Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 August 2020

FDA CIRCULAR
No. 2020-026

SUBJECT : **Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA)**

1. RATIONALE

Pursuant to DOH AO No. 2020-0015 known as "Guidelines on the Risk-Based Public Health Standards for COVID-19 Mitigation", the FDA has been strictly implementing minimum health standards and health safety protocols to prevent the transmission of COVID-19 and other infectious diseases.

The alarming increase in the number of infections due to COVID-19 poses a threat to the health and safety of employees and clients of FDA. With the recent developments and consultation with internal and external stakeholders, the following guidelines shall be enforced to safely continue serving our clients and to ensure the safety of everyone.

2. OBJECTIVE

The objective for the issuance of this Order is to provide clear and consistent guidelines for the safety of FDA employees and clients in order to prevent infection and the spread of COVID-19 and other infectious diseases at the FDAC.

3. SCOPE

This Order shall cover all FDA clients from the industries transacting business at the FDAC and FDA employees or staff providing regulatory services at the FDA.

4. GUIDELINES

4.1. GENERAL GUIDELINES

The FDA clients, employees and staff shall be guided with the following FDAC new operational guidelines in times of COVID-19 pandemic to provide quality, effective and efficient frontline delivery of service.

4.1.1. There shall be **no face to face interaction at FDAC. Only online transactions through email** shall be entertained.

4.1.2. There shall be limited FDA staff at the frontline counters in compliance with social distancing measures. The FDA staff shall wear face mask and face shield while on duty at FDAC.

4.1.3. The operating hours of FDAC shall be from nine (9) o'clock in the morning until four (4) o'clock in the afternoon during weekdays, Monday to Friday, except during non-working holidays.

4.1.4. Acknowledgment Receipt for every online transaction shall be emailed within two (2) working days upon receipt of the documents, including those with proof of payments, by the concerned FDAC or FDA employees or staff.

4.1.5. For inquiries and follow-ups, the clients may email directly to the following concerned FDA offices:

4.1.5.1.User Account, Schedule, e-Portal Issues - fdac@fda.gov.ph

4.1.5.2. Filing of Complaints – eReport@fda.gov.ph

4.1.5.3. Customer Feedback – customersatisfactionteam@fda.gov.ph

4.1.5.4. Cashier – cashier@fda.gov.ph

4.1.5.5. Records Section – records-releasing@fda.gov.ph

4.1.5.6. Center for Drugs Regulation and Research – cdrr.od@fda.gov.ph

4.1.5.7. Center for Food Regulation and Research – cfrr@fda.gov.ph

4.1.5.8. Center for Device Regulation, Radiation Health and Research – cdrrhr@fda.gov.ph

4.1.5.9. Center for Cosmetics Regulation and Research – ccrr@fda.gov.ph

4.1.5.10. Common Services Laboratory – csl@fda.gov.ph

4.1.6. The FDAC shall act on clients' inquiries within twenty-four (24) hours and follow-up on any referrals to the FDA Centers and other offices.

4.1.7. Payment of Fees. Over-the-counter payments shall no longer be available at FDAC. All payments shall conform with the current prescribed schedule of fees and all clients may avail of the following payment channels:

4.1.7.1. On-Coll payment through LBP branches using the On-Coll payment slip

4.1.7.2. Bancnet online, including LBP Bills payment

4.1.7.3. Online fund transfers to FDA Bank Account No. 0392-1030-58. Clients shall ensure that proof of successful fund transfer, such as confirmation/ transaction receipt, together with the copy of Order of Payment (OP) or DTN, shall be emailed to cashier@fda.gov.ph immediately to facilitate validation and posting of payment. Delay in providing the necessary information/ document will cause delay in validation of the funds transferred. The FDA cashier can only trace the details of payment from the client's email since LBP's bank statement does not include the name of depositor

and the reference number of what is being paid for. *[This channel is only a temporary measure until such time that other channels will be available.]*

4.1.8. Records Releasing.

4.1.8.1. Releasing of authorizations at FDAC shall be temporarily suspended until further notice/ announcement. Clients will be advised through email/ notified via e-portal by the respective Centers on the approval of such. The Administrative and Finance Service - Records Section shall send the hard copy of the approved authorizations to the registered mailing address of the Company as indicated in their application through courier.

4.1.8.2. For the Sales Promotion Permit, clients shall arrange for the delivery of their Permits through their preferred Courier Service Provider by sending a prepaid/ self-addressed envelope to the FDA Main Office Records Section through FDAC. The FDA Records Section shall mail the documents within three (3) days upon receipt of the prepaid envelope.

4.1.8.3. Requests made outside of NCR for Clearance to Hand-Carry/ Mailing of Health Products or to be brought or exported outside the Philippines intended for personal consumption shall be processed at the Regional Offices.

4.1.8.4. The status of mailing and/or printing of the Certificate can be tracked at https://www.fda.gov.ph/fda-kiosk/ or inquiry/follow-up through email may be sent to FDAC or to the concerned Regional Office.

4.2. SPECIFIC GUIDELINES

The following specific guidelines on the procedures and schedules of submission of applications shall be observed for the effective and efficient delivery of frontline service:

4.2.1. **CDRR Applications and Compliance Documents**

Applications under CDRR shall follow the prescribed schedule and mode of submission as indicated in **Annex-A: Schedule of Submissions Concerning CDRR.**

4.2.1.1. The number of applications received by FDAC will be **limited to ten (10) applications/company/day** regardless of application type.

4.2.1.2. The subject of the email shall follow the following format:

4.2.1.2.1. **For Registration Applications:**
[Application Type] Generic Name (Brand Name) Dosage Form and Strength.
E.g. [Initial – OTC] Paracetamol (Brand Name) 500 mg Tablet.

4.2.1.2.2. **For GMP Applications**
[Application Type] Manufacturing Site Name (Market Authorization Holder)

E.g. [Initial Foreign cGMP] ABC Manufacturing (MAH Name)
4.2.1.2.3. **For Clinical Trial and Related Applications [Application Type] Study Protocol Number/Subject Request**
E.g. [Compassionate Special Permit] Request for CSP for Patient (Patient Initials)

4.2.1.3. Procedural guidelines on the submission of product dossier

4.2.1.3.1. The applicant shall download and fill out the Integrated Application Form (IAF) at the FDA website as per FDA Circular No. 2014-003.

4.2.1.3.2. The client shall secure a schedule of appointment/ submission to FDAC.

4.2.1.3.3. The client shall submit the application dossier on the assigned scheduled date through email.

4.2.1.3.4. FDAC shall share the application to the pre-assessment team for appropriate action.

4.2.1.3.5. FDAC shall release the result of the pre-assessment within the given processing days upon receipt of the application.

4.2.1.3.6. An email shall be sent to the company and an update at the Doc Track System informing them of the result of the pre-assessment and instruction to proceed with payment. If the application did not satisfactorily pass the pre-assessment, the applicant will be advised to secure a new appointment schedule to submit the application for pre-assessment.

4.2.1.3.7. Upon payment, the applicant shall send the proof of payment to the FDAC. Upon receipt of the proof of payment, the application shall be endorsed to CDRR for evaluation.

4.2.1.3.8. Non-acceptable application will be immediately deleted in the FDA servers. Non-acceptable application shall be required to request for a new Document Tracking Number (DTN) and schedule of appointment. The use of old DTN shall not be allowed for resubmission of applications for pre-assessment.

4.2.1.3.9. Documents for submission should adhere to the following:

a. Each section of the dossier corresponding to a specific documentary requirement shall be properly labelled and bookmarked.
b. Each specific document identified in the checklist of requirements must be in separate PDF Files.
c. The name of the document/folder shall follow as indicated on the checklist of requirement.

d. The files should be saved in PDF format and readable even with 100x magnification.
e. Failure to follow the prescribed document submission format shall mean non-acceptance of the application.

4.2.1.4. An application shall be pre-assessed based on the following criteria:

4.2.1.4.1. Completeness

4.2.1.4.2. Correctness of information indicated on the Integrated Application Form

4.2.1.4.3. Applicable Fees and Charges

4.2.1.4.4. Compliance to the prescribed document submission format

4.2.1.5. An approved pre-assessment to an application does not signify that the application is considered as approved by this Office. The pre-assessment process is done to ensure a more expeditious action on the application or request.

4.2.1.6. The pre-assessment shall only be valid for three (3) months upon its issuance. Failure to pay within the given validity shall deem the pre-assessment as expired and would require another request for schedule for the appointment/submission of the application.

4.2.1.7. Email to fdac.pacd.cdrr@fda.gov.ph through file-sharing platforms.

4.2.1.7.1. Registration Applications – every Tuesday and Wednesday

4.2.1.7.2. Generic Labeling Exemption (GLE) – every Tuesday and Wednesday

4.2.1.7.3. Sales Promo Permit – every Friday

4.2.1.7.4. Compliance – any working day

4.2.1.7.5. Other Authorizations (e.g. Certificate of Pharmaceutical Product; Certificate of Free Sale) – any working day

4.2.1.8. Email to fdac.letters.cdrr@fda.gov.ph.

4.2.1.8.1. Minor Variation – Notification – every Tuesday and Wednesday only. Refer to **Annex – B: Receiving of CDRR Applications for Variation-Notification** and **Annex – C: Notification Form for Minor Variations of Registered Pharmaceutical Product**

4.2.1.8.2. Foreign cGMP Clearance – every Tuesday and Wednesday only

4.2.1.8.3. Local GMP Certificate – any working day

4.2.1.8.4. Reconstruction – every Tuesday and Wednesday

4.2.1.8.5. Animal Feeds Certification – any working day

4.2.1.8.6. Clinical Trial Applications – every Tuesday and Wednesday

4.2.1.8.7. Post Marketing Study Protocol – every Tuesday and Wednesday

4.2.1.8.9. Protocol Amendment – every Tuesday and Wednesday

4.2.1.9. Email directly to **clinicalresearch@fda.gov.ph.**

4.2.1.9.1. Compassionate Special Permit (CSP) – any working day

4.2.1.9.2. BOC Clearance – any working day

4.2.1.9.3. Clinical Trial Applications related to COVID-19

4.2.2. **CFRR Applications and Compliance Documents**

Refer to **Annex – E: Submissions Concerning CFRR**

4.2.2.1. Email to fdac.pacd@fda.gov.ph

4.2.2.1.1. Food Supplement Samples for submission – any working day

4.2.2.1.2Sales Promo Permit – every Friday

4.2.2.2. Email to fdac.letters@fda.gov.ph

4.2.2.2.1 BOC Clearance/Import Permit – any working day

4.2.2.2.2. HACCP Certificate – any working day

4.2.2.2.3. Sangkap Pinoy Seal – any working day

4.2.3. **CCRR Applications and Compliance Documents**

Refer to **Annex – F: Submissions Concerning CCRR**

4.2.3.1. Email to fdac.pacd@fda.gov.ph

4.2.3.1.1. Registration Applications for Household Urban Pesticides (HUP) – every Thursday from 9 a.m. to 12 noon only. All emails received after 12 noon shall be acted upon on the next working day.

4.2.3.1.2. Certificate of Free Sale (CFS) – any working day

4.2.3.1.3. Compliance – any working day

4.2.3.1.4. Sales Promo Permit – every Friday

4.2.3.2. Email to fdac.letters@fda.gov.ph

4.2.3.3. Local GMP – any working day
4.2.3.4. BOC Clearance for special cases – any working day

4.2.4. **CDRRHR Applications and Compliance Documents**

The CDRRHR email template below shall be strictly followed for a successful online submission. Refer to **Annex – G: Schedule of Submissions Concerning CDRRHR.**

SUBJECT: Type of Application – CDRRHR LRD/ RRD (for example: Compliance, Sales Promo Permit, COVID-19 Test Kits)
BODY OF EMAIL:
Name of Applicant: Last Name, First Name, Middle Initial
COMPANY NAME
LTO Number
DTN (when applicable)

4.2.4.1. For Medical Device, email the following to fdac.pacd@fda.gov.ph.

4.2.4.2. Certificate of Product Registration – Licensing and Registration Division (CPR-LRD) Compliance – any working day

4.2.4.3. Sales Promo Permit – every Friday

4.2.4.2. For Medical Device, email the following to fdac.letters@fda.gov.ph.

4.2.4.2.1. Certificate of Medical Device Listing (CMDL) – any working day

4.2.4.2.2. Applications related to COVID-19 (Test Kits, Clinical Thermometer, Sterile Surgical Gloves) – any working day

4.2.4.2.3. Compassionate Special Permit (CSP) – any working day

4.2.4.2.4. Certificate of Free Sale (CFS) – any working day

4.2.4.2.5. Notification of Sources (no payment required) – any working day

4.2.4.2.6. Application for Good Manufacturing Practice (GMP) – any working day

4.2.4.2.7. Renewal Applications for Medical Devices and In-vitro Diagnostic Devices (IVD)

a. Company names starting with numbers and letters A to M – every Thursday
b. Company names starting with letters N to Z – every Friday
c. Maximum of only five (5) applications per company
d. Multiple Certificates of Product Registration (CPR) should be applied as one (1) application. Failure to comply with this requirement shall result to the automatic disapproval of the applications done individually.

4.2.4.2.8. Renewal Applications for Water Purification Devices/ System and Equipment/ Devices Used to Treat Sharps, Pathological and Infectious Wastes – every Thursday

4.2.4.2.9. Variation Applications for Medical Devices and In-vitro Diagnostic Devices

a. Company names starting with numbers and letters A to M – every Thursday
b. Company names starting with letters N to Z – every Friday
c. Maximum of only two (2) applications per company

4.2.4.2.10. The Certificate of Medical Device Notification (CMDN) shall be applied through the e-portal.

4.2.4.2.11. The manual application for initial Certificate of Medical Device Registration (CMDR) of Classes B, C and D are suspended. Acceptance of application, except for COVID-19 related products, shall resume on 17 September 2020.

4.2.4.3. **Radiation Facility Application and Compliance Documents**

4.2.4.3.1. The acceptance of applications for Ionizing and Non-Ionizing Radiation Facilities shall be in accordance with Administrative Order No. 2020-0035 known as "Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations".

4.2.4.3.2. The following applications shall be emailed to cdrrhr.rrd@fda.gov.ph until such time that the e-portal at the FDA website intended for such purpose is fully operational. The emailed application and its attachments shall be in PDF file format with appropriate file name.

a. Application for the issuance of initial and renewal authorization of medical and non-medical radiation facilities for License to Operate (LTO), Certificate of Facility Registration (CFR),

Certificate of Compliance (COC) for hospital and non-hospital based x-ray facilities under the One-Stop Shop (OSS) Licensing System, Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI) facilities.

b. Clearance for Customs Release (CFCR) of radiation emitting devices
c. Application for issuance of authorization for hospital based x-ray facilities and "temporary treatment and monitoring facilities (TTMFs)" using mobile x-ray devices intended for use in the diagnosis of COVID-19 patients in need of medical imaging procedure.

4.2.5. **CSL Applications and Compliance Documents**

Refer to **Annex-H: Schedule of Submissions Concerning CSL**

4.2.5.1. Food Export Certificate and Food Commodity Clearance

4.2.5.2. Applications are accommodated online through csl@fda.gov.ph, from 8 a.m. to 2 p.m., Mondays to Fridays except holidays.

4.2.5.3. Applications received after 2 p.m. will be treated as submitted on the next working day.

4.2.5.4. Failure to submit the mandatory documentary requirements and submission of incorrect and misleading information shall be grounds for denial of the application. Once denied, applicant company shall submit new application together with the required documents.

4.2.5.2. Lot Release Certification (LRC)

4.2.5.2.1. Online pre-assessment of applications will only be accommodated through cslvbu@fda.gov.ph from Mondays to Fridays, 8 am to 3 pm. All submissions shall contain the documentary requirements for LRC in PDF format.
Note: *In lieu of the actual submission of the samples, pictures of the representative samples will be accepted. It shall contain primary and secondary packaging material bearing the applied lot, diluent and sterile needles, if applicable. Pictures must be colored and clear.*

4.2.5.2.2. All applications found acceptable during the pre-assessment shall be given 14-digit Document Tracking Number (DTN) for payment and tracking purposes. All online applications received after 3 p.m. will be pre-assessed on the next working day.

4.2.5.2.3. Clients with accepted online pre-assessed applications shall send an email to csl@fda.gov.ph with the subject: Lot Release

Initial Application_DTN Number (For example, Lot Release Initial Application_DTN20200814124567).

4.2.5.2.4. The following documents should be attached in order to process the application.

a. Excel copy of the application form
b. Scanned copy (in PDF format) proof of acceptance
c. Accomplished Assessment Slip
d. Official Receipt of machine-validated Landbank Oncoll Payment Slip

4.2.5.2.5. The CSL – Receiving and Releasing Unit (RRU) shall acknowledge receipt of the email and provides Lot Release Application Number for request with complete attachments.

4.2.5.2.6. Applications for Additional Shipment, Compliance, Amendment and other submissions related to LRC shall be forwarded to csl@fda.gov.ph copy furnished: cslvbu@fda.gov.ph with appropriate subject heading and the previously issued DTN.

a. Documentary requirements necessary for Additional Shipment and Amendment shall be incorporated in the online submission in PDF format. Incomplete documents shall not be accommodated.
b. Application for additional shipment with different packaging lot (e.g. from Lot No. 01AB to Lot No. 01AC) shall include pictures of representative samples in their submission.

4.2.5.2.7. Post submission of actual samples and notarized application form are required once community quarantine has been lifted.

4.2.5.3. Batch Notification (BN)

4.2.5.3.1. Online submissions through cslbn@fda.gov.ph will be accepted from 9AM to 2PM, any working day. Applications including proof of payments submitted beyond the given schedule will be processed on the next working day.

4.2.5.3.2. Post-submission of previous online applications may be submitted at the drop box provided at the main entrance of FDAC, any working day.

4.2.5.3.3. The on-site application of Batch Notification shall be temporarily suspended until further notice.

4.2.5.4. Acceptance of Request for Laboratory Analysis together with the samples maybe submitted via drop box at FDAC, any working day.

4.2.6. **Application for Certifications and Compliance Documents to the Regional Field Office (RFO)** – Refer to **Annex – I: Receiving of Applications for Certifications at RFO** and **Annex – J: Regional Field Office Contact Details**

4.2.6.1. Clients may email to fdac.pacd@fda.gov.ph upon the instruction of the RFO/inspector within their area of jurisdiction.

4.2.6.1.1. Corrective Action and Preventive Action (CAPA) Plan and corresponding objective evidences

4.2.6.2. Clients may email the following applications for Certification with its corresponding Letter of Intent and complete requirements to fdac.letters@fda.gov.ph upon the instruction of the RFO/inspector within their area of jurisdiction.

4.2.6.2.1. Hazard Analysis Critical Control Points (HACCP) Application

4.2.6.2.2. Sangkap Pinoy Seal Application

4.2.6.2.3. Foreign Drug Manufacturer Good Manufacturing Practice (GMP) Inspection Application

5. SEPARABILITY CLAUSE

The provisions of this Order are hereby declared to be separable. In the event that one or more of its provisions are held to be invalid, the validity of the other provisions shall not be affected thereby.

6. REPEALING CLAUSE

This Order repeals Section III. C. Electronic Filing of Applications for Certain FDA Certificates and Permits, Section III. D. Payment of Fees and Charges and Section III. E. Release of FDA Market Authorizations and Certificates of FDA Circular No. 2020-006-A known as "Amendment to FDA Circular No. 2020-006 Guidance for Applications and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration" dated 2 April 2020.

7. EFFECTIVITY

This policy shall be effective immediately.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX – A: SCHEDULE OF SUBMISSIONS SUBJECT TO PRE-ASSESSMENT CONCERNING CDRR

Submit Applications to the Following Email Addresses	To be Received DAILY (released within one working day)	To be Received on TUESDAYS and WEDNESDAYS (released within one working day)	To be Received on TUESDAYS and WEDNESDAYS (released after five working days)	To be Received on FRIDAYS (released within one working day)
clinicalresearch@fda.gov.ph	CSP			
	BOC Clearance (for registration samples, BE samples)			
	Clinical Trial Application for the treatment and vaccine of COVID-19			
fdac.pacd.cdrr@fda.gov.ph	CPP	PCPR / CLIDP	Initial	Sales Promo Permit
	CFS	Automatic Renewal	Monitored Release	
	DEU	GLE	Major Variation and Minor Variation – Prior Approval	
	Compliance		Regular Renewal	
fdac.letters.cdrr@fda.gov.ph	Local GMP Certificate	Minor Variation – Notifications	Foreign GMP Clearance	
	Animal Feeds Certificate	Reconstruction	Clinical Trial Application & CT Notification	
	Foreign Donations		CT – Import License, IL – Amendment, and IL – Notification	
	COE		Product Classification	
			Protocol Amendment	
			Post Marketing Study Protocol	

LEGEND:
BE – Bioequivalence; BOC – Bureau of Customs; COE – Certificate of Exemption; CFS – Certificate of Free Sale; CPP – Certificate of Pharmaceutical Product; CLIDP – Certificate of Listing of Identical Drug Product; CT – Clinical Trial; CSP – Compassionate Special Permit; CPR – Certificate of Product Registration; DEU – Drug for Emergency Use; GLE – Generic Labeling Exemption; GMP – Good Manufacturing Practice; IL – Import License; MR – Monitored Release; PCPR – Principal Certificate of Product Registration

ANNEX – B: RECEIVING OF CDRR APPLICATIONS FOR MINOR VARIATION – NOTIFICATION

All applications for Minor Variation – Notification (MiV-N) shall be processed as follows.

1. RECEIVING OF APPLICATIONS AT FDAC
   - 1.1 Applications shall be received by a Food and Drug Action Center (FDAC) Officer at the Letters Section of FDAC through email at fdac.letters.cdrr@fda.gov.ph every Tuesdays and Wednesdays, without need for prior appointment.
   - 1.2 Applicants shall have a maximum of ten (10) applications filed per MAH per day.
   - 1.3 Only up to three (3) variations to a specific product shall be submitted in a single application under a given DTN.
   - 1.4 Upon receipt of the application, the application shall be assigned with a Document Tracking Number (DTN) and will undergo pre-assessment process.
   - 1.5 If the application is acceptable, a pre-assessment slip shall be issued to the applicant, indicating to proceed to payment. All non-acceptable notification applications as per the pre-assessment shall not proceed to payment.
   - 1.6 Upon payment, the applicant shall send the copy of the Official Receipt to the FDAC through email.
   - 1.7 The application shall be endorsed to Center for Drug Regulation and Research (CDRR) for post-acknowledgement evaluation.

2 The following are the requirements that shall be submitted.
   - 2.1 Signed Integrated Application Form (IAF), Annexes 1 and 4, in both Portable Document Format (PDF) and Microsoft Excel (XLS/XLSX) format
   - 2.2 Copy of notarized Notification Form for Minor Variation (ANNEX – C)
   - 2.3 Copy of the Certificate Product Registration (CPR) and/or proof of renewal
   - 2.4 Copy of previously approved/acknowledged PACs (if not yet incorporated in the current CPR)
   - 2.5 Proof of payment, i.e. copy of official receipt (OR), Oncoll payment and/or Assessment Slip indicating the DTN
   - 2.6 For variations of Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval/acknowledgement (whenever applicable)
   - 2.7 Amended relevant section/s of the dossier following ACTD or national requirements (where applicable)
   - 2.8 Complete documentary requirements and pertinent evidence supporting the change/s based on the latest FDA issuance on variation guidelines

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

ANNEX- C:
NOTIFICATION FORM FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: _____

FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

DOCUMENT TRACKING NUMBER (DTN)	
TO BE FILLED OUT BY FDA	
Received by:	
Signature:	
Date:	
PAYMENT DETAILS	
Amount Paid:	
OR No.:	
OR Date Issued:	

Sir/Madam:

In accordance with Administrative Order No. 2013-0021 and related issuances, we wish to apply and notify FDA of our intention to make Minor Variation/s to our pharmaceutical product described below:

PRODUCT PARTICULARS
Details should be consistent with the current CPR/CLIDP.

Generic Name _____
Dosage Strength and Form _____
Brand Name _____
_____
Approved Shelf-life _____
Storage Condition _____
Packaging/Presentation _____

FDA Registration No. _____ **Validity** _____
Registration Status _____
State the validity or the DTN of the renewal application, if the CPR/CLIDP has not yet been renewed

COMPANY PARTICULARS
Details should be consistent with the current CPR/CLIDP. Complete name/s and address/es of the involved establishment/s should be reflected.

Manufacturer _____
_____
Trader _____
_____
Importer _____
_____
Distributor _____
_____
Packer/Repacker _____
_____

[redacted]
Received by:	

POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Variation** *For MiV-PH-N7, indicate the original variation code applied for the PCPR, e.g. MiV-PH-N7 (MaV-15)*

***** NOTHING FOLLOWS *****

Received by:	

DECLARATION

In support of our notification, I, the undersigned, hereby declare under oath that:

1. I am duly authorized to bind the establishment I represent pursuant to the authority attached to this Notification Form for Minor Variation/s of registered pharmaceutical product (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized).
2. On behalf of my company, the pharmaceutical product identified in the notification form meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product.
3. All conditions for the variations have been fulfilled and all required supporting documents are submitted.
4. The particulars given in this notification are true and all data and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.
5. I agree that the acknowledgement of this notification shall not preclude the Food and Drug Administration (FDA) in imposing appropriate regulatory actions in the event that there is/are outright negligence on the conditions for minor variation – notification and explicit misdeclaration of the applied changes as notification; lacking and deficient documentary requirements as stipulated in current Circulars on Post-Approval Changes; subsequent findings of misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified of fraudulently filed; and/or in case the samples of the identified pharmaceutical product collected through post marketing surveillance shall be found not to conform to the product's registered specifications or approved labeling.
6. The company I represent shall automatically cease and desist from further distributing the identified pharmaceutical product subject of revocation upon receipt of the notice of revocation and pending any administrative proceeding until further notice from FDA.
7. I, or my company undertake to:
   a) Ensure the identified pharmaceutical product's technical and safety information is made readily available to FDA anytime when requested, and to keep records of the distribution of the products for product recall purposes.
   b) Notify FDA of any adverse events consistent with the requirements of pharmacovigilance.
   c) Respond to and cooperate fully with Food-Drug Regulation Officers (FDROs) with regard to any subsequent post-marketing activity initiated by FDA.
   d) Exhaust the remaining stocks **of labeling materials and products** bearing the old product information up to a maximum of one (1) year from the date of receipt of the notification, at the manufacturing level.
   e) Submit a commercial sample of the first batch of manufacturing/importation/packaging/repackaging of the subject product, for all pack sizes, including the package insert or patient information leaflet (whichever is applicable) reflecting the notified change, as soon as available.
8. I understand that our company or establishment cannot place reliance on the acceptance of the notification by FDA in any legal proceedings concerning the above product, in the event that the identified product has failed to conform to any standards or specifications previously declared to FDA.
9. There is/are no other change/s made to/proposed for the drug product aside from what is/are specified in the Post-Approval Changes Particulars of this Notification Form.

Received by:	

HEAD OF REGULATORY OFFICE

Signature: _____
Name: _____
Designation: _____
Date: _____

COMPANY PHARMACIST

Signature: _____
Name: _____
Designation: _____
Date: _____

SUBSCRIBED AND SWORN TO BEFORE ME this personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.

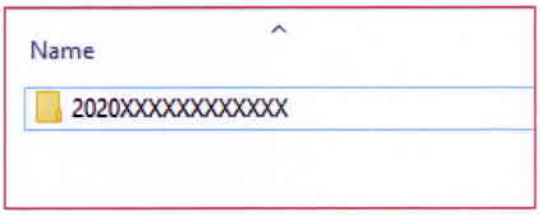
WITNESS MY HAND AND SEAL on the date and place first above written.

Doc No. _____
Page No. _____
Book No. _____
Series of _____

ANNEX – D:
PRESCRIBED DOCUMENT SUBMISSION FORMAT

Sample folder format for Initial Application for Generic Prescription Drug Product

1. Each application shall be submitted in one folder. The folder will be renamed to its assigned 14-Digit Document Tracking Number (DTN) upon endorsement to CDRR by the FDAC.



2. The contents of the application folder shall follow as per the posted list of requirements at the FDA Website (www.fda.gov.ph).

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF GENERIC PRESCRIPTION DRUG PRODUCTS

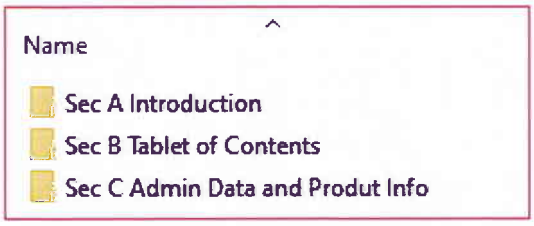
A. Initial Application

Part I: Administrative Data and Product Information
Sec. A Introduction
Sec. B Table of Contents
1. Integrated Application Form
2. Letter of Authorization (where applicable)
3. Certifications
4. Labeling
5. Product Information

Sec. C Guidance on the Administrative Data and Product Information
1. Application Form
2. Letter of Authorization (where applicable)
3. Certifications
For contract manufacturing:
a. License of pharmaceutical industries and contract manufacturer
b. Contract manufacturing agreement
c. GMP certificate of contract manufacturer
For manufacturing "under-license"
a. License of pharmaceutical industries
b. GMP certificate of the manufacturer
c. Copy of "under-license" agreement
For locally manufactured
a. License of pharmaceutical industries
b. GMP certificate (country specific)
For imported products
a. License of pharmaceutical industries/importer/wholesaler (country specific)
b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format
4. Labeling
5. Product Information
5.1. Package Insert

Subfolder of Initial Application

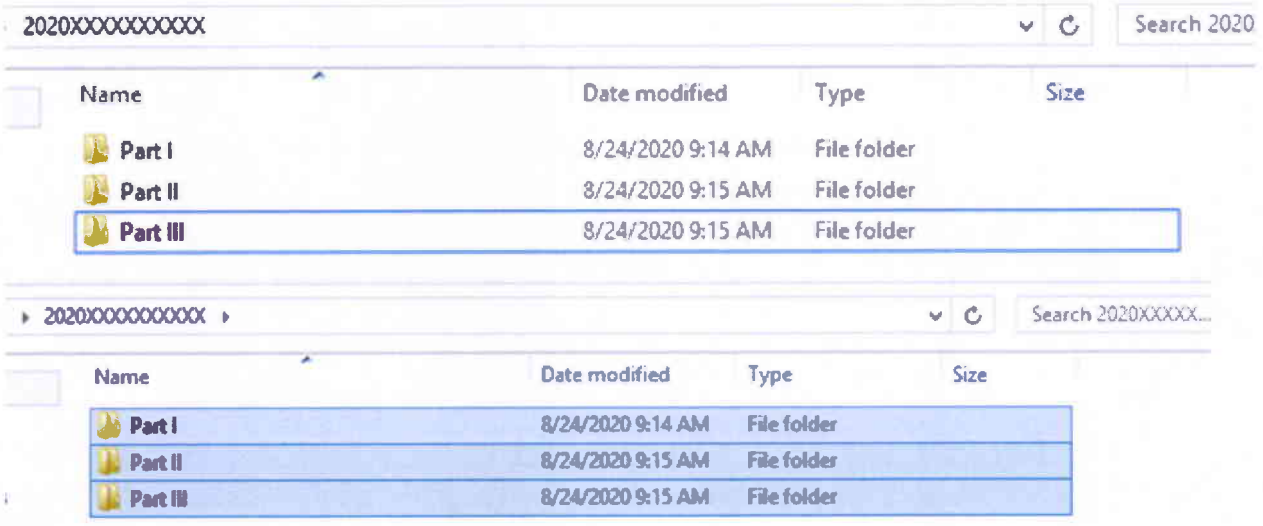
Subfolder of Part I



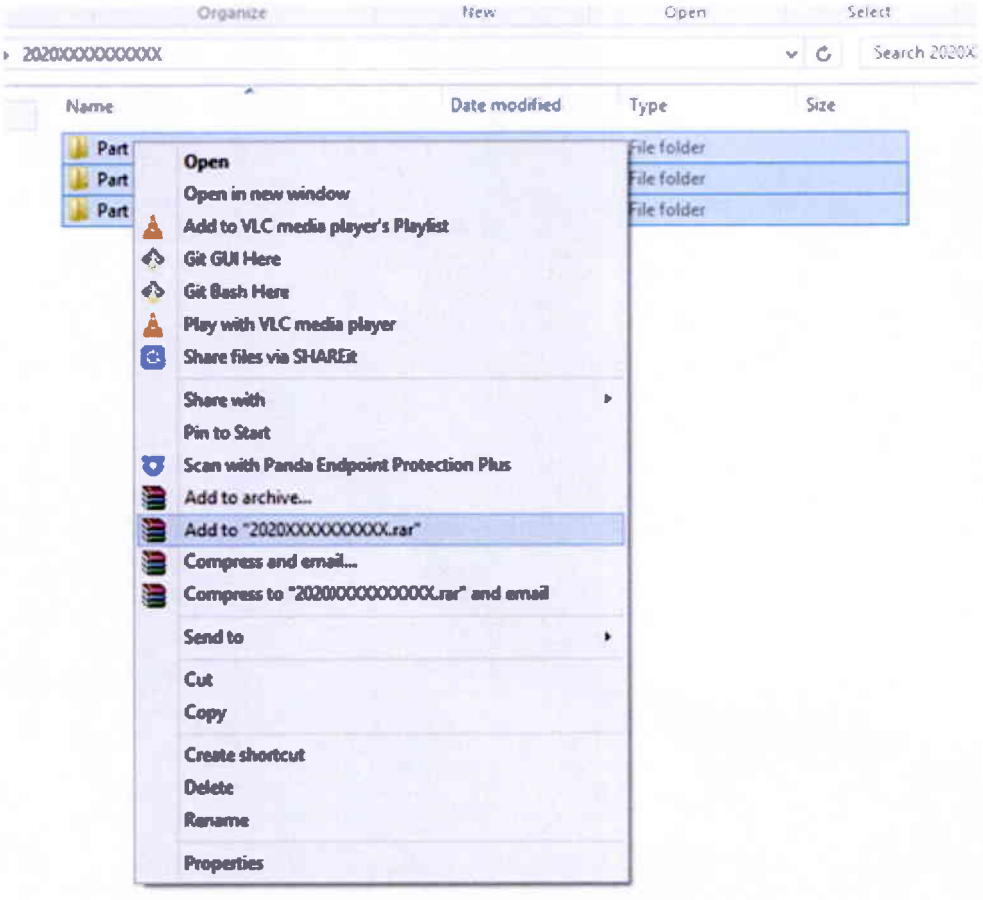
Subfolder of Section C Guidance on the Administrative Data and Product Information

3. All folders shall be compressed using the following application:

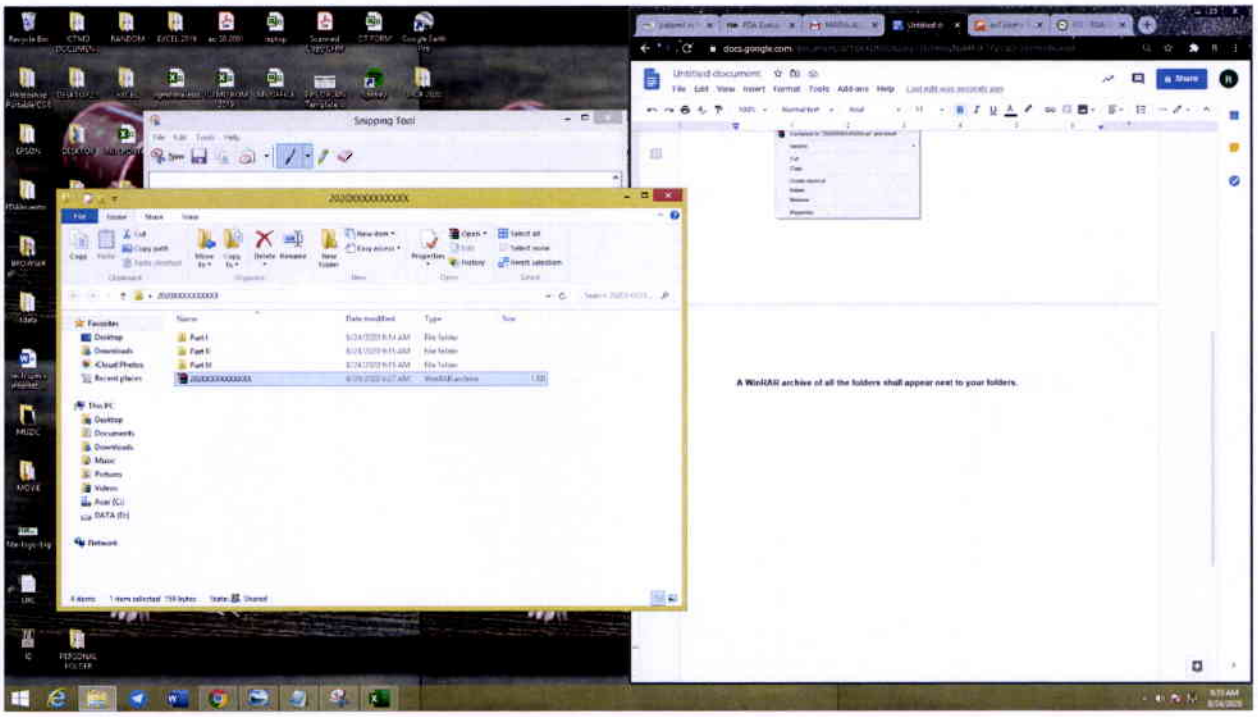
Highlight all folders and right click.



Click Add to "Folder Name ex: 2020XXXXXXXXX.rar"



A WinRAR archive of all the folders shall appear next to your folders.



ANNEX – E: Schedule of Submissions Concerning Center for Food Regulation and Research (CFRR)

Submit Applications to the Following Email Addresses	**To be Received DAILY (transmitted to CFRR within one working day)**	**To be Received on FRIDAYS (transmitted to CFRR within one working day)**
fdac.pacd@fda.gov.ph	Food Supplement Samples	Sales Promo Permit
fdac.letters@fda.gov.ph	BOC Clearance / Import Permit	
	HACCP Certificate	
	Sangkap Pinoy Seal	

LEGEND:
BOC – Bureau of Customs; HACCP – Hazard Analysis Critical Control Point

ANNEX – F: Schedule of Submissions Concerning Center for Cosmetics Regulation and Research (CCRR)

Submit Applications to the Following Email Addresses	**To be Received DAILY (transmitted to CCRR within one working day)**	**To be Received on THURSDAYS (transmitted to CCRR within one working day)**	**To be Received on FRIDAYS (transmitted to CCRR within one working day)**
fdac.pacd@fda.gov.ph	CFS	Registration Applications for HUP	Sales Promo Permit
	Compliance		
fdac.letters@fda.gov.ph	BOC Clearance		
	Local GMP		

LEGEND:
BOC – Bureau of Customs; CFS – Certificate of Free Sale; GMP – Good Manufacturing Practice;
HUP – Household Urban Pesticides

ANNEX – G: SCHEDULE OF SUBMISSIONS CONCERNING CDRRHR

To be Received on THURSDAYS	To be Received on FRIDAYS	To be Received DAILY
To be emailed to fdac.pacd@fda.gov.ph		
	Sales Promo Permit	CPR Compliance – NOD
To be emailed to fdac.letters@fda.gov.ph		
Renewal of Medical Devices and IVD: Company Names starting from A-M **Limit to 5 applications per company**	Renewal of Medical Devices and IVD: Company Names starting from N-Z	CMDL
Variation – Medical Devices and IVD: Company Names starting from A—M **Limit to 2 applications per company**	Variation – Medical Devices and IVD: Company Names starting from N-Z	Applications related to COVID-19
Renewal of Water Purification Devices/ System and Equipment/ Devices Used to Treat Sharps, Pathological and Infectious Wastes		CSP
		CFS
		GMP
		Through e-Portal: CMDN
To start on 17 September 2020 (A dedicated email address with flow chart for receiving of applications will follow in a separate issuance.)		
Initial applications of Medical Devices and IVD: Company Names starting from A-M (Issuance of DTN and Order of Payment. Documents shall be submitted through Google Drive) **Limit to 5 applications per company**	Initial applications of Medical Devices and IVD: Company Names starting from N-Z (Issuance of DTN and Order of Payment. Documents shall be submitted through Google Drive)	
	Initial application for Water Purification Devices/ System and Equipment/ Devices Used to Treat Sharps, Pathological and Infectious Wastes (Issuance of DTN and Order of Payment. Documents shall be submitted through Google Drive)	
For Radiation Facilities (to be emailed at cdrrhr.rrd@fda.gov.ph)		
		Initial and Renewal Application for LTO, CFR, COC, COR for MRI
		CFCR
		Hospital based x-ray facilities and "Temporary Treatment and Monitoring Facilities" (TTMFs) using mobile x-ray devices intended for use in the diagnosis of COVID-19 patients

Note: Incomplete submission based on the existing checklist shall result to outright disapproval.

LEGEND:

CFCR – Clearance for Customs Release; CFS – Certificate of Free Sale; CMDL – Certificate of Medical Device Listing; CMDN – Certificate of Medical Device Notification; CFR – Certificate of Facility Registration; COC – Certificate of Compliance; COR – Certificate of Registration; CPR – Certificate of Product Registration; CSP – Compassionate Special Permit; GMP – Good Manufacturing Practice; IVD – In-Vitro Diagnostic Device; LTO – License to Operate; MRI – Magnetic Resonance Imaging; NOD – Notice of Defici

ANNEX – H: SCHEDULE OF SUBMISSIONS CONCERNING CSL

To be Received on MONDAYS	To be Received on TUESDAYS	To be Received on WEDNESDAYS	To be Received on THURSDAYS	To be Received on FRIDAYS	To be Received DAILY
					Food Export Certificate and Food Commodity Clearance (Online)
					Request for Laboratory Analysis (Drop Box)
					Lot Release Certificate (Online)
					Batch Notification (Online)

NOTE: On-site Batch Notification has been suspended on 13 August 2020 until further notice.

ANNEX – I: Receiving of Applications for Certifications and Compliance Documents Concerning the Regional Field Office (RFO) Upon the Instruction of the Inspector Within Their Area of Jurisdiction

Submit Applications to the Following Email Addresses	To be Received on ANY WORKING DAY (transmitted to RFO within one working day)
fdac.pacd@fda.gov.ph	Corrective Action and Preventive Action (CAPA)
	One-Stop Shop (OSS) Hospital Licensing System
fdac.letters@fda.gov.ph	HACCP
	Sangkap Pinoy Seal Application
	Foreign GMP Inspection Application

LEGEND:
GMP – Good Manufacturing Practice; HACCP – Hazard Analysis Critical Control Point

ANNEX – J: REGIONAL FIELD OFFICE CONTACT DETAILS

FDA Regional Field Office	Email
1. RFO I	rfo1@fda.gov.ph
2. RFO II	rfo2@fda.gov.ph
3. RFO III	rfoiii@fda.gov.ph
4. RFO CAR	rfocar@fda.gov.ph
5. RFO NCR	rfoncr@fda.gov.ph
6. RFO IV-A	rfoiv-a@fda.gov.ph
7. RFO IV-B	rfoiv-b@fda.gov.ph
8. RFO V	rfov@fda.gov.ph
9. RFO VI	rfo6@fda.gov.ph
10. RFO VII	rfo7@fda.gov.ph
11. RFO VIII	rfoviii@fda.gov.ph
12. RFO IX	rfo9@fda.gov.ph
13. RFO X	rfo10@fda.gov.ph
14. RFO XI	rfo11@fda.gov.ph
15. RFO XII	rfo12@fda.gov.ph
16. RFO XIII	rfox13@fda.gov.ph

Regulatory Enforcement Unit	reu@fda.gov.ph
Foreign GMP Inspectorate	fieldgmp@fda.gov.ph
Office of the Deputy Director General for Field Regulatory Operations	oddgfroo@fda.gov.ph