ANNEX B

Guidelines on Clearance for Customs Release (CFCR)
Using eServices Portal System

I. Guidelines

1. All Clearance for Customs Release (CFCR) applications shall be accomplished using the online application 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 applicant company 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 application process.
3. In completing the fields in the eApplication form, the applicant 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 applicant applying for CFCR shall ensure that the declared information in the eApplication form is consistent with the uploaded supporting documents.
4. The declared e-mail address under the Contact Information is unalterable once submitted. Hence, the applicant 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 eApplication Form shall be in portable document file (PDF), with no more than 2 megabytes (MB) file size.
6. Once the eApplication 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 Application Summary shall be automatically sent to the applicant's registered email address to indicate the successful submission of the application in the eServices portal.

8. Applications 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 Application can be monitored at the eServices and validated through the email used for the application.

The step-by-step procedure for CFCR applications through eServices Portal is attached as Annex (Annex C) in this issuance.

II. Pre-assessment

1. An evaluator/assessor from the Center for Drug Regulation and Research (CDRR) shall conduct pre-assessment on the submitted application and documentary requirements with regard to their completeness. Applications with incomplete or incorrect data entry and document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. The pre-assessment of applications shall be done within the working days and office hours of the FDA.
3. The CDRR shall inform the applicant through the registered email address of the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. However, if the application failed the pre-assessment step, the FDA shall notify the reason/s for non-acceptance (e.g., deficiencies found and prompt the applicant to apply again through the eServices Portal).

III. Payment of Fees

1. The payment of the total application fee as indicated in the Order of Payment (OP) shall be done through LandBank Link.BizPortal.
2. Once the full payment is made, a record of the transaction shall automatically be posted on the eServices Portal.
3. Applicants shall receive a system-generated message on the successful payment through the registered e-mail address.

IV. Evaluation of Application

1. The veracity of the application and its compliance with all relevant FDA requirements and standards shall be checked.
2. Evaluation shall be done within the prescribed working days and office hours. Applications filed after working hours and during weekends/holidays shall be considered filed on the next working day.
3. Applications with complete documentary requirements and payment shall receive an Acknowledgement Receipt from FDA. This shall contain the number/code of the employee who received the application, reference number, the agency's logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.
4. If the application is approved, the FDA shall send the CFCR to the registered email address of the applicant. If the application is disapproved, the FDA shall inform the applicant of the reason for such action on the application through their registered email address.

V. Disapproval of Application

1. For emphasis, the grounds for disapproval of CFCR application may be any of the following:
    a. The documentary requirements submitted does not meet the required technical requirements and/or appropriate standards,
    b. the applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards,
    c. the applicant has violated any of the terms and conditions of its license, and/or
    d. such other analogous grounds or causes as determined by the FDA.

    The disapproval of an application is without prejudice to reapplication. However, disapproval shall mean outright forfeiture of payment.

VI. Release of CFCR

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