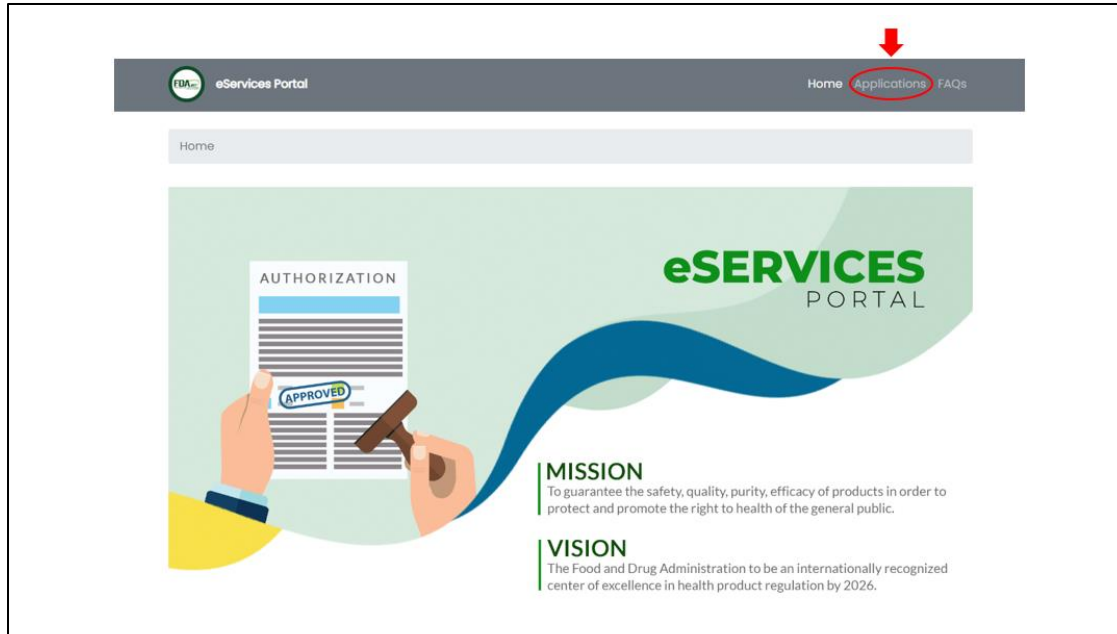


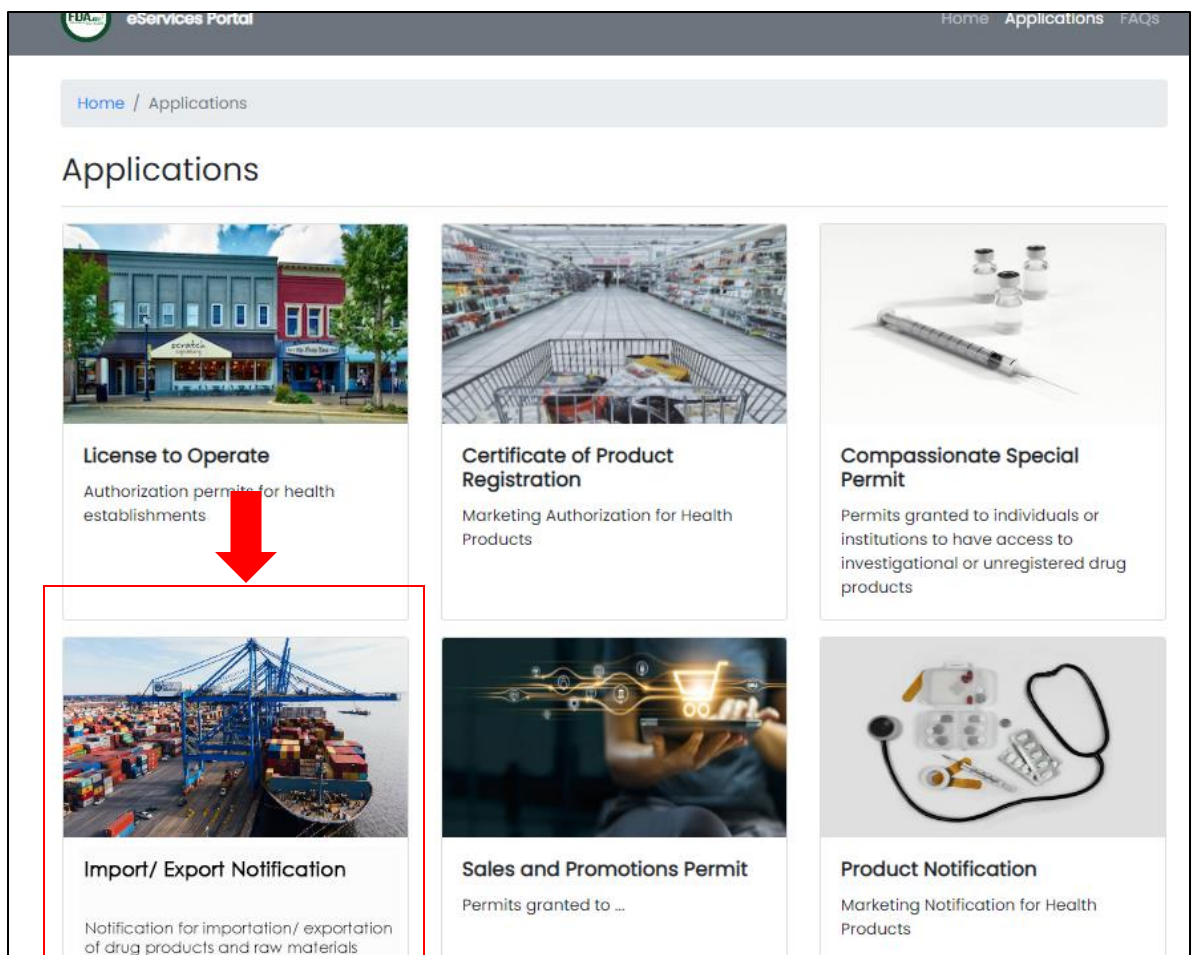
## ANNEX C

### Procedure on the Use of the FDA eServices Portal System for Import/Export Notification

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 **Import/ Export Notification**.



3. Click on the **Drug**.

**A. Import Notification**

The screenshot shows the FDA eServices Portal interface. At the top, there is a navigation bar with the FDA logo, 'eServices Portal', and links for 'Home', 'Applications', and 'FAQs'. Below this is a breadcrumb trail: 'Home / Applications / Notification / Import'. The main heading is 'Import Notification'. There are two main options displayed as cards: 'Drug' (Importation of Drug Products) and 'Xray' (Clearance for Customs Release for Radiation Emitting Devices). The 'Drug' card is highlighted with a red border, and a red arrow points from the 'Xray' card towards it.

**B. Export Notification**

The screenshot shows the FDA eServices Portal interface. At the top, there is a navigation bar with the FDA logo, 'eServices Portal', and links for 'Home', 'Applications', and 'FAQs'. Below this is a breadcrumb trail: 'Home / Applications / Notification / Export'. The main heading is 'Export Notification'. There are two main options displayed as cards: 'Drug' (Exportation of Drug Products) and 'Xray' (Clearance for Customs Release for Radiation Emitting Devices). The 'Drug' card is highlighted with a red border, and a red arrow points from the 'Xray' card towards it.

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

### A. Import Notification

eServices Portal Home Applications FAQs

Home / Applications / Notification / Import / Drugs

## Import Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details
- 5 Uploading of Documents
- 6 Self-Assessment Review

### Declaration & Undertaking

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 notification 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**

### B. Export Notification

eServices Portal Home Applications FAQs

Home / Applications / Notification / Import / Drugs

## Import Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details
- 5 Uploading of Documents
- 6 Self-Assessment Review

### Declaration & Undertaking

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 notification 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**

5. 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**.

### A. Import Notification

The screenshot shows the 'Import Notification' form in the eServices Portal. The form is divided into two main sections: 'Applicant Information' and 'Details of the Contact Person'. The 'Applicant Information' section includes fields for Entity, LTO Number, Company Name, Address, Email Address, Mobile Number, and Landline Number. The 'Details of the Contact Person' section includes fields for First Name, Middle Name, Last Name, Designation or Profession, Government Issued Identification Document (ID Type, ID Number, Expiry Date). The 'Next' button is highlighted in blue.

### B. Export Notification

The screenshot shows the 'Export Notification' form in the eServices Portal. The form is divided into two main sections: 'Applicant Information' and 'Details of the Contact Person'. The 'Applicant Information' section includes fields for Entity, LTO Number, Company Name, Address, Email Address, Mobile Number, and Landline Number. The 'Details of the Contact Person' section includes fields for First Name, Middle Name, Last Name, Designation or Profession, Government Issued Identification Document (ID Type, ID Number, Expiry Date). The 'Next' button is highlighted in blue.

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

**A. Import Notification**

## Import Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details**
- 5 Uploading of Documents
- 6 Self-Assessment Review

**Product Details**

\* Invoice Number

\* Port of Entry

---

**Product #1**

\* Registration Number

\* Date of Expiry

\* Product Type

\* Generic Name

\* Dosage Strength and Form

Brand Name   
leave blank if unbranded

\* Packaging

\* Manufacturer

\* Lot/Batch No.

\* Quantity

[+ Add Product](#)

## B. Export Notification

### Export Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details**
- 5 Uploading of Documents
- 6 Self-Assessment Review

**Product Details**

\* Invoice Number

\* Port of Entry

---

Product #1

\* Registration Number

\* Date of Expiry

\* Product Type

\* Generic Name

\* Dosage Strength and Form

Brand Name   
leave blank if unbranded

\* Packaging

\* Manufacturer

\* Lot/Batch No.

\* Quantity

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

**A. Import Notification**  
**a. Finished Drug Product**


The screenshot shows the 'Finished Drug Product' document upload step. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The page title is 'Import Notification'. A progress bar on the left shows steps 1 through 6, with step 5 'Uploading of Documents' highlighted in blue. A light blue information box contains the text: 'Indicate or upload the following documents for verification of compliance to existing local and international standards:'. Below this, the section 'Finished Drug Product:' lists three documents: 'Certificate of Analysis', 'Proforma Invoice', and 'Packing list'. Each document has a text input field with the document name and a 'File Upload' button. A note 'merge files into a single file' is located below the input fields. At the bottom right, there are 'Back' and 'Next' buttons.

**b. Raw Materials**

The screenshot shows the 'Raw Materials' document upload step. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The page title is 'Import Notification'. A progress bar on the left shows steps 1 through 6, with step 5 'Uploading of Documents' highlighted in blue. A light blue information box contains the text: 'Indicate or upload the following documents for verification of compliance to existing local and international standards:'. Below this, the section 'Raw Materials:' lists three documents: 'Certificate of Analysis', 'Invoice', and 'Packing list'. Each document has a text input field with the document name and a 'File Upload' button. A note 'merge files into a single file' is located below the input fields. At the bottom right, there are 'Back' and 'Next' buttons. The 'Next' button is circled in red.



**B. Export Notification**  
**a. Finished Drug Product**

 eServices Portal Home Applications FAQs

Home / Applications / Notification / Export / Drugs

## Export Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details
- 5 Uploading of Documents**
- 6 Self-Assessment Review

**Uploading of Documents**

Indicate or upload the following documents for verification of compliance to existing local and international standards:

**Finished Drug Product:**

Certificate of Analysis	<input type="text" value="Copy of Certificate of Analysis"/>	<input type="button" value="File Upload"/>
Proforma Invoice	<input type="text" value="Proforma Invoice"/>	<input type="button" value="File Upload"/>
Packing list	<input type="text" value="Packing list"/>	<input type="button" value="File Upload"/>

merge files into a single file

**b. Raw Materials**

Home / Applications / Notification / Export / Drugs

## Export Notification

- 1 Declaration & Undertaking
- 2 Applicant Information
- 3 Contact Person
- 4 Product Details
- 5 Uploading of Documents**
- 6 Self-Assessment Review

**Uploading of Documents**

Indicate or upload the following documents for verification of compliance to existing local and international standards:

**Raw Materials:**

Certificate of Analysis	<input type="text" value="Copy of Certificate of Analysis"/>	<input type="button" value="File Upload"/>
Invoice	<input type="text" value="Invoice"/>	<input type="button" value="File Upload"/>
Packing list	<input type="text" value="Packing list"/>	<input type="button" value="File Upload"/>

merge files into a single file



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

**A. Import Notification**

The screenshot displays the 'Import Notification' page on the FDA eServices Portal. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The page title is 'Import Notification'. A progress bar on the left lists six steps: 1. Declaration & Undertaking, 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents, and 6. Self-Assessment Review. The 'Self-Assessment Review' step is circled in red. The main content area is divided into two sections: 'Applicant Information' and 'Contact Information'. The 'Applicant Information' section includes fields for Entity (a dropdown menu with 'select entity' below it), LTO Number, Company Name, and Address. The 'Contact Information' section includes fields for Email Address, Mobile Number, and Landline Number (with a note 'Landline Number of MAH'). Below these sections is a light blue box with an information icon and the text 'Must be the company pharmacist or personnel in charge of regulatory affairs'. The 'Details of the Contact Person' section includes fields for First Name, Middle Name, and Last Name.

## B. Import Notification

The screenshot shows the 'eServices Portal' interface for 'Export Notification'. The breadcrumb trail is 'Home / Applications / Notification / Export / Drugs'. The main heading is 'Export Notification'. A vertical sidebar on the left lists six steps: 1. Declaration & Undertaking, 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents, and 6. Self-Assessment Review. The 'Self-Assessment Review' step is highlighted with a red circle. The main content area is titled 'Applicant Information' and contains several input fields: 'Entity' (a dropdown menu with 'select entity' below it), 'LTO Number', 'Company Name', and 'Address'. Below these is the 'Contact Information' section with fields for 'Email Address', 'Mobile Number', and 'Landline Number' (with a pre-filled value 'Landline Number of MAH'). A blue information box states: 'Must be the company pharmacist or personnel in charge of regulatory affairs'. The 'Details of the Contact Person' section includes fields for 'First Name', 'Middle Name', and 'Last Name'.

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

The screenshot shows the confirmation step of the application process. At the top left, there is a reCAPTCHA widget with a green checkmark and the text 'I'm not a robot', which is circled in red. Below this is a large red-bordered box containing a confirmation statement: 'I hereby confirm that all information I have provided are true and correct to the best of my knowledge.' Below the statement, 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.' At the bottom of the form, there are two buttons: a grey 'Back' button and a blue 'Confirm' button, which is circled in red.