ANNEX B

Guidelines on Notification of Importation/Exportation of Finished Drug Products and Raw Materials Using eServices Portal System

I. Guidelines

1. All notifications of importation/exportation of finished drug products and raw materials shall be accomplished using the online notification form through the 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 eServices portal.
8. Notifications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.
9. Status of the Notification can be monitored at the eServices and validated through the email used for the application.

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

II. Release of Notification Acknowledgment

1. Notification with complete documentary requirements shall receive an 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.
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.