

**FDA Circular**

No. \_\_\_\_\_

**SUBJECT: Guidelines on the Importation and Exportation Notification for Pharmaceutical Products and Raw Materials****I. RATIONALE**

Republic Act (RA) No. 3720, as amended by RA No. 9711, otherwise known as the “Food and Drug Administration (FDA) Act of 2009”, mandates the FDA to regulate and subsequently issue appropriate authorizations to establishments engaged in the manufacture, distribution, importation, exportation and retailing of health products, among others. Also, Section 5 of RA No. 9711 declares the following powers of the FDA, “(b) to assume primary jurisdiction in the collection of samples of health products; (c) to analyze and inspect health products in connection with the implementation of this Act; (l) to strengthen the post-market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products; and (p) to maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the Director-General for confiscated goods in strategic areas of the country especially at major ports of entry.”

Further, Section 23 of Executive Order No. 175 s. 1987 which amended Section 30 of RA No. 3720, states that “The Commissioner of Customs shall cause to be delivered to the Bureau samples taken at random from every incoming shipment of food, drugs, devices, and cosmetics which are being imported or offered for import into the Philippines, giving notice thereof to the owner or consignee.” In addition, Article I Section 6 (Requirements for Every Incoming Shipment of Health Products) of the Book II of the Implementing Rules and Regulation (IRR) of RA No. 9711, states that “The FDA in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to importation of health products such as, but not limited to, sampling and examination, in accordance with relevant existing laws and regulations, of every incoming shipment of health products”. In order to effectively regulate importation activities on health products, inter-agency cooperation needs to be well-established.

To implement this, FDA Memorandum Circular (FMC) No. 2013-032, entitled “Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs”, was issued, wherein only valid FDA License to Operate (LTO) and Certificate of Product Registration (CPR) were required to be presented to the Bureau of Customs (BOC) for the release of pharmaceutical products. However, there is a need to strengthen market control within the distribution chain through measures to ensure that the public only receives quality-assured pharmaceutical products. The infiltration of substandard and counterfeit pharmaceutical products into the supply system shall be prevented through risk-based surveillance schemes and rigorous control. Therefore, as part of the FDA’s powers and functions under RA No. 9711, requiring the concerned pharmaceutical establishments to notify each



51 importation/exportation of pharmaceutical products and raw materials is necessary to  
52 strengthen the FDA's overall market surveillance and control regulatory function.

53  
54 In the interest of public health, importation and exportation activities relative to  
55 pharmaceutical products and raw materials shall be regulated and monitored by the  
56 FDA. Hence, issuance of this Circular is imperative in ensuring consistency and  
57 effectiveness of these regulatory activities.

## 60 **II. OBJECTIVES**

61  
62 This Circular aims to achieve the following:

- 63  
64 A. Provide detailed guidelines and clear procedures in the notification process of  
65 importation and exportation of pharmaceutical products and raw materials.
- 66  
67 B. Establish and identify the authorized ports of entry and exit of pharmaceutical  
68 products and raw materials into and out of the country for effective border  
69 control.

## 72 **III. SCOPE**

73  
74 This Circular shall apply to all FDA-licensed pharmaceutical establishments engaged  
75 in the manufacture, importation, and exportation of finished, semi-finished products  
76 or raw materials of pharmaceutical products for human and veterinary use, except for  
77 pharmaceutical products for personal use covered under DOH-FDA-BOC Joint  
78 Circular No. 1 s. 2015.

79  
80 This Circular shall also apply to Sponsors and Contract Research Organizations  
81 (CRO) for investigational pharmaceutical products, and to Compassionate Special  
82 Permit (CSP) Holders and Donee/Recipient/Consignee for pharmaceutical products  
83 for compassionate use and donation, respectively.

## 86 **IV. DEFINITION OF TERMS**

87  
88 All the terms or words used herein that are already defined under RA No. 3720 as  
89 further amended by EO No. 175 and RA No. 9711, other related FDA-implemented  
90 health laws and their respective IRRs, for the purpose of implementing this Circular,  
91 shall have the same meaning as defined therein. In addition, the following terms shall  
92 be defined as follows for the purpose of this issuance:

- 93  
94 A. **Air Way Bill (AWB)** refers to a transport document for airfreight, used by  
95 airlines and international freight forwarders, which specifies the holder or  
96 consignee of the bill who has the right to claim delivery of goods when they arrive  
97 at the port of destination. It is a contract of carriage that includes carrier  
98 conditions, such as limits of liability and claims procedures. In addition, it  
99 contains transport instructions to airlines and carriers, a description of the goods,  
100 and applicable transportation changes.

101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134  
135  
136  
137  
138  
139  
140  
141  
142  
143  
144  
145  
146  
147  
148  
149  
150

- B. **Bill of Lading (B/L)** refers to a transport document issued by shipping lines, carriers, and international freight forwarders or non-vessel operating common carriers for water-borne freight. It is a contract of carriage between the carrier and the shipper which defines the liabilities of each party. The holder or consignee of the bill has the right to claim delivery of the goods at the port of destination. It may refer to a Master Bill of Lading or a House Bill of Lading.
  
- C. **Bureau of Customs (BOC)** refers to the national agency under the Department of Finance in charge of imports, exports, and foreign trade. The mandate of BOC is to implement an effective revenue collection by preventing and suppressing smuggling and the entry of prohibited imported goods. It supervises and controls the entrance of vessels and aircraft engaged in foreign commerce. It also enforces the Tariff and Customs Code of the Philippines and all other laws, rules and regulations related to Tariff and customs administration.
  
- D. **Commercial Invoice** refers to a legal document between the supplier and the customer that clearly describes the sold goods, and the amount due on the customer.
  
- E. **Compassionate Special Permit (CSP) Holder** refers to a qualified institution or qualified licensed physician who has applied before the FDA and has been granted the CSP.
  
- F. **Finished Pharmaceutical Product** refers to a pharmaceutical product that has undergone all stages of production and quality control, including packaging in its final container and labeling.
  
- G. **Law Enforcement Agencies (LEAs)** refer to agencies responsible for enforcing the law, particularly the activities of prevention, detection, and investigation of crimes and the apprehension of the criminals or offenders.
  
- H. **Packing List** refers to the itemized list of articles usually included in each shipping package, giving the quantity, description and weight of the contents.
  
- I. **Proforma Invoice** refers to a draft invoice given by the shipper to a recipient/consignee prior to the shipment of goods. It provides information on the nature, quantity, value and weight of goods to be imported.
  
- J. **Raw Material** refers to all substances whether active or excipients that are employed in the processing of a finished pharmaceutical product.
  
- K. **Semi-finished Pharmaceutical Product** refers to a pharmaceutical product that is obtained during the manufacturing process, and that, with further processing, can become a finished pharmaceutical product.

151 **V. GENERAL GUIDELINES**

152  
153  
154  
155  
156  
157  
158

A. A notification must be submitted for every shipment and all batches/lots of pharmaceutical products or raw materials covered by this guideline. The following entities/establishments with valid FDA-LTO and CPR/authorization of the pharmaceutical product or raw materials, if applicable, shall notify the FDA of all of their importation/exportation activities:

<b>Establishment</b>	<b>Pharmaceutical product</b>
Manufacturer, Trader	Raw material, semi-finished pharmaceutical product
Distributor/Importer/Exporter	Finished pharmaceutical product, Investigational pharmaceutical product
Sponsor, CRO	Investigational pharmaceutical product
CSP Holder (Institution/Physician)	Pharmaceutical products under CSP
Donee/Recipient/Consignee	Donated pharmaceutical product

159  
160  
161  
162  
163  
164  
165  
166  
167  
168  
169  
170  
171  
172  
173  
174  
175  
176  
177  
178  
179  
180  
181  
182  
183  
184  
185  
186  
187  
188  
189

B. All notifications shall be filed within one month (1 day to 30 days) prior to the arrival/departure of the shipment to/from the Philippines.

C. The pharmaceutical establishments, including the CSP Holders and donees/recipients/consignees, shall submit documentary requirements to support the notification through the FDA eServices Portal System. The applicants shall undertake responsibility for the submission of complete and correct application documents to the FDA, in accordance to the list of requirements and acceptable equivalent document stipulated by the guidelines. The FDA eServices Portal System for this process shall accept notifications during the operating period of FDA Online Services.

D. The pharmaceutical establishment shall indicate the date of arrival/departure at their chosen port of entry/exit in the notification. Importation/Exportation of pharmaceutical products and raw materials shall be channeled exclusively through the established and identified Bureau of Customs (BOC) port listed in Annex A. Should there be changes in the port of entry/exit (i.e. due to port congestion), the pharmaceutical establishment shall amend their previous notification.

E. The Notification Acknowledgement shall be issued through the official email to the pharmaceutical establishments after the successful submission of notification through the FDA eServices Portal System.

F. The list of pharmaceutical products and raw materials notified for importation and exportation shall be posted in the FDA Verification Portal System.

G. Following the existing regulations, the BOC shall process and release the importation or exportation shipment without the need to present the notification acknowledgment but upon presentation of the FDA authorizations cited below:

<b>Authorization</b>	<b>Type</b>
Valid LTO and CPR	Pharmaceutical products for distribution

Valid LTO and Import License	Investigational pharmaceutical products
Valid CSP	Pharmaceutical products for compassionate use
Valid CPR for Donation	Pharmaceutical products for donation

190  
191  
192  
193  
194  
195  
196  
197  
198  
199  
200  
201  
202  
203  
204  
205  
206  
207  
208  
209  
210  
211  
212  
213  
214  
215  
216  
217  
218  
219  
220  
221  
222  
223  
224  
225  
226  
227  
228  
229  
230  
231  
232  
233  
234

- H. BOC ports and third-party warehouses shall be inspected by the FDA to ensure compliance with Good Distribution and/or Storage Practices (GDP/GSP) and other relevant existing rules and regulations.
- I. The FDA shall conduct risk-based post-marketing surveillance activities upon arrival/departure including but not limited to collection of pharmaceutical product samples for testing, inspection of involved establishments/ facilities, collaboration with BOC and Law Enforcement Agencies (LEAs), and other regulatory actions as necessary.
- J. The foregoing general guidelines are nonexclusive and shall not preclude the FDA from performing other regulatory and enforcement activities, and the covered establishments to allow inspection of their regulated activities and collaborate with the FDA authorities on action taken for consumer protection, as may be authorized by law, other rules, and regulations.

**VI. SPECIFIC GUIDELINES**

**A. Documentary Requirements**

1. The required details of the LTO, CPR and local GMP Certificate issued by the FDA shall be encoded, and the following documentary requirements both for import and export of finished, semi-finished pharmaceutical products and raw materials shall be uploaded to the FDA eServices Portal System:
  - a. Certificate of Analysis (COA), if available
  - b. Proforma Invoice/Commercial Invoice
  - c. Packing list, if applicable
2. The required details of the LTO and Import License issued by the FDA shall be encoded, and the proforma invoice/commercial invoice shall be uploaded to the FDA eServices Portal System both for import and export of investigational pharmaceutical products.
3. The required details of the CSP issued by the FDA shall be encoded to the FDA eServices Portal System for importation of pharmaceutical products for compassionate use.
4. The required details of the CPR issued by the FDA for importation of pharmaceutical products for donation shall be encoded to the FDA eServices Portal System.

235 **B. Notification Process**

- 236
- 237 1. Guidelines on notification using FDA eServices Portal System are provided in
- 238 Annex B and the procedure on the use of the FDA eServices Portal System for
- 239 Notification of finished, semi-finished pharmaceutical products and raw materials
- 240 is provided in Annex C.
- 241
- 242 2. Procedure on the use of the FDA eServices Portal System for Notification of
- 243 investigational pharmaceutical products, and pharmaceutical products for
- 244 compassionate use and donation shall be released on separate issuances.
- 245
- 246 3. In case where the cause of delay is due to force majeure or fortuitous events
- 247 which result to damage or destruction of documents, and/or system failure of the
- 248 computerized processing, other official modes of notification (i.e., registered mail
- 249 or personal delivery) shall be resorted to and the prescribed processing times shall
- 250 be suspended and appropriate adjustments shall be made, provided the same shall
- 251 be made known to the affected applicants or stakeholders.
- 252

253 **C. Post-Notification Commitments**

254

255 All entities/establishments with notification for importation and exportation of

256 pharmaceutical products, raw materials, investigational pharmaceutical products, and

257 pharmaceutical products under CSP and donation, shall be required to input and

258 submit the following within fifteen (15) working days from the arrival/departure of

259 the shipment, through the FDA eServices Portal System, as post-notification

260 commitments:

261

- 262 1. Date of Arrival/Departure of the pharmaceutical products
- 263 2. Bill of Lading/Airway Bill
- 264 3. Certificate of Analysis (COA), if not provided during the notification process
- 265 for finished pharmaceutical products/raw materials
- 266

267 Procedure on the Use of the FDA eServices Portal System for Post-Notification

268 Commitment is provided in Annex D. Noncompliance with the submission of post-

269 notification commitments shall result in regulatory action without prior notice.

270

271 **D. Inspection of BOC Ports and Third-Party Warehouses**

- 272
- 273 1. All the identified designated BOC ports and third-party warehouses to be used for
- 274 the importation and exportation of pharmaceutical products and raw materials
- 275 shall be inspected.
- 276
- 277 2. Designated ports shall have secured storage facilities, including cold storage
- 278 areas. The FDA and BOC shall ensure that the appropriate environmental
- 279 conditions are maintained for storage, and monitor that the equipment is
- 280 maintained and in good working order.
- 281
- 282 3. Inspections shall be done by the FDA to ensure compliance with GDP/GSP and
- 283 other relevant existing rules and regulations.

284  
285  
286  
287  
288  
289  
290  
291  
292  
293  
294  
295  
296  
297  
298  
299  
300  
301  
302  
303  
304  
305  
306  
307  
308  
309  
310  
311  
312  
313  
314  
315  
316  
317  
318  
319  
320  
321  
322  
323  
324  
325  
326  
327  
328  
329  
330

**E. Post-Marketing Surveillance**

1. The FDA in coordination with BOC, following a risk-based approach, shall collect pharmaceutical products and raw materials based on established procedures and subject the sample to physical and chemical analysis. The consignment will be released from the BOC but shall be inspected in the MAH warehouse
2. All unauthorized shipments and shipments containing unauthorized pharmaceutical products and raw materials, shall be seized by the BOC, in coordination with FDA, and hold the shipment for further investigation.
3. The FDA shall ensure that the BOC has access to the FDA eServices Portal System for verification of the importation/exportation notification.
4. The FDA shall collaborate with the BOC and LEAs for the relevant investigation and legal actions, when necessary.
5. The FDA shall inspect involved establishments/entities and take necessary regulatory actions against violative products and establishments/entities.

**VII. REGULATORY ACTION**

Noncompliance with the provisions of this Circular will subject the product and establishment/entities to stricter post-marketing surveillance and appropriate regulatory actions.

**VIII. SEPARABILITY CLAUSE**

If any part, term, of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

**IX. EFFECTIVITY CLAUSE**

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines-Office of the National Administrative Register (UP-ONAR).

**DR. SAMUEL A. ZACATE**  
Director General

## ANNEX A

### **List of Bureau of Customs Authorized Ports for Finished Pharmaceutical Products and Raw Materials**

1. Port of Manila (POM)
2. Manila International Container Port (MICP)
3. Ninoy Aquino International Airport (NAIA)
4. Port of Batangas
5. Port of Subic
6. Port of Clark
7. Port of Cebu
8. Sub-Port of Mindanao Container Terminal (MCT)
9. Port of Davao

*Note: The list may be updated at any time as determined by BOC and FDA through an FDA Advisory. When necessary, FDA Field Regulatory officials may be stationed/on-call at the designated ports of entry/exit and collect pharmaceutical products and raw materials through risk-based sampling.*



## ANNEX B

### **Guidelines on Notification of Importation/Exportation of Finished Pharmaceutical Products and Raw Materials Using FDA eServices Portal System**

#### **I. Guidelines**

1. All notifications of importation/exportation of finished pharmaceutical products and raw materials shall be accomplished using the online notification form through the FDA eServices Portal System (<https://eservices.fda.gov.ph>). Creation of account and password is no longer a requirement to obtain access to the online portal.
2. The “Declaration and Undertaking” conveys a binding agreement of the notifying company/Marketing Authorization Holder (MAH) with the FDA to provide accurate information, affirm primary responsibility over the products, and comply with all the rules and regulations set forth during and after the notification process.
3. In completing the fields in the eNotification form, the notifying company will be assisted with written warnings/pop-ups/reminders before proceeding to the next step to ensure the accuracy of the information being provided. The MAH notifying the importation/exportation shall ensure that the declared information in the eNotification form is consistent with the uploaded supporting documents.
4. The declared e-mail address under the Contact Information is unalterable once submitted. Hence, the MAH shall be responsible for making sure that the email address is within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable in any way for loss of access to the declared email address. The Company Authorized Officer or Qualified Personnel shall have the responsibility to comply with the regulatory and technical requirements of the FDA wherein:
  - a. The **Authorized Person** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity; and
  - b. The **Qualified Person** refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment’s activities and health products by virtue of his profession, training, or experience. A Qualified Person has the responsibility to comply with the technical requirements of FDA or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting an inspection or post-market surveillance activities. The Qualified Person may also be the duly Authorized Person of the establishment.
5. Documents required to be uploaded in the eNotification Form shall be in portable document file (PDF), with no more than 2 megabytes (MB) file size.
6. Once the eNotification Form is completed, applicants can review the duly

filled out form in the Self-Assessment Review. By agreeing to the terms and conditions, the applicant confirms the correctness of the information provided and data privacy terms.

7. The Notification Summary shall be automatically sent to the applicant's registered email address to indicate the successful submission of the notification in the FDA eServices Portal System.
8. Notifications may be filed anytime to ensure there are no delays in the shipment.
9. Status of the Notification can be monitored at the FDA eServices Portal System and validated through the email used for the application.

The step-by-step procedure for notification process through FDA eServices Portal System is attached as Annex C in this issuance.

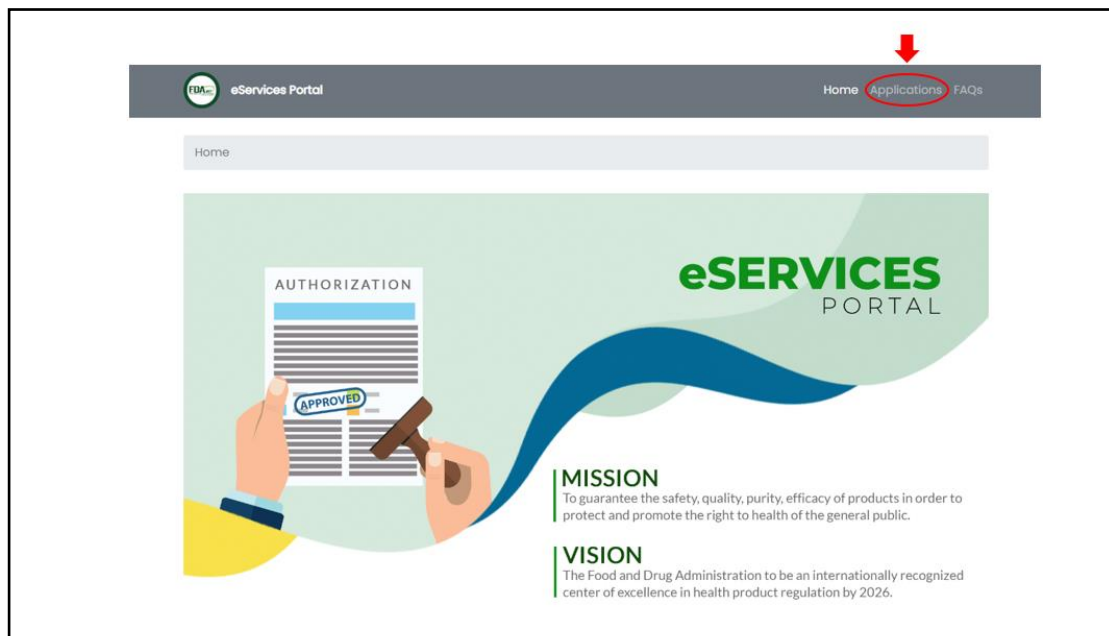
## **II. Release of Notification Acknowledgment**

1. Notification with complete documentary requirements shall receive a notification acknowledgment.
2. The MAH shall receive the notification acknowledgment in their registered email address and may also be accessed through the FDA eServices Portal System.
3. Upon receipt of the notification acknowledgment, MAH may print it on a standard A4 size (21 cm by 29.7 cm) paper, on full-colored page and in portrait orientation.
4. A QR Code verifier shall be included in the notification acknowledgment as the basis of legitimacy of the document.

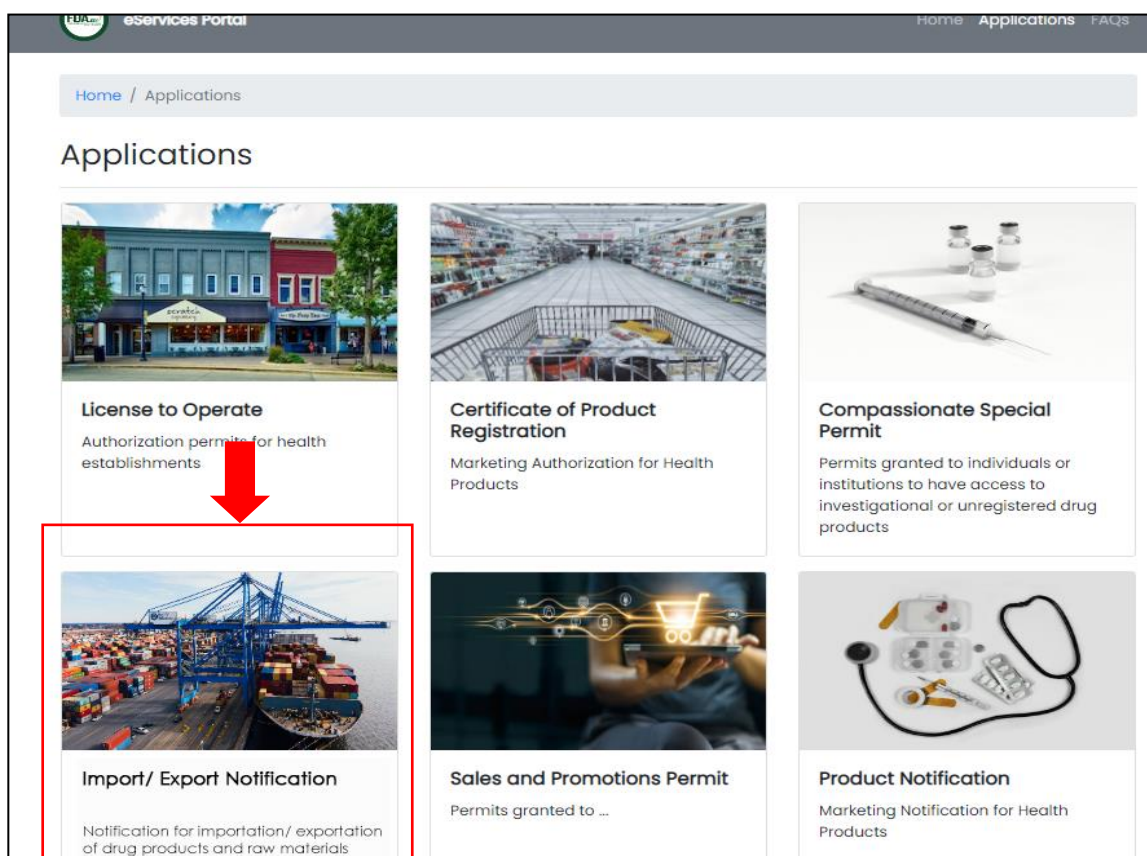
## ANNEX C

### 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 (highlighted), 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 'Import Notification'. 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 (highlighted), 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.

- 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

\* 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

\* 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**

**EBA** 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	<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**

**EBA** 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	<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**

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 'eServices Portal' interface for 'Export Notification'. The breadcrumb trail is 'Home / Applications / Notification / Export / Drugs'. The page title is 'Export Notification'. A 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 (highlighted with a red circle). The main form area is titled 'Applicant Information' and contains the following fields: Entity (dropdown menu), LTO Number, If expired, Case Number/ DTN, Company Name, Address, Email Address, Mobile Number, and Landline Number (with a sub-field for 'Landline Number of MAH'). Below this is a section titled 'Details of the Contact Person' with 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'.

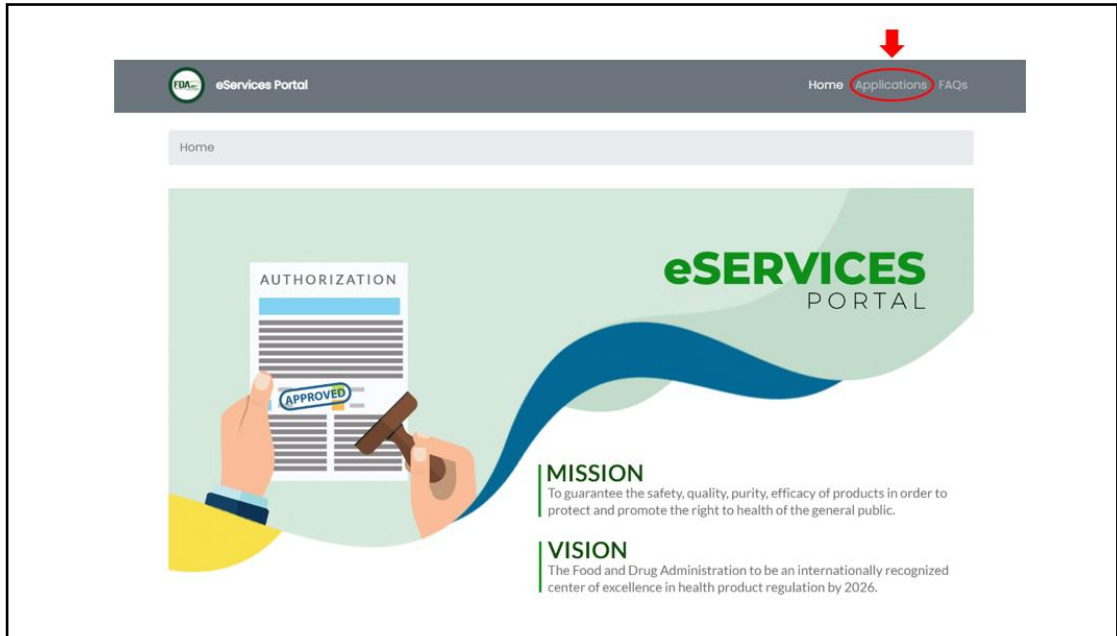
9. Once reviewed, the Applicant shall confirm the correctness of the data given and click on **Confirm** to submit the application.

This screenshot shows the final 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 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.', 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 page, there are two buttons: a grey 'Back' button and a blue 'Confirm' button, which is circled in red.

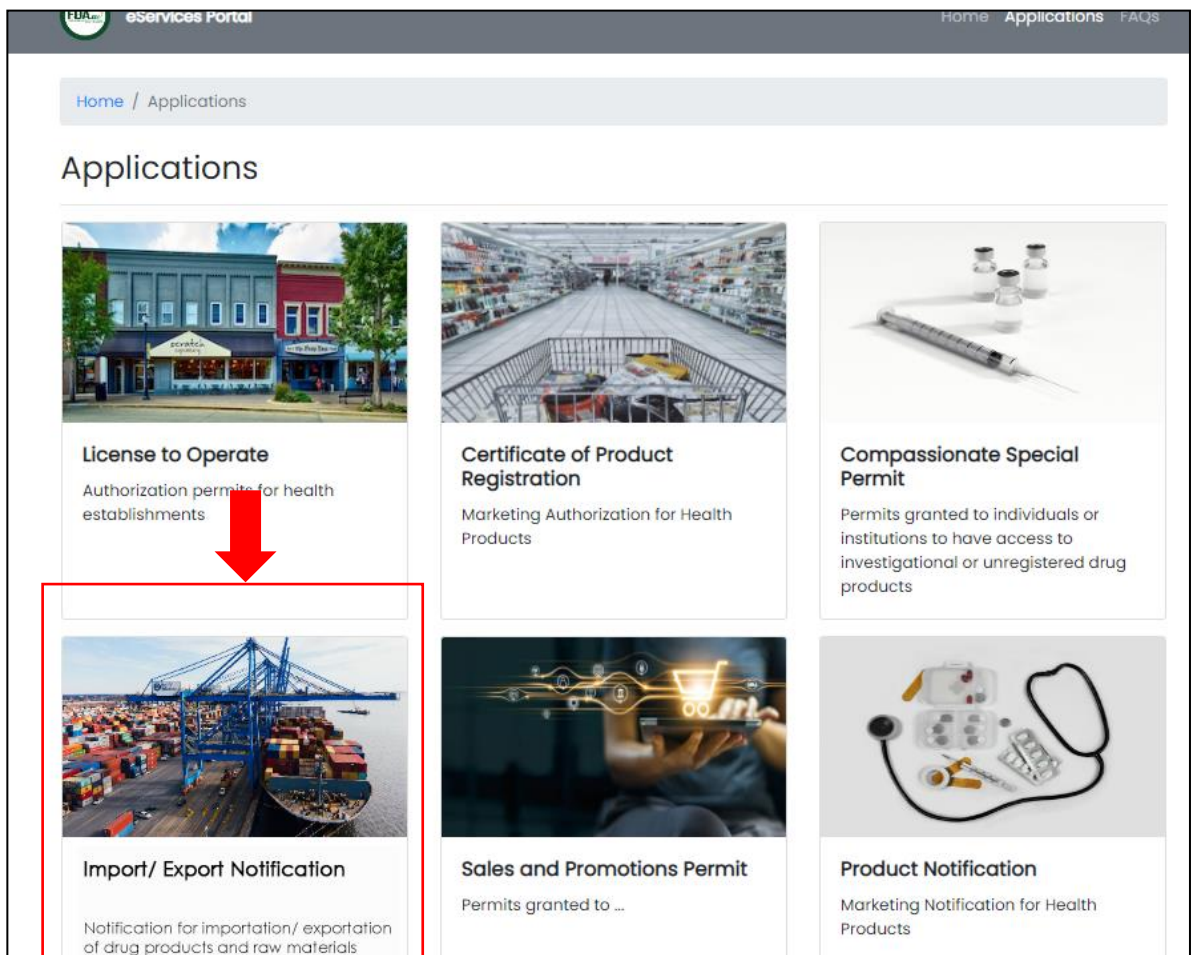
## ANNEX D

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

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 Post-Notification Commitment.**

Home / Applications / Import Clearance


## Import Clearance



**Drug Import Clearance**  
Importation of Drug Products



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



**Post-Notification Commitment**  
Submission of post-notification commitments.

**4. Input the Notification Number and Date of Issuance.**



5. Modify the **Quantity**, if needed.

Home / Applications / Notification / Post-Notification Commitments

## Post-Notification Commitments

- 1 Notification Number
- 2 Verification**
- 3 Documents Submission
- 4 Self-Assessment Review

### Verification

\* Notification Number

\* Date of Issuance

Importer's / Exporter's Name

Importer's / Exporter's Address

LTO Number

Drug Product (1) / Raw Material (1)

Generic Name	<input type="text" value="Generic Name"/>	
Dosage Strength & Form	<input type="text" value="Dosage Strength &amp; Form"/>	
Brand Name	<input type="text" value="Brand Name"/>	
Packaging	<input type="text" value="Packaging"/>	
Manufacturer	<input type="text" value="Manufacturer"/>	
Batch/ Lot No.	Quantity	<input type="text" value="Quantity"/> <small>Modify quantity</small>
		<input type="text"/>
Batch/ Lot No.	Quantity	<input type="text" value="Quantity"/> <small>Modify quantity</small>
		<input type="text"/>

## 6. Submit the **Required documents**.

[Home](#) / [Applications](#) / [Notification](#) / Post-Notification Commitments

### Post-Notification Commitments

- 1 Notification Number
- 2 Verification
- 3 Documents Submission
- 4 Self-Assessment Review

#### Documents Submission

\* Notification Number

\* Date of Issuance

Importer's / Exporter's Name

Importer's / Exporter's Address

LTO Number

#### Uploading of Documents

\* Date of Arrival of the Finished Drug Products/ Raw Materials

\* Bill of Lading/ Airway Bill

\* Certificate of Analysis (COA)

\* Proforma Invoice/ Commercial invoice

\* Packing List

7. The applicant shall **review** the submission. Once reviewed, the Applicant will click on **Submit** to submit the post-notification commitment.

Home / Applications / Notification / Post-Notification Commitments

## Post-Notification Commitments

**1** Notification Number      **Self-Assessment Review**

**2** Verification

**3** Documents Submission

**4** Self-Assessment Review

\* Notification Number

\* Date of Issuance

Importer's / Exporter's Name

Importer's / Exporter's Address

LTO Number

Drug Product (1) / Raw Material (2)

Generic Name

Dosage Strength & Form

Brand Name

Packaging

Manufacturer

Batch/ Lot No.	<input type="text" value="Batch/ Lot No."/>	Quantity	<input type="text" value="Quantity"/>
		<a href="#">Modify quantity</a>	<input type="text"/>
Batch/ Lot No.	<input type="text" value="Batch/ Lot No."/>	Quantity	<input type="text" value="Quantity"/>
		<a href="#">Modify quantity</a>	<input type="text"/>

\* Date of Arrival of the Finished Drug Products/ Raw Materials

\* Bill of Lading/ Airway Bill

\* Certificate of Analysis (COA)

\* Proforma Invoice/ Commercial invoice

\* Packing List