), and 6. Self-Assessment Review. A light blue information box states: 'Indicate or upload the following documents for verification of compliance to existing local and international standards:'. Below this, there are four rows of document upload fields:

Certificate of Analysis	Copy of Certificate of Analysis	File Upload
Proforma Invoice	Proforma Invoice	File Upload
Bill of Lading	Bill of Lading	File Upload
	merge files into a single file	
BOC Requirements	BOC Requirements	File Upload
	merge files into a single file	

At the bottom right, there are two buttons: 'Back' and 'Next' (highlighted with a red circle).

8. The Applicant shall review if all the details are correct in the **Self-Assessment Review**.

The screenshot shows the 'Clearance for Customs Release' page in the eServices Portal. The breadcrumb trail is 'Home / Applications / Customs Release Clearance / Drugs'. The page title is 'Clearance for Customs Release'. A progress indicator on the left shows six steps: 1. Declaration & Undertaking, 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents, and 6. Self-Assessment Review (highlighted with a red circle). The main content area is titled 'Applicant Information' and contains the following fields:

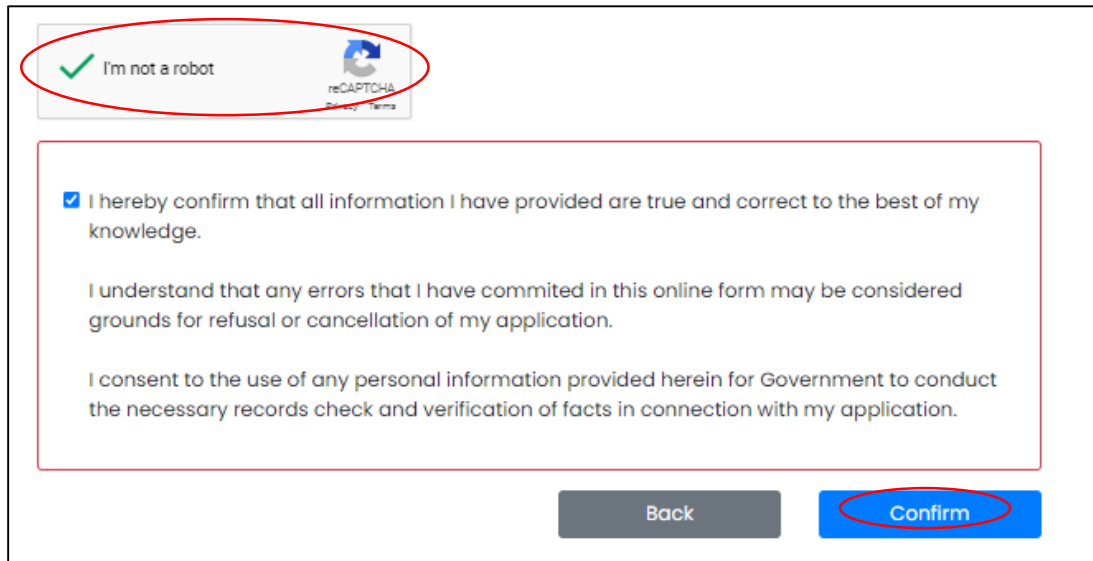
**Applicant Information**

- \* Entity:  (dropdown menu, select entity)
- \* LTO Number:
- \* Company Name:
- \* Address:

**Contact Information**

- \* Email Address:
- \* Mobile Number:
- Landline Number:  (Landline Number of MAH)

9. Once reviewed, the Applicant shall confirm the correctness of the data given and click on **Confirm** to submit the application.



The screenshot shows a web form with the following elements:

- A reCAPTCHA widget at the top left, showing a green checkmark and the text "I'm not a robot".
- A central text area containing a checked checkbox and the text: "I hereby confirm that all information I have provided are true and correct to the best of my knowledge." Below this, there are two paragraphs of text: "I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application." and "I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application."
- Two buttons at the bottom right: a grey "Back" button and a blue "Confirm" button.

Red circles highlight the reCAPTCHA widget and the "Confirm" button. A red rectangle highlights the central text area.