Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-006-A

02 APR 2020

SUBJECT: AMENDMENT TO FDA CIRCULAR NO. 2020-006 ENTITLED "GUIDANCE FOR APPLICATIONS AND TRANSACTIONS AT THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATION" ISSUED ON 17 MARCH 2020

I. INTRODUCTION

The Food and Drug Administration (FDA) issued Circular No. 2020-006 entitled "Guidance for Applications and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration" on 17 March 2020 as the Agency's response to the Community Quarantine declaration.

The subsequent declaration of an Enhanced Community Quarantine (ECQ) prompted Local Government Units to impose lockdowns, including the proclamation of the City of Muntinlupa to place the city under twenty-four (24) hour curfew through Muntinlupa City Ordinance No. 2020-074. As a result, work from home scheme will be strictly implemented by the FDA to ensure continuity of government service during the period of Covid-19 outbreak to prevent further spread of the disease. Thus, modification and adjustment in the existing systems and procedures in the application for authorization is in order and hereby adopted.

This issuance aims to provide supplemental guidance relative to the interim changes in FDA's work arrangement.

II. SCOPE

This Circular, in addition, also covers the application of specific FDA market authorizations, certificates, and permits with respective Center/Office of jurisdiction, as follows:

Center/Office	Market Authorizations/Certificates/Permits
Center for Cosmetic Regulation and Research (CCRR)	1. Certificate of Free Sale (CFS) 2. Compliance Report 3. Import Clearance 4. License to Operate (LTO) for Cosmetic Distributors 5. Local GMP Certificate 6. Registration Applications 7. Sales Promotion Permit
Center for Device Regulation, Radiation Health and Research	1. Applications related to COVID-19: a. Covid-19 Test Kits b. Personal Protective Equipment (PPE)

(CDRRHR)	c. Initial Application for hospital-based x-ray facilities using x-ray devices d. Clearance for Customs Release (CFCR) for x-ray device 2. Certificate of Product Registration (CPR) Compliance 3. Compassionate Special Permit (CSP) 4. Sales Promo Permit
Center for Drug Regulation and Research (CDRR)	1. Animal Feeds Certificate 2. Certificate of Pharmaceutical Product (COPP) 3. Certification (as a result of Post-Approval Changes) 4. CFS 5. CSP 6. Clinical Trial Approval and its related authorizations 7. Drug Product Registration applications and other CPR-related applications 8. Donations endorsed by DOH (Foreign and Local) 9. Generic Labeling Exemption (GLE) 10. Import License 11. Local and Foreign GMP Certificate 12. Major and Minor Variations including Notification 13. Sales Promotion Permit
Center for Food Regulation and Research (CFRR)	1. BOC Clearance/ Import Permit 2. Food Supplement Samples (actual samples for submission once the ECQ has been lifted) 3. HACCP Certificate 4. Sales Promo Permit 5. Sangkap Pinoy Seal
Field Regulatory Operations Office (FROO) -Regional Field Office (RFO)	1. Corrective and Preventive Action (CAPA) Report 2. One Stop Shop (OSS) applications 3. RFO Inspection Report for: a. Hazard Analysis and Critical Control Point (HACCP) b. Sangkap Pinoy Seal c. Foreign GMP Inspection Application
Common Services Laboratory (CSL)	1. Food Export Certificate and Food Commodity Clearance 2. Batch Notification 3. Lot Release Certification

III. GUIDELINES

A. Renewal Application of FDA Market Authorizations

LTO, Certificate of Product Registration (CPR), and Certificate of Product Notification (CPN) with validity until 01 March 2020 to 30 June 2020 shall be given additional four (4) months validity extension from the date of expiration of the market authorization. All applicants are required to apply for renewal within the given extension period.

The automatic validity extension shall not preclude the FDA from revoking the relevant market authorization if the evaluation of the application so warrants.

All applicants transacting with the Bureau of Customs (BOC) shall provide copy of this Circular and the proof of their renewal application as received and accepted by the FDA as attachments in support of the expired market authorization.

B. Center for Cosmetic Regulation and Research (CCRR) Transactions

Provision No. 1 is hereby amended **to include all products containing up to 80% alcohol** used as antiseptic, antibacterial, and sanitizer**.** This is in view of the recommendations of the US Food and Drug Administration (USFDA, Mach 2020) and the World Health Organization Guidelines on Hand Hygiene on Health Care: A Summary (2009).

C. Electronic Filing of Applications for Certain FDA Certificates and Permits

Electronic application and submission of documentary requirements for the following FDA certificates and permits may be sent to the corresponding FDAC email addresses below:

<table>
<tr><th>CDRR
Email to:
fdac.pacd.cdrr@fda.gov.ph</th><th>CCRR/CDRRHR/CFRR/RFO
Email to: fdac.pacd@fda.gov.ph</th></tr>
<tr><td rowspan="4">▪ Registration Application
▪ Sales Promo Permit
▪ Compliance
▪ Major and Minor Variation, including Notification
▪ Additional Documents related to applications
▪ Other Authorizations (CoPP, GLE, CFS)

For additional guidelines, see Annex A of this Circular</td><td>CFRR:
▪ Food Supplement Samples for submission once the ECQ has been lifted
▪ HACCP Certificate
▪ Sales Promo Permit
▪ Sangkap Pinoy Seal</td></tr>
<tr><td>CCRR:
▪ Certificate of Free Sale (CFS)
▪ Compliance
▪ Registration Applications
▪ Sales Promotion Permit</td></tr>
<tr><td>CDRRHR:
▪ CPR Compliance – See Annex B of this Circular for additional guidelines
▪ Sales Promo Permit</td></tr>
<tr><td>Regional Field Office (RFO):
▪ CAPA
▪ OSS</td></tr>
<tr><td colspan="2">Other pertinent documents as may be required by the FDA</td></tr>
</table>

<table>
<tr><th>CDRR
Email to:
fdac.letters.cdrr@fda.gov.ph</th><th>CCRR/CDRRHR/CFRR/RFO
Email to: fdac.letters@fda.gov.ph</th></tr>
<tr><td>▪ Local and FGMP Certificate</td><td>CFRR: BOC Clearance/Import Permit</td></tr>
</table>

<table>
<tr><td rowspan="2">▪ Animal Feeds Certification
▪ Reconstruction/ Correction of CPR

For additional guidelines, see Annex A of this Circular</td><td>CCRR: Local GMP</td></tr>
<tr><td>CDRRHR:
▪ Applications related to COVID-19 (Test Kits, PPE) - See Annex B of this Circular
▪ CSP
▪ Notification of Sources (no payment required)</td></tr>
<tr><td></td><td>RFO Inspection Report:
▪ HACCP
▪ Sangkap Pinoy Seal
▪ Foreign GMP Inspection Application for FROO GMP Unit processing</td></tr>
<tr><td>For the following applications, kindly email directly to clinicalresearch@fda.gov.ph:
▪ Initial Clinical Trial (CT) and Import License (IL)
▪ Protocol Amendment
▪ Post Marketing Study Protocol
▪ CSP
For additional guidelines, see Annex A of this Circular</td><td></td></tr>
<tr><td colspan="2">Other pertinent documents as may be required by the FDA

For Common Services Laboratory (CSL) applications and transactions, see Annex C of this Circular</td></tr>
</table>

1. Applications for these certificates and permits may be done thru submission of **scanned copy of the documentary requirements** and **proof of payment** of prescribed fees to the corresponding email addresses of FDAC. For documentary requirements that exceed the maximum file size of 25 Megabytes, the applicant may create Google Drive folder with the documentary requirements and share the folder link to the above FDA email address.

2. Notarization of required documents shall be waived during the ECQ period. In lieu of this, the applicant shall submit the document together with a signed letter stating that the notarized copy of the document will be submitted upon lifting of the ECQ.

3. Only the complete and correct submissions shall be received for evaluation. Applications with incorrect and incomplete requirements and payment shall not be accepted. For ease of identification of applications, the following information are requested to be included in the subject and body of the email, as applicable:

   Email Subject: Type of Application and Center Concerned

   Email Body:
   1. 14-Digit Document Tracking Number
   2. Schedule Given by FDAC
   3. Proof of Payment

4. Product Category
5. Product Classification
6. Type of Application

Refer to Annexes of this Circular for specific guidelines of the following Centers:
Annex A: Additional Guidelines for CDRR Transactions and Applications
Annex B: Additional Guidelines for CDRRHR Transactions and Applications

D. Payment of Fees and Charges

The procedure of payment of fees and charges implemented by the FDA follows FDA Circular No. 2017-010 entitled "New Collection Policy and Procedure" issued on 15 September 2017. To reiterate the modes of payment (FDA Circular No. 2017-010, Section IV. Payment Procedures), FDA accepts Bancnet Online Payment Facility for applications with Document Tracking Number (DTN), to wit:

> "For Bancnet Online Payment Facility transactions, please log in to www.bancnetonline.com, and follow these simple instructions:
> - Register
> - Proceed as instructed by the system
> - Wait for the approval from the bank
>
> Note: Only ATM cards approved by the banks can be used to transact (Please see www.bancnetonline.com for more details)."

The printed system-generated Bancnet Reference Number and LBP-validated deposit slip shall be considered as proof of payment. All payment concerns may be coursed through **cashier@fda.gov.ph**.

E. Release of FDA Market Authorizations and Certificates

Results of applications and scanned copy of FDA market authorizations and certificates shall be sent to the registered email of the company's authorized representative. The schedule of pick-up or mailing of FDA market authorizations and certificates with printed copies shall resume once the ECQ is lifted. All inquiries and concerns on the release of FDA Market Authorizations and Certificates may be coursed through **records@fda.gov.ph**.

IV. EFFECTIVITY

This Circular shall take effect immediately. All other provisions of FDA Circular No. 2020-006 not affected by this issuance shall stand in effect.

ROLANDO ENRIQUE D. DOMINGO, MD.
Director General

Annex A. Additional Guidelines for CDRR Transactions and Applications

1. Automatic Extension of Validity

a. For clarity, the validity of the following authorizations/certifications issued by CDRR that expires from 1 March 2020 until 30 June 2020 shall be deemed automatically extended for four (4) months from the date of its expiry date:
   - CPR under Automatic Renewal Application
   - CPR under Regular Renewal Application
   - CPR under Monitored Release to Initial Applications
   - CPR under Compliance and/or Revalidation
   - Compliance for Foreign Good Manufacturing Practice (GMP) Certificate under Renewal Application
   - GLE Certificate

b. Manual submission of the aforementioned applications thru FDAC shall be temporarily suspended until further notice.

c. The extension of validity stamped at the back of CPRs shall not be done and not be applicable for the abovementioned applications.

2. E-mail Submission of Applications

a. For Applications with Scheduled Date of Submission

   i. The following applications shall require the schedule prior to submission following F.C. 2014-003 entitled "Filing and Receiving Registration, Licensing and Other Applications Using the Integrated Application Form":
      1. Initial Application (including Monitored Release) for CPR
      2. Initial Application for Certificate of Listing of Identical Drug Product (CLIDP)
      3. Major Variation and Minor Variation – Prior Approval
      4. Principal CPR Conversion Application
      5. Certificate of Pharmaceutical Product
      6. CFS
      7. Sales Promo Permit

   ii. The applicant shall submit the application through **fdac.pacd.cdrr@fda.gov.ph**.
      1. Before submission, the applicant must provide a Google Drive folder and upload the electronic copy of the documentary requirements in the respective Google Drive folder.

         Documentary submissions in the Google Drive Link must include the following:
         a. Documentary Requirements as listed in the Checklist of Requirements in PDF Format (do not zip or compress).
         b. Letter of Intent in PDF Format
         c. Integrated Application Form (IAF) in excel format
         d. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

2. The format of submission e-mail shall include the following information:

Email Subject:	Type of Application and 14-Digit Document Tracking Number
Email Body:	1. Type of Application 2. 14-Digit Document Tracking Number 3. Google Drive Link containing the documentary submissions

iii. The submitted applications shall be considered received by the FDAC once the applicant receives the acknowledgement receipt that will be sent via e-mail.
iv. Incomplete submission shall not be received.

b. Applications Without Scheduled Date of Submission

i. The following applications can be submitted through e-mail submission at fdac.letters.cdrr@fda.gov.ph:
   1. Initial application for Compliance to Foreign GMP Certificate (desktop evaluation)
   2. Animal Feeds Certificate

ii. Submissions must include the following:

Email Subject:	Type of Application
Email Body:	1. Documentary Requirements in **PDF format** as listed in the Checklist of Requirements. For large file sizes, a Google Drive Link containing the documentary requirements can be provided. 2. Letter of Intent in PDF Format 3. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

iii. The submitted applications shall be considered received by the FDAC once the applicant receives the acknowledgement receipt that will be sent via e-mail. A Document Tracking Number shall also be assigned to the application.
iv. Incomplete submission shall not be received.

c. Clinical Trial applications and Compassionate Special Permit (CSP)

i. The following applications can be submitted through e-mail submission at clinicalresearch@fda.gov.ph:
   1. Initial Clinical Trial (CT) and Import License (IL)
   2. Protocol Amendment
   3. IL Notification
   4. CT Notification
   5. Post Marketing Study Protocol
   6. CSP

ii. Submissions must include the following:

Email Subject:	Type of Application
Email Body:	1. Documentary Requirements in PDF or if necessary, WORD format. For large file sizes, a Google Drive Link containing the documentary requirements can be provided. 2. Letter of Intent in PDF Format 3. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip)

iii. The submitted applications shall be considered received by the FDAC once the applicant receives the acknowledgement receipt that will be sent via e-mail. A Document Tracking Number shall also be assigned to the application.

iv. Incomplete submission shall not be received.

d. Only one transaction/application per e-mail shall be made. Multiple transactions shall not be received.

e. Processing of received applications via e-mail can be done from Monday to Friday, 8:00 am to 5:00 pm. Applications received after 5:00 pm shall be processed on the next working day.

f. Acknowledgement receipt shall be emailed within three (3) working days after submission of the application. Any application may be denied for the following reasons:

i. The submission (documents or proof of payment) is incomplete;

ii. The submission was made outside of its schedule provided by the FDAC;

iii. The documents uploaded in the Google Drive Link are not downloadable or may be corrupt, or contain malicious files; or

iv. The application is not covered and/or is not eligible under this Circular for e-mail submission.

3. Interim Measures for CDRR Transactions and Applications

a. The use of e-signatures shall temporarily be allowed during the implementation of this Circular.

b. The requirement for notarized documents as prescribed in certain applications and transactions shall be temporarily suspended. In lieu of the notary, the applicant shall be required to submit a **self-declaration** to read as follows:

"I declare under the penalties of perjury that the herein submissions are true and correct to the best of my knowledge."

Annex B. Additional Guidelines for CDRRHR Transactions and Applications

1. **Notice of Deficiency**

   a. Notice of Deficiency (NOD) for Certificate of Product Registration (Initial/Renewal/Variation) of Medical Devices that will end on 23 March 2020 onwards shall be extended for one (1) month from the end of their compliance period.
   b. However, those with compliance documents may submit thru email the scanned copy of the documents at **fdac.pacd@fda.gov.ph**, following the Email Subject format:
   Email Subject: Compliance_CDRRHR_<Type of Application>_<Document Tracking Number>

2. **The following applications for the following devices related to Covid-19 are hereby accepted thru email:**

   a. Application for Special Certification for Covid-19 Test Kits shall be accepted thru email. Documentary requirements (scanned or in .pdf format) following FDA Memorandum No. 2020-006 issued on 12 March 2020 may be submitted to **fdac.letters@fda.gov.ph**. Applications with complete and correct requirements will be received for evaluation.

   b. Application for Covid-19-related hospital-based x-ray facilities and x-ray devices, such as:
      - Initial applications for hospital-based x-ray facilities using x-ray devices intended for use in the diagnosis of Covid-19 patients in need of immediate imaging procedures;
      - Applications for the issuance of Clearance for Customs Release (CFCR) of x-ray device used for medical applications for Covid-19

      i. The applicants may submit the scanned copy of their documentary requirements thru email together with the machine-validated Landbank OnColl Payment Slip as proof of payment to **cdrrhr.rrd@fda.gov.ph** or **cdrrhr@fda.gov.ph**.

      ii. Applicants shall follow the procedural guidelines for the payment of applications through the FDA payment portals. Refer to FDA Circular 2018-004 dated 06 March 2018.

      iii. Results of application to these authorizations shall be sent to the facility/establishment's email address.

Annex C. Guidelines for CSL Transactions and Applications

1. **Receiving of Food Export Certificate and Food Commodity Clearance**

   a. Submission of Food Export Certificate and Food Commodity Clearance by food manufacturers/traders/exporters shall be accommodated via online thru **csl@fda.gov.ph** as an alternative arrangement until such time that the ECQ has been lifted.

   b. Please be guided of the following instructions:

      i. All submissions shall have the required documents in scanned copies **(PDF),** e.g signed Application Form, CPR, LTO, Packing List/Sales Invoice and electronic copies e.g. database and draft templates as indicated on Page 2 of the Application Form.

      ii. Electronic submission shall be accepted only from **9:00am to 3:00pm** to give ample time for the processing of the Certificate/Clearance. Applications received after 3:00pm shall be deemed received on the next working day.

      iii. Once accepted after evaluation, a Reference Number will be issued for each application. The CSL will provide this Reference Number via email to the applicant company for releasing purposes.

      iv. Failure to submit the mandatory requirements cited above and submission of incorrect and misleading information shall be grounds for denial of the application.

2. **Releasing of Food Export Certificate and Food Commodity Clearance**

   a. The CSL will send the copy of the approved Food Export Certificate/Food Commodity Clearance in PDF file to the company applicant's email address. Hardcopy of the issued Food Export Certificate/Food Commodity Clearance will still be endorsed to FDAC Releasing Section.
      - This new arrangement shall subsist for the period 30 March - 14 April 2020 or until such time the ECQ has been lifted over Metro Manila.

3. **Lot Release Certification Application**

   a. Submission of Lot Release Certificate application will follow the normal submission procedure at FDA Central Office Lobby, CSL-RRU desk. However, schedule of acceptance will be changed to **Monday and Friday ONLY**, from **9:00am to 2:00pm** until such time that the ECQ has been lifted.

   b. All submission shall have a scanned copies (**PDF**) of all application dossier saved in flash drive or can be sent through email to **cslvbu@fda.gov.ph** after securing the payment at FDA Central Office Lobby, Cashier desk.

c. Additional Shipment, Compliance, Request for Amendments and other submission related to Lot Release Certification shall be accommodated via online. Pertinent documents must be scanned and send to **cslvbu@fda.gov.ph.**

d. Application for Additional Shipment with different packaging lot (e.g. from Lot No: 01AB to 01AC), submission of actual sample bearing the new packaging lot is required. Moreover, same submission schedule applies until such time that the ECQ has been lifted.

e. The CSL-VBU may send the copy of the approved Lot Release Certificate in PDF file to the company applicant's email address upon request. Hardcopy of the issued Lot Release Certificate will still be endorsed to FDAC Releasing Section.
   - This new arrangement shall subsist for the period 30 March - 14 April 2020 or until such time that the ECQ has been lifted.

4. Procedure for Online Application and Submission of Requirements for Batch Notification (BN)

a. Pre-Evaluation
   i. Download BN On-line Form (ECQ-COVID19) that was sent to you via **cslbn@fda,gov.ph**.
   ii. Accomplish batch notification application form completely and correctly filled out by the current company pharmacist and print in A4 size paper.
   iii. Notarize online BN application form and Prepare other required documents:
      1) Clear scanned copy of CPR and/or COV application
      2) Clear scanned copy of valid LTO of the:
         a) Manufacturer (if applicable)
         b) Wholesaler (if applicable)
         c) Trader
         d) Importer
      3) Clear scanned copy of valid COA of the finished product reflecting similar batch/lot number with sample submitted, batch size, theoretical and actual yield.
      4) For Imported products: clear scanned copy of commercial invoice and /or packing list reflecting the expiry date and batch/lot number of the product or any document to prove actual volume of importation; Airway bill/Bill of lading of the particular shipment.
   iv. Prepare a letter of commitment to the FDA CSL indicating that you will be submitting the unnotarized online BN application form and shall then follow the regular protocol as soon as the ECQ is lifted.
   v. Take a clear picture of the representative sample, its primary and secondary packaging where in the company name and address, CPR registration number, Batch/Lot No., manufacturing date and expiration date can be seen visibly.
   vi. Scan the notarized/unnotarized BN application form together with the other required documents, as well as the picture of the representative sample and its packaging.
   vii. Compress/zip or save in one folder all the scanned documents, together with the soft copy of the BN application form and rename with Generic Name_Batch/Lot Number.

viii. Upload file in Google Drive and share the folder's link, or attach file/s directly to your message and e-mail at **cslbn@fda.gov.ph**.

b. Evaluation
   i. Wait for confirmation email and payment details.
      1) If found acceptable, payment details will be provided; or
      2) If found unacceptable, you will be informed of the deficiency and unless rectified, the application will be frozen and/or cancelled.
   ii. Proceed to payment through Landbank Online Collection Scheme.
   iii. Send copy of the ONCOLL PAYMENT SLIP with signature over printed name and date.
   iv. Wait for the electronic copy of signed/approved BN application form. A unique password will be provided for you to access the said document.

c. Post-Submission
   i. Submit the hard copy of the APPROVED NOTARIZED BATCH NOTIFICATION APPLICATION ON-LINE FORM, with the company pharmacist's signature (Page 3 of BN Form) together with the required documents and the representative sample as soon as such time that the ECQ has been lifted.

NOTE: Failure to submit documents and samples within seven (7) working days after ECQ has been lifted will be penalized and/or will be subject for termination of the application and non-refundable payment. The company will not be allowed to proceed with their new applications unless post-submission requirements are settled.