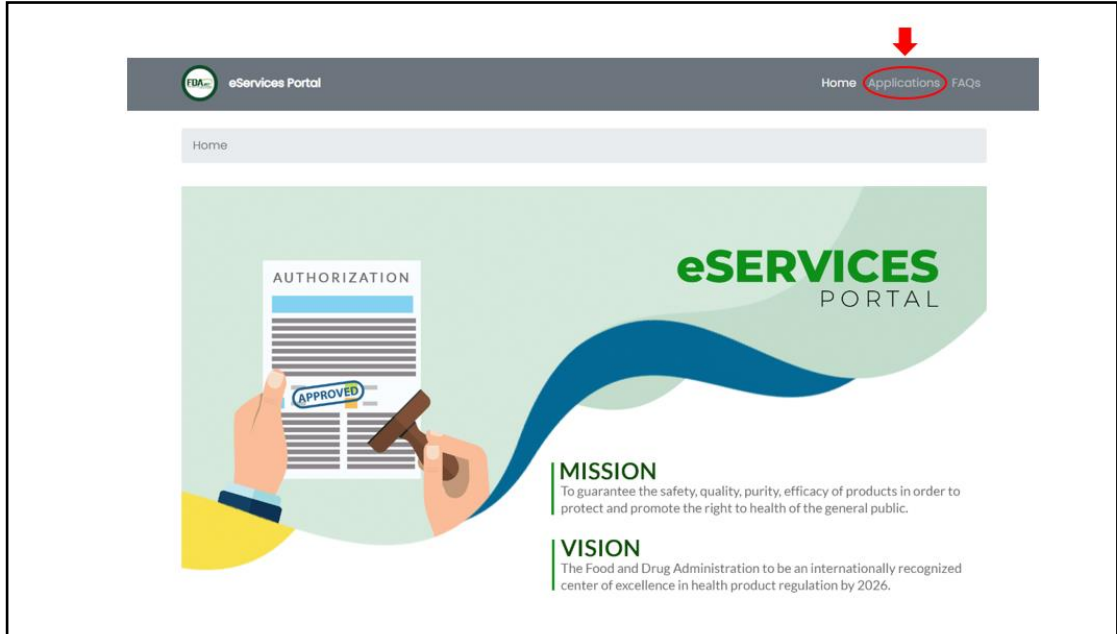


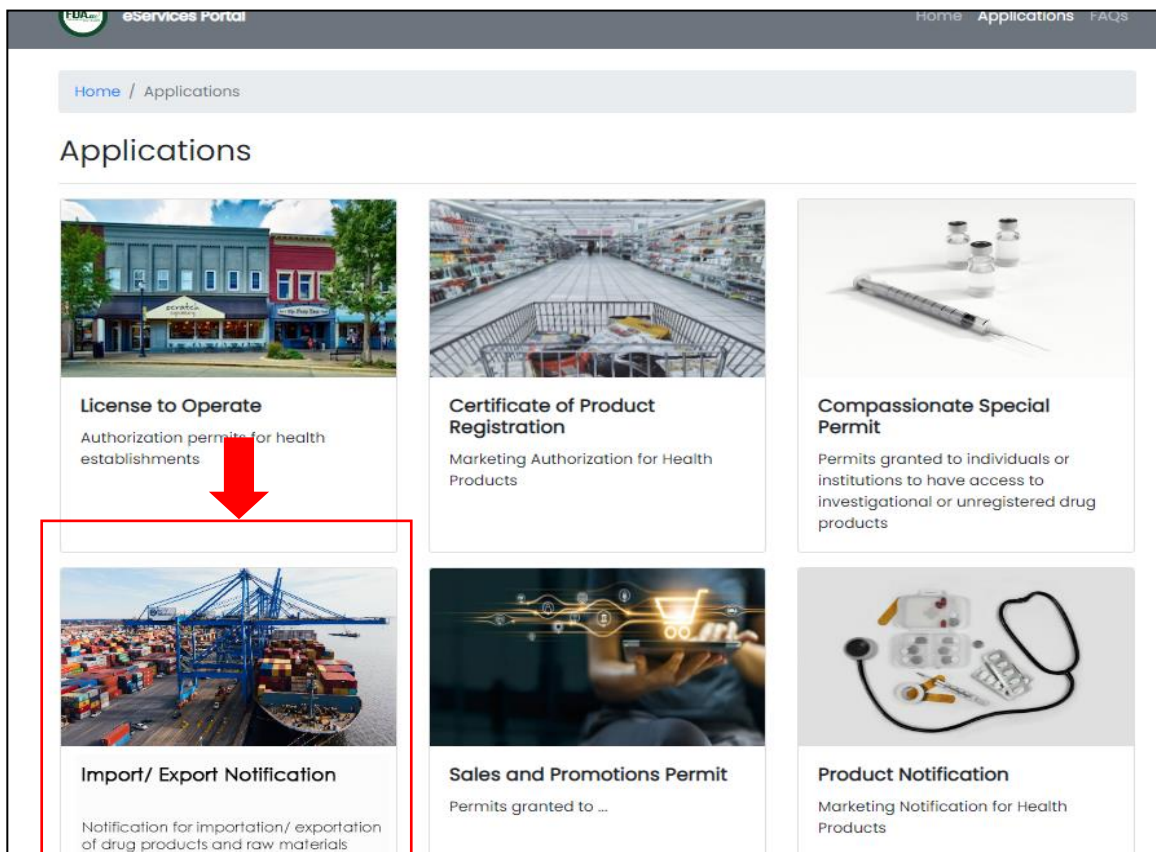
ANNEX C

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 for 'Import Notification'. The breadcrumb trail is 'Home / Applications / Notification / Import'. The page title is 'Import Notification'. There are two main options: 'Drug' (Importation of Drug Products) and 'Xray' (Clearance for Customs Release for Radiation Emitting Devices). The 'Drug' option is highlighted with a red border, and a red arrow points to the 'Xray' option.

B. Export Notification

The screenshot shows the FDA eServices Portal interface for 'Export Notification'. The breadcrumb trail is 'Home / Applications / Notification / Export'. The page title is 'Export Notification'. There are two main options: 'Drug' (Exportation of Drug Products) and 'Xray' (Clearance for Customs Release for Radiation Emitting Devices). The 'Drug' option is highlighted with a red border, and a red arrow points to the 'Xray' option.

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

The screenshot shows the 'eServices Portal' interface. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The main heading is 'Import Notification'. On the left, a vertical list of steps is shown: 1. Declaration & Undertaking (active), 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents, and 6. Self-Assessment Review. The main content area is titled 'Declaration & Undertaking' and contains a scrollable text box with the following text:

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

Below the text box, there is a checked checkbox labeled 'I agree to the declaration and undertaking'. At the bottom, a blue 'Start Application' button is circled in red, with a red arrow pointing to it from the left.

B. Export Notification

This screenshot is identical to the one above, showing the 'eServices Portal' interface for the 'Import Notification' page. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The main heading is 'Import Notification'. The left sidebar shows the same steps: 1. Declaration & Undertaking (active), 2. Applicant Information, 3. Contact Person, 4. Product Details, 5. Uploading of Documents, and 6. Self-Assessment Review. The main content area is titled 'Declaration & Undertaking' and contains the same text box with the declaration and undertakings. Below the text box, the 'I agree to the declaration and undertaking' checkbox is checked. At the bottom, the blue 'Start Application' button is circled in red, with a red arrow pointing to it from the left.

- 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 qualified person or authorized person 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

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

* Entity: Please Select

* LTO Number: LTO Number

* Company Name: Company Name

* Address: Address

* Contact Information

* Email Address: Email Address of MAH

* Mobile Number: Mobile Number of MAH

Landline Number: Landline Number of MAH

Back Next

Must be the company pharmacist or personnel in charge of regulatory affairs

Details of the Contact Person

* First Name: First Name

Middle Name: Middle Name

* Last Name: Last Name

* Designation or Profession: Designation or Profession

Government Issued Identification Document

* ID Type: Please Select

* ID Number: ID Number

Expiry Date: Expiry Date

Back Next

B. Export Notification

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

* Entity: Please Select

* LTO Number: LTO Number

* Company Name: Company Name

* Address: Address

* Contact Information

* Email Address: Email Address of MAH

* Mobile Number: Mobile Number of MAH

Landline Number: Landline Number of MAH

Back Next

Must be the company pharmacist or personnel in charge of regulatory affairs

Details of the Contact Person

* First Name: First Name

Middle Name: Middle Name

* Last Name: Last Name

* Designation or Profession: Designation or Profession

Government Issued Identification Document

* ID Type: Please Select

* ID Number: ID Number

Expiry Date: Expiry Date

Back Next

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

A. Import Notification

Import Notification

1 Declaration & Undertaking **Product Type**

2 Applicant Information

3 Contact Person

4 Product Details

5 Uploading of Documents

6 Self-Assessment Review

Please Select
Raw Materials
Drug Product

Raw Material #1

* Date of Expiry Date of Expiry

* Dosage Strength Dosage Strength

* Packaging Packaging

* Manufacturer Manufacturer

* Lot/ Batch No. Lot/ Batch No. * Quantity Quantity

+ Add Lot/ Batch No. and Quantity

+ Add Product Type

Back **Next**

Import Notification

1 Declaration & Undertaking

2 Applicant Information


3 Contact Person

4 Product Details

5 Uploading of Documents

6 Self-Assessment Review

Product Type

Please Select 

- Raw Materials
- Drug Product

Finished Product # 1

* Registration Number	<input type="text" value="Registration Number"/>
* Date of Expiry	<input type="text" value="Date of Expiry"/>
If expired, Case Number/ DTN	<input type="text" value="Case Number/ DTN"/>
* Dosage Strength and Form	<input type="text" value="Dosage Strength and Form"/>
Brand Name	<input type="text" value="Brand Name"/>
	<small>leave blank if unbranded</small>
* Packaging	<input type="text" value="Packaging"/>
* Manufacturer	<input type="text" value="Manufacturer"/>
* Lot/ Batch No.	<input type="text" value="Lot/ Batch No."/> * Quantity <input type="text" value="Quantity"/>

 Add Lot/ Batch No. and Quantity

 Add Product Type

Back

Next

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 Type

Please Select

Raw Materials

Drug Product

Raw Material #1

* Date of Expiry

* Dosage Strength

* Packaging

* Manufacturer

* Lot/Batch No. * Quantity

[+ Add Lot/ Batch No. and Quantity](#)

[+ Add Product Type](#)

[Back](#) [Next](#)

Export Notification

1 Declaration & Undertaking

2 Applicant Information


3 Contact Person

4 Product Details

5 Uploading of Documents

6 Self-Assessment Review


Product Type

Please Select 

- Raw Materials
- Drug Product

Finished Product #1

* Registration Number	<input type="text" value="Registration Number"/>
* Date of Expiry	<input type="text" value="Date of Expiry"/>
If expired, Case Number/ DTN	<input type="text" value="Case Number/ DTN"/>
* Dosage Strength and Form	<input type="text" value="Dosage Strength and Form"/>
Brand Name	<input type="text" value="Brand Name"/>
	<small>leave blank if unbranded</small>
* Packaging	<input type="text" value="Packaging"/>
* Manufacturer	<input type="text" value="Manufacturer"/>
* Lot/Batch No.	<input type="text" value="Lot/Batch No."/> * Quantity <input type="text" value="Quantity"/>

 Add Lot/ Batch No. and Quantity

 Add Product Type

Back

Next

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

A. Import Notification
a. Finished Pharmaceutical Product

The screenshot shows the 'Import Notification' page for a 'Finished Drug Product'. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The page title is 'Import Notification'. A progress bar 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 instruction box states: 'Indicate or upload the following documents for verification of compliance to existing local and international standards:'. Under the heading 'Finished Drug Product:', there are three rows of document upload fields: 'Certificate of Analysis' with a text input containing 'Copy of Certificate of Analysis' and a 'File Upload' button; 'Proforma Invoice' with a text input containing 'Proforma Invoice' and a 'File Upload' button; and 'Packing list' with a text input containing 'Packing list' and a 'File Upload' button. Below these fields is the text 'merge files into a single file'. At the bottom right, there are two buttons: a grey 'Back' button and a blue 'Next' button (highlighted with a red circle).

b. Raw Materials

The screenshot shows the 'Import Notification' page for 'Raw Materials'. The breadcrumb trail is 'Home / Applications / Notification / Import / Drugs'. The page title is 'Import Notification'. A progress bar 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 instruction box states: 'Indicate or upload the following documents for verification of compliance to existing local and international standards:'. Under the heading 'Raw Materials:', there are three rows of document upload fields: 'Certificate of Analysis' with a text input containing 'Copy of Certificate of Analysis' and a 'File Upload' button; 'Invoice' with a text input containing 'Invoice' and a 'File Upload' button; and 'Packing list' with a text input containing 'Packing list' and a 'File Upload' button. Below these fields is the text 'merge files into a single file'. At the bottom right, there are two buttons: a grey 'Back' button and a blue 'Next' button (highlighted with a red circle).

B. Export Notification
a. Finished Pharmaceutical Product

eServices Portal Home Applications FAQs

Home / Applications / Notification / Export / Drugs

Export Notification

1 Declaration & Undertaking **Uploading of Documents**

2 Applicant Information

3 Contact Person

4 Product Details

5 **Uploading of Documents**

6 Self-Assessment Review

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

Finished Drug Product:

Certificate of Analysis	Copy of Certificate of Analysis	File Upload
Proforma Invoice	Proforma Invoice	File Upload
Packing list	Packing list	File Upload

merge files into a single file

Back Next

b. Raw Materials

eServices Portal Home Applications FAQs

Home / Applications / Notification / Export / Drugs

Export Notification

1 Declaration & Undertaking **Uploading of Documents**

2 Applicant Information

3 Contact Person

4 Product Details

5 **Uploading of Documents**

6 Self-Assessment Review

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

Raw Materials:

Certificate of Analysis	Copy of Certificate of Analysis	File Upload
Invoice	Invoice	File Upload
Packing list	Packing list	File Upload

merge files into a single file

Back Next

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

A. Import Notification

FDA 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

Self-Assessment Review

Applicant Information

* Entity

select entity

* LTO Number

If expired, Case Number/ DTN

* Company Name

* Address

Contact Information

* Email Address

* Mobile Number

Landline Number Landline Number of MAH

! Must be the company pharmacist or personnel in charge of regulatory affairs

Details of the Contact Person

* First Name

Middle Name

* Last Name

B. Import Notification

The screenshot shows the 'Export Notification' form in the FDA eServices Portal. The breadcrumb trail is 'Home / Applications / Notification / Export / Drugs'. The form is divided into 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 form contains the following sections:

- Applicant Information:** Fields for Entity (dropdown), LTO Number, If expired, Case Number/ DTN, Company Name, and Address.
- Contact Information:** Fields for Email Address, Mobile Number, and Landline Number (with a sub-field for Landline Number of MAH).
- Details of the Contact Person:** Fields for First Name, Middle Name, and Last Name.

A blue information box states: 'Must be the company pharmacist or personnel in charge of regulatory affairs'.

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. It features a reCAPTCHA widget with a green checkmark and the text 'I'm not a robot'. Below the widget is a red-bordered box containing the following text:

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

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, there are two buttons: a grey 'Back' button and a blue 'Confirm' button, which is circled in red.