Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Prescribing the Guidelines on Good Manufacturing Practice (GMP) for Drug Manufacturers repealing AO No. 2013-0022**

I. RATIONALE

Consistent with the constitutionally declared policy to protect and promote the right to health of the Filipino people, Republic Act No 3720, as amended, mandated the Department of Health (DOH), through the Food and Drug Administration (FDA) adopt measures to ensure pure, safe, efficacious and good quality pharmaceutical products in the country and to ensure their rational use. Republic Act No. 9711 further asserted the State's policy to adopt, support, establish, institutionalize, improve, and maintain structures, processes, mechanisms, and initiatives that are aimed, directed, and designed to ensure compliance with the above constitutional principle; and help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Accordingly, to enhance the State's regulatory capacity and strengthen its capability, through the DOH and FDA, with regard to the inspection, licensing, and monitoring of pharmaceutical establishments, Administrative Order (AO) No. 2013-0022, entitled "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers," was promulgated mandating foreign pharmaceutical manufacturers and their designated local importers and distributors of their responsibility in assuring strict compliance to the standards of Good Manufacturing Practices (GMP).

For further inclusivity and coherence in the FDA's regulatory system for pharmaceutical establishments and products, to address emerging concerns, and to be abreast with internationally acceptable standards in keeping with its vision, the FDA's relentless effort to enhance its regulatory capacity and strengthen its capability with regard to licensing, inspection, and monitoring of pharmaceutical establishments is in order. Hence, in addition to the foregoing and under the authority of Sections 3 (a) and (b), and Section 26 (a) of Republic Act No. 3720, as amended respectively by Sections 4 and 19 of Executive Order No. 175; and Section 7, Chapter 2, and Section 3, Chapter I, Title IX, Book IV of Executive Order No. 292, this Administrative Order is hereby issued.

II. OBJECTIVES

The purpose of this Order is to prescribe the regulations, requirements, and systems of evaluating, determining, and monitoring the suitability of GMP compliance of local and foreign pharmaceutical manufacturers.

III. SCOPE

These guidelines shall apply to all local and foreign pharmaceutical manufacturers, whether government or private, and their duly authorized distributor/importer.

Pharmaceutical traders shall not be covered under these rules but by the guideline/regulation on Good Distribution and Storage Practices.

IV. DEFINITION OF TERMS

A. **Applicant** refers to local pharmaceutical manufacturers and foreign pharmaceutical manufacturers through their licensed pharmaceutical distributors/importers securing Certificate of GMP Compliance.

B. **Category I –** In this category, the FDA may issue a Certificate of GMP Compliance based on the evaluation of the manufacturer's documentation and compliance with GMP regulations or based on the principle of reliance.

Reliance on assessments conducted by other National Regulatory Authorities (NRAs) refers to a regulatory strategy wherein the assessments and inspections performed by stringent NRAs and other regulatory bodies as the basis for the issuance of the clearance to a pharmaceutical manufacturer. This approach aims to streamline regulatory procedures, minimize redundancy in assessments, and promote international collaboration to uphold the quality and safety standards of the products produced by the manufacturers.

C. **Category II** – In this category, the Certificate of GMP Compliance is contingent upon conducting an onsite inspection of the manufacturer's facilities. This approach involves inspection to assess adherence to GMP. During the GMP inspection, various aspects such as, but not limited to, manufacturing processes, equipment, facilities, personnel, and quality control measures are scrutinized to ensure compliance with regulatory standards. The decision to grant a Certificate of GMP Compliance is made based on the findings from the onsite inspection, with clearance indicating that the manufacturer's operations meet the required GMP criteria. This method underscores the importance of direct observation and evaluation of manufacturing practices to uphold product quality and safety standards.

D. **Certificate of Good Manufacturing Practice (GMP) Compliance**, formerly known as GMP Clearance, refers to the certificate issued to pharmaceutical manufacturers after regulatory determination of their compliance with GMP standards.

E. **Corrective Action** refers to measure(s) taken by the establishments to eliminate the cause of a detected nonconformity or other undesirable situation.

F. **Deficiency** refers to a non-fulfillment of a GMP requirement that is classified as critical, major, or others as defined in international standards adopted by the FDA in accordance with its internal rules.

G. **Declaration and Undertaking** refers to a binding agreement of the applicant-establishment with the FDA in providing accurate information, affirming primary responsibility over the products and facilities, and complying with all the rules and regulations set forth during and after the application process, among others. Declaration of false, other forms of misrepresentation, or withholding of data or information are grounds for disapproval of the application, or suspension or revocation of the issued authorization and may subject the person involved to criminal prosecution.

H. **Desktop Assessment** refers to the detailed evaluation of the specified documentary evidence supplied by the applicants. It includes an assessment of reports of recent inspections of the manufacturer undertaken by a competent regulatory authority recognized by the FDA, together with other available regulatory information.

I. **GMP Inspection** refers to the assessment conducted within the establishments to determine the company's compliance with GMP standards. GMP inspection is sometimes referred to as a GMP audit. It may be through any of the following:
    a. **On-site Inspection** refers to the actual and physical inspection within the manufacturing facility to assess the establishment's conformity to GMP requirements and standards.
    b. **Remote Inspection** refers to distant assessment processes in certain conditions that prevent on-site inspection through interactive tools in communication and information technology and sharing of documents.
    c. **Hybrid Inspection** refers to a combination of on-site and remote inspection assessing GMP compliance of pharmaceutical manufacturers.

J. **Good Manufacturing Practice (GMP)** is the aspect of quality assurance that ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

K. **GMP Certificate** refers to the document issued by the NRA as evidence of GMP Compliance.

L. **Manufacturing Site** refers to the location/address where a manufacturing operation covering pharmaceutical product(s) is conducted in one or more buildings or structures in an area owned, leased, or controlled by a manufacturer.

M. **Pharmaceutical Manufacturer** refers to establishments engaged in any or all operations involved in the production of pharmaceutical products including the preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling, preparatory to their storage, sale, or distribution, except the compounding and filling of prescriptions in pharmaceutical outlets.

N. **Pharmaceutical Product** refers to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/ specialties, veterinary products, veterinary biologics, and veterinary medicinal products.

O. **Pharmaceutical Trader** refers to an establishment that is a registered owner of a pharmaceutical product, procures the raw materials and packing components, provides the production, monographs, quality control standards, and procedures, but subcontracts the manufacture of such a product to a licensed pharmaceutical manufacturer. In addition, a pharmaceutical trader may also engage in the distribution and/or marketing of its pharmaceutical products.

P. **Preventive Action** refers to measure(s) taken by the establishments to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Q. **Product line** refers to product category per dosage form in reference to the list of product line and dosage form attached as Annex A.

R. **Re-issuance of Certificate of GMP Compliance** refers to the issuance of a new certificate to a facility that has a previously issued certificate and includes automatic revocation of the previously issued Certificate of GMP Compliance.

S. **Risk Categorization on Establishment** is a classification system used to assess and categorize pharmaceutical manufacturers based on the complexity of the site, the processes involved in production, and the types of products manufactured. The classification can be low, medium, or high risk. (See Annex B)

In the case of more than one product line in a manufacturer with a different identified risk category, the highest risk shall prevail.

T. **Site Master File** refers to a document prepared by a manufacturer that provides specific, factual information about the production and control of manufacturing operations at a named site, as well as any closely integrated operations nearby buildings. (TGA Australia)

All other applicable terms not provided above but are defined under RA No. 3720 as amended EO No. 175 and RA No. 9711 and its implementing rules, and other applicable regulations are hereby adopted.

V. GENERAL GUIDELINES

A. All pharmaceutical manufacturers (whether local or foreign), their distributors and importers, whether public or private, shall be knowledgeable of, and comply with, the current good manufacturing practices, including specific requirements of the FDA-implemented laws relevant to their activities in the supply chain and the procedures adopted by the FDA. They shall adopt, apply, and be well-informed of codes and principles for good practices and be jointly responsible and accountable in ensuring the safety, efficacy, quality, and/or purity of pharmaceutical products they manufacture or distribute.

B. A Certificate of GMP Compliance is a requirement for the registration of the covered pharmaceutical product.

C. The Certificate of GMP Compliance shall be secured either through desktop assessment of the application or inspection (on-site, remote, or hybrid) of the manufacturer.

Assessment and/or inspection of local manufacturers shall take precedence especially if the pharmaceutical product(s) to be manufactured and locally distributed is/are essential, to address an emerging or re-emerging disease, or solely for export.

Least priority shall be accorded to those applications covering pharmaceutical products that have exceeded one hundred registration with FDA per formulation (in case of pharmaceutical products registered as Certificate of Listing of Identical Drug Products, each shall be counted separately), unless if it will be locally manufactured in which case the preceeding paragraph shall apply.

D. The application shall be filed following the existing system of the FDA for Certificate of GMP Compliance application.
    a. All documents submitted shall be in English. Otherwise, the application shall not be accepted and will be disapproved.
    b. The applicant shall ensure that any translated English version of the documentation provided to the FDA is clear and legible. Translation must be performed by a technically competent translator and accompanied by a signed and dated declaration that the translation is an accurate translation of the original document, otherwise, the translated English version shall be invalidated and the application shall not be accepted.

E. The application shall be per product line per manufacturing site and per distributor/importer.

F. A new Certificate of GMP Compliance application shall be submitted six (6) months prior to the validity date of the issued Certificate. Applications filed after the validity date of the Certificate of GMP Compliance shall be subject to surcharge as prescribed in the IRR of RA No. 9711 and FDA Circular No. 2011-004 on the computation of surcharge or penalty.

G. The pharmaceutical manufacturer and/or importer shall inform the FDA, through an application of either minor or major variation, as the case may be, of any changes that may have a direct or indirect impact on the quality and safety of the product or material introduced in the Philippine Market.

Furthermore, the pharmaceutical manufacturer and/or importer are/is responsible for the following:
    a. To inform the FDA promptly of any reports on the suspension or revocation of the Certificate of GMP Compliance by the NRA in the country of manufacture or any GMP issues in countries where the foreign pharmaceutical manufacturer is supplying.
    b. To report to the FDA any incident that reasonably indicates that their product introduced into the Philippines has:
        a. Caused or contributed to the death, serious illness, or serious injury to a consumer, a patient, or any person; or

b. Been banned, recalled, and/or withdrawn in the country of origin or in any other country where the same product was distributed.

c. Such other changes or circumstances that may have a direct or indirect impact on the quality and safety of the product or starting and packaging materials introduced in the Philippines.

H. In any of the above instances in the preceding paragraph, the following shall apply:

a. If the pharmaceutical product is declared by the FDA to be injurious, unsafe, or dangerous the concerned covered establishment shall immediately recall, withdraw, seize, and/or ban the manufacture, import, offer for sale, promotion, advertisement, sponsorship, sale, distribution, transfer, and/or donation to the public, or from further clinical trial study.

b. In case the pharmaceutical product has been banned or withdrawn for health and/or safety reasons in the country of origin or manufacture, the importer and distributor of the pharmaceutical product shall immediately undertake the necessary measures to ban its import, offer for sale, promotion, advertisement, sponsorship, sale, distribution, transfer, non-consumer use, or donation, and initiate its immediate recall, withdrawal, or seizure from the Philippine market.

I. The FDA reserves the right to require, schedule, conduct on-site GMP inspection, and collect samples at any time, and the manufacturer and/or importer allow inspection and collaborate with the FDA and its regulatory officers on action taken to avoid risks posed by the pharmaceutical product which they have manufactured, distributed, or sold in the Philippines.

J. All GMP-related non-compliance reports or product-related GMP issues, once verified and confirmed, shall trigger appropriate regulatory and legal action.

K. In case the cause of delay in the processing of applications is due to force majeure or fortuitous events, which result in damage or destruction of documents, and/or system failure of the computerized processing, the prescribed processing times shall be suspended, and appropriate adjustments shall be made, provided the same shall be made known to the affected applicants or stakeholders.

On the part of the applicant, any delay of compliance on grounds of force majeure or fortuitous events may be allowed unless fully supported by evidence subject to further evaluation and disposition by the FDA.

L. The foregoing general guidelines are non-exclusive 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

The following are the specific guidelines:

A. **Types of Application Pathways**

Certificate of GMP Compliance may be secured through the following types of regulatory action/schemes:

a. **Category I – Desktop Assessment**

   a. Applications falling under any of the following conditions shall be covered under this category:
      i. Manufacturers from a PIC/S member country with a valid Certificate of GMP compliance issued by an NRA listed as PIC/S participating authority;
      ii. Manufacturers from a non-PIC/S member country but inspected, and with a valid Certificate of GMP Compliance issued by an NRA listed as PIC/S participating authority;
      iii. Manufacturers from a country with an NRA listed under the ASEAN MRA on GMP with a valid certificate of GMP compliance;
      iv. Manufacturers from a non-ASEAN MRA on GMP but inspected, and with a valid Certificate of GMP Compliance issued by an NRA listed under the ASEAN MRA on GMP;
      v. Manufacturers with a valid pre-qualification certificate issued by WHO under its prequalification inspection program;
      vi. Manufacturers intending to register pharmaceutical products categorized as low risk with a valid Certificate of GMP Compliance issued by the local NRA (Refer to Annex B).
      vii. All minor variations (Refer to Annex C).

   b. This shall apply to subsequent importer/distributor with application involving the same pharmaceutical manufacturer, site, and product line that is covered by a valid certificate of GMP compliance.

   c. GMP applicants for desktop assessment shall be responsible as follows:
      i. Ensure that all required evidence documents are submitted together with the applications for GMP desktop assessment. Incomplete applications found during pre-assessment shall be disapproved;
      ii. Pay all application fees and, as far as applicable, surcharges at the time of lodging an application for GMP desktop assessment;
      iii. Submit applications for re-issuance of a Certificate for GMP compliance within six (6) months prior to the expiry of the current certificate; and
      iv. Collaborate with the FDA and its regulatory officers on action taken to avoid risks posed by the pharmaceutical product that they have manufactured, distributed, or sold in the local market.

   Notwithstanding the desktop assessment, the FDA shall not be precluded from pursuing subsequent inspection based on safety and/or quality issues of the covered products, subject to corresponding fees and charges.

b. **Category II – On-site Inspection**

   This category shall apply to local and foreign pharmaceutical manufacturers that do not qualify under Category I, and to pharmaceutical manufacturers with an

existing Certificate of GMP Compliance issued by the FDA that have a new/ additional product line that was not covered by the previously issued certificate of GMP compliance or final Closed Out Report.

B. **Documentary Requirements**

a. **Category I – Desktop Assessment**

a. Accomplished eApplication Form with Declaration and Undertaking
b. Site Master File as prescribed under PIC/S PE 008-04 and its future amendments
c. Contract Agreement between Manufacturer and Importer, and in case of toll manufacturer, agreement with the trader, including the list of covered specific products for commercial distribution
d. GMP Evidence (any)
   The GMP Evidence apostilled/authenticated by the issuing NRA Country shall be the following:
   i. Valid certificate of GMP compliance issued by any of the following:
      (1) The NRA in the PIC/S country of manufacture;
      (2) The NRA from a PIC/S Member Countries;
      (3) The NRA listed under ASEAN MRA on GMP;
      (4) The WHO through its prequalification inspection program

   ii. In case the NRA does not issue the respective documents identified above, an unredacted copy of the latest (within the last two [2] years) closed/final inspection report issued by the NRA of the manufacturing country.

   For the list of the countries or recognized NRA and other regulatory bodies refer to the respective website (i.e., PIC/S, ASEAN MRA, and WHO prequalified)
e. Proof of Payment - Pre-Assessment Fee and Application Fee
f. For variation, the following shall apply:
   i. Major Variation (Local and Foreign)
      (1) Transfer of manufacturing site, additional product line, and additional manufacturing operations:
         (i) Same requirements as above + pre-assessment and application fee equivalent to initial application.
   ii. Minor Variation (Foreign)
      (2) Change of business name (manufacturer and/or Importer), Zonal address, Qualified Personnel, Authorized Person for Batch Release
         (i) Certification on the applied change + Variation Fee

2. **Category II – On-site Inspection**

a. Accomplished eApplication Form with Declaration and Undertaking
b. Site Master File as prescribed under PIC/S PE 008-04 and its future amendments
c. Quality Manual

d. Contract Agreement between Manufacturer and Importer, including a list of specific products for supply in the Philippines
e. Latest Inspection Report issued by the local NRA covering the applied product line(s) for the specific production area of the manufacturing site and, if applicable, Closed-Out Report
f. GMP Evidence (any)
    i. A valid GMP Certificate issued by the NRA of the manufacturing country
    ii. A copy of the latest closed inspection report issued by the NRA of the manufacturing country
    iii. A valid GMP Certificate or other certificate issued by any designated certifying authority/body by the country of origin.
    iv. Certificate of Pharmaceutical Product (CoPP) or Certificate of Free Sale
g. Proof of Payment – Pre-Assessment Fee
h. For variation the following shall apply:
    i. Major Variation
        (1) Foreign relating to transfer of manufacturing site, additional product line, and additional manufacturing operations:
            (i) Same requirements as above + pre-assessment and application fee equivalent to initial application.
        (2) Local relating to transfer of manufacturing site
            (i) Transfer of manufacturing site:
                (a) Same requirements as above + pre-assessment and application fee equivalent to initial application.
            (ii) Additional product line and/or additional manufacturing operations and other major variations:
                (a) Payment fee shall be covered under the Licensing-Variation Application
    ii. Minor Variation shall apply as Category I Minor Variation.

These documentary requirements shall be submitted by the qualified person (QP) who represents the local manufacturer, or in case of foreign, the importer/distributor.

C. **Validity of Documentary Requirements**

1. No GMP Evidence with a validity of less than six (6) months shall be accepted, except when the pharmaceutical product locally produced or to be imported is intended to address the threat in times of declared epidemic or state of public health emergency.

2. For GMP Evidence without an expiration date, the reckoning date for purposes of determining the 3-year period and the 6-month requirement shall be the date of issuance or the date of the latest inspection report issued by the NRA covering the applied product line(s) for the specific production area of the manufacturing site and, if applicable, Closed-Out Report.

The previously submitted GMP evidence without an expiration date can no longer be used for purposes of application for re-issuance of GMP compliance. A new GMP evidence from the issuing NRA shall be provided.

D. **Filing of Application**

1. All covered establishments applying for initial, renewal, or variation shall submit their applications including the documentary requirements through the FDA eServices Portal System.

2. Filing of applications shall be the responsibility and accountability of the Qualified Personnel of the applicant.

3. Only one (1) official e-mail address of the establishment shall be used for online applications, communications, and/or compliances, as the case may be, and not inquiry-related. The official e-mail address used shall be unalterable and the FDA shall not be held liable in any way for loss or breach of access to the official e-mail.

   Any communication or compliance made outside of the official email address shall not be considered authorized and disregarded.

   The applicant, through its QP, shall formally inform the FDA of any change in the official e-mail address.

4. The applicant is expected to agree with the "Declaration and Undertaking" by clicking on the "I agree to the Declaration and Undertaking" tab in order to continue with the application.

5. Consultants, liaison officers, or freelancers who are not authorized as Qualified Personnel shall not be recognized by FDA for any application-related transaction.

6. The FDA eServices Portal System shall be accessible in accordance with the prevailing schedule of the FDA online systems.

7. The filed application through the FDA eServices Portal System shall be issued with the corresponding Order of Payment for the pre-assessment fee.

E. **Pre-Assessment**

1. Pre-assessment shall be conducted to determine the completeness of the requirements specific to each submitted application. Incomplete submissions shall be disapproved. No pre-assessment shall be conducted without proof of payment of the pre-assessment fee.

2. The receiving officer or employee shall perform a preliminary assessment of the application submitted with its supporting documents. The applicant shall receive any of the following results of pre-assessment through its official registered e-mail address:

a. Issued Order of Payment (Application Fee) with Reference Number indicating the fees to be paid; or

b. The lacking requirements in relation to the requirement prescribed in the Documentary Requirements of this AO specific to the type of application. The applicant shall be prompted to file a new application with complete documentary requirements.

3. In case of system failure due to force majeure or fortuitous event, other official modes of notification (i.e., registered mail or personal delivery) shall be resorted to.

4. A successfully pre-assessed application is not equivalent to an approved application. The evaluation of the correctness and sufficiency of the submitted documentary requirements and compliance with the operation or activity of the applicant establishments with reference to existing administrative and technical standards, rules, and regulations shall be conducted only during the evaluation and inspection steps.

F. **Payment of Fees**

1. **Pre-Assessment Fee**

a. Pre-assessment fee shall be paid upon the filing of the application.

b. After the successful filing of the application, an Order of Payment for the pre-assessment fee shall be issued.

c. The Order of Payment has a validity of ten (10) working days from the date of its issuance to the applicant.

Non-payment after the lapse of the validity period shall automatically cancel the application and invalidate the Order of Payment. The applicant shall be prompted to file a new application with complete documentary requirements and shall undergo pre-assessment process.

d. For applications with complete documentary requirements and posted payment, the FDA shall issue an Acknowledgement Receipt (AR). An application shall only be considered filed once the applicant receives the AR from the FDA.

e. Payment of the prescribed pre-assessment fee as indicated in the Order of Payment, exclusive of bank charges, if any, shall be done through the payment channels which can be accessed through the FDA eServices Portal System. Refer to Annex D of this Order for the FDA payment procedures.

2. **Application Fee**

a. For successfully pre-assessed applications, the pre-assessment fee paid shall be deducted from the total application fee due.

b. Payment of the prescribed application fee [including Legal Research Fund (based on the application and pre-assessment fees) and applicable surcharges] as indicated in the Order of Payment, exclusive of bank charges, for successfully pre-assessed application shall be done through the payment channels which can be accessed through the FDA eServices Portal System. Refer to Annex D.

c. The Order of Payment has a validity of 10 working days from the date of OP issuance or on the day of expiration of the Certificate of GMP Compliance, whichever comes first.

d. Non-payment after the lapse of the validity period shall automatically disapprove the application and forfeit the pre-assessment fee paid. The applicant shall be issued a notice of disapproval due to non-payment within the prescribed validity period of the Order of Payment. The disapproval is final. The applicant shall file a new application with complete documentary requirements and shall undergo the pre-assessment process.

e. All payments shall be paid through the prescribed FDA payment channels and are non-refundable and non-transferable.

f. Any of the following application payment made shall be automatically forfeited in favor of the FDA and a ground for disapproval of the application:
    i. Application payment made with an incorrect reference number provided;
    ii. Application payment made beyond the validity of the issued FDA Order of Payment;
    iii. Such other cases as determined by the FDA.

g. The FDA may issue further guidelines for matters involving payment.

G. **Desktop Assessment**

a. Upon receipt of the application, the evaluator shall conduct a detailed evaluation of the correctness and substance of the requirements supplied by the applicants. It includes an assessment of the GMP evidence together with other available regulatory information.

b. Evaluation shall be done within the timelines prescribed in the Citizen's Charter of the FDA.

c. Prior to the lapse of the initial processing period, the concerned office of the FDA shall notify the applicant through the official email address used for GMP applications. The applicant shall have a period of seven (7) calendar days within which to acknowledge receipt of the notice, otherwise, it is deemed received and conformed with.

d. The regulatory decision shall either be an approval or disapproval of applications as further provided under Item K of this section.

H. **On-Site Inspection Process**

1. Upon receipt of the application, the Field Regulatory Operation Office (FROO) shall commence the pre-inspection process, including the scheduling of the onsite inspection.

2. The applicant shall be notified of the confirmed date of inspection through an official Notice of Inspection from the FDA. The date of the inspection determined and provided by the FDA shall be final.

3. Any request for cancellation or rescheduling of the inspection shall forfeit any paid application fee and a new application shall be filed following the requirements and processes specified above, and payment of a new application fee.

4. In case of force majeure or fortuitous events, cancellation or rescheduling may be allowed provided it is fully supported by evidence subject to further evaluation and disposition by the FDA. If the cancellation or rescheduling is granted, all costs and expenses attendant to such cancellation or rescheduling shall be borne by the applicant.

5. Any favorable disposition, a rescheduled date will be determined by the FDA following paragraph b of this on-site process.

6. The FDA shall have the authority to enter, at reasonable hours, any covered establishments, including facility(ies), factory, warehouses used in FDA-regulated activities, or vehicle, in which pharmaceutical products are manufactured, processed, packed, or held, for introduction into domestic commerce, to conduct routine or spot check inspections of the premises and all pertinent equipment, finished or unfinished materials, containers, and labeling therein.

7. Whenever necessary, appropriate, and solely as evidence on the inspection conducted, take copies of documents related to the covered activity(ies) subject of inspection, or capture photographs, obtain voice or video recordings of documents or the premises and/or equipment subject to the rules on confidentiality.

8. In countries with security issues or emergency situations as confirmed and advised by the Department of Foreign Affairs (DFA) which will endanger the safety of the FDA inspectors, a virtual inspection will be conducted. Onsite inspection may be pursued as soon as the emergency situation ceases.

9. In case there is a need for a language interpreter, it shall be arranged by the applicant at its own cost. The interpreter must be knowledgeable in the technical aspects of manufacturing medicinal products. The statements made by the interpreter shall be considered official.

10. An inspection report shall be issued to the foreign and local pharmaceutical manufacturers after the GMP inspection.

11. For the foreign pharmaceutical manufacturer:
    a. In case of findings of critical deficiencies, the application will be disapproved. The applicant has to file a new application for the FDA to conduct another on-site inspection of the foreign pharmaceutical manufacturer.
    b. In case of multiple product line applications, only the product line(s) with critical finding/s shall be disapproved.
    c. In cases of findings of major and/or other deficiencies, a Corrective Action and Preventive Action (CAPA) Plan shall be submitted including objective evidence, as required, within the timeline prescribed by the FDA. Inspection is not mandatory to be conducted. Clarifications with the applicant to verify submitted evidence of compliance may be pursued.

12. For local pharmaceutical manufacturers:
    a. In cases of critical, major, and other deficiencies, a Corrective Action and Preventive Action (CAPA) Plan shall be submitted including objective evidence, as required, within the timeline prescribed by the FDA.
    b. Further, for local manufacturers with critical deficiencies appropriate regulatory tools shall be recommended by the inspection team.
    c. Should there be no deficiencies after the conduct of the on-site inspection, a Certificate of GMP Compliance shall be issued accordingly.

I. Schedule of Fees

Refer to Annex E for the schedule of fees.

J. Tracking of Application Status

The status of the application shall be checked and verified in the FDA-available online application platforms.

K. Regulatory Decision

A regulatory decision on the application may consist of the following:

1. Approval

a. Only applications that are compliant with all the requirements and/or standards and passed either through the desktop assessment (Category I) or GMP inspection process (Category II) shall be granted a Certificate of GMP Compliance with a validity period as provided under Item L of this section as the case may be.

b. A Certificate of GMP Compliance issued shall bear, at least, the following information:
    i. The name of the manufacturer and, if applicable, the importer;
    ii. The complete address of the manufacturing site;

iii. The date of issue and expiry of the document;
iv. The approved product line;
v. The approved steps of manufacture at the site; and
vi. Names of the following key personnel:
(1) Production Manager/Head
(2) Quality Assurance Manager/Head
(3) Quality Control Manager/Head
(4) Authorized Person for Batch Release

2. **Disapproval**

a. Any of the following or similar instances shall be a ground for the disapproval of an application for Certificate of GMP Compliance:
i. The correctness and substance of the specified documentary evidence supplied by the applicants and/or the inspection show that the manufacturer does not meet the requirements or appropriate standards.

In cases of findings requiring a CAPA, the non-submission of the required CAPA if any or non-implementation of the FDA-accepted CAPA within the approved timeline is deemed not meeting the requirements for appropriate standard;
ii. The applicant (manufacturer and or the distributor/importer) made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the applicable FDA-implemented laws, Rules and Regulations or appropriate standards;
iii. In case of re-issuance applications, the manufacturer and or the distributor/ importer has violated any of the terms and conditions of the Certificate of GMP Compliance, approved scope of activity, or product line;
iv. Other analogous grounds or causes, such as but not limited to:
(1) Failure to pay either the pre-assessment or application fee within the prescribed period;
(2) The applicant refuses entry of FDA inspection officers or access to pertinent records upon request, or caused fear, force, intimidation, threat, violence, before or during the conduct of inspection or immediately thereafter.
(3) The applicant or its officers connive with other establishments or the inspection or evaluation officer or other FDA officer related to findings during the conduct of evaluation or inspection, which may result in health product safety risks to the consumers.
(4) Findings of violation of any other laws that affects the regulatory compliance of the applicant.

b. Every disapproval of an application rendered by the FDA shall be fully explained in writing, stating the name of the person making the denial and the grounds upon which such denial is based.

c. The applicant shall be notified of the disapproval through the FDA available online application platforms used in applying for a Certificate of GMP

Compliance and the official e-mail address of the establishment on record at the FDA.

d. The applicant shall have a period of 3 calendar days within which to acknowledge receipt of the Notice of Disapproval otherwise it is deemed received.

e. The applicant may opt to request for administrative reconsideration of the disapproval by filing with the Office of the Director General of the FDA, copy furnished the concerned office, a formal request for reconsideration within fifteen (15) calendar days after receipt of a copy of the decision disapproving the application and paying the required reconsideration fees as provided in the current FDA's schedule of fees and charges. No extension for filing of the request for reconsideration shall be entertained.

f. No request for reconsideration shall be entertained unless the reconsideration fee is paid. The procedure on payment of application fee shall be followed as far as applicable.

g. The applicant shall point specifically the findings or conclusions stipulated in the Notice of Disapproval which are not supported by facts, rules or technical standards, otherwise the request for reconsideration shall be denied.

h. The FDA shall resolve the request for reconsideration within twenty (20) working days from receipt of the request for reconsideration and payment of the required reconsideration fees.

The FDA shall publish and make available for public inspection, subject to the procedure in place, all final decisions of approved or disapproved applications for Certificate of GMP Compliance, variations, including and as far as practical, those with CAPA, subject to the rules on Freedom of Information and Data Privacy.

L. Validity of the Certificate of GMP Compliance

1. Desktop Assessment

a. For desktop, the Certificate of GMP Compliance shall follow the remaining validity of the submitted GMP Evidence or equivalent documents but in no case shall exceed three (3) years.

b. For GMP Evidence without an expiration date, the reckoning date for purposes of determining the 3-year period shall be the date of issuance or the date of the latest inspection report issued by the NRA covering the applied product line(s) for the specific production area of the manufacturing site and, if applicable, Closed-Out Report.

2. Onsite Inspection

The Certificate of GMP Compliance shall be valid for a period based on the outcome of the risk assessment after GMP inspection**.** (Refer to Annex F)

M. **Variation of Certificate of GMP Compliance**

1. The manufacturer/distributor/importer shall notify the FDA in all cases of variations or changes incurred by the manufacturer under all product categories.

2. Only variation applications covered by a valid certificate of GMP compliance and submitted complete requirements including payment of fees shall be accepted.

3. For foreign manufacturing facilities under all product Categories, a certificate or document showing the approval of the NRA of the country of origin on the variation shall be attached to the application.

N. **Re-issuance of GMP Compliance**

1. The re-issuance application shall be filed within six (6) months prior to the expiry of the current Certificate of GMP Compliance. For this purpose, the following rules shall apply:
   a. If the applicant has made a timely and sufficient application within the six (6) months period with reference to its previously approved activity of a continuing nature, the existing certificate of GMP Compliance is deemed valid until the application has been finally determined by the FDA.

   b. If the applicant has filed beyond the expiry date of the current Certificate of GMP Compliance, the manufacturer is prohibited to produce, or in the case of foreign manufacturer, the importer is prohibited to import the covered pharmaceutical products until a new Certificate of GMP Compliance is issued.

   The application is regarded as an initial application and shall pay the corresponding initial fee and follow the process for initial applications. The previously FDA-issued Certificate of GMP Compliance shall not be accepted as GMP evidence.

2. Applicants shall submit the documentary requirements stated under Section VI.B. above depending on the category of application.

O. **Grounds for Suspension, Cancellation, or Revocation of the Issued Certificate of GMP Compliance**

1. No Certificate of GMP Compliance may be suspended, canceled, or revoked without notice and hearing except in cases of willful violation of FDA-implemented laws, rules, and regulations, or when public health or safety requires otherwise.

   In any of the instances in the preceding paragraph, the Certificate of GMP Compliance may be automatically suspended, canceled, or revoked and the establishment shall, within forty-eight (48) hours from receipt of the order suspending, canceling, or revoking the certificate without notice and hearing, show cause as to why the said order should not remain in force. Thereafter, if the establishment contests such order, the case shall ensue following the Uniform Rules of Procedures under Book III of the IRR of RA No. 9711 for purposes of

whether or not the explanation of the establishment will be sustained, or the initial regulatory action will be maintained, and further appropriate penalty shall be imposed.

2. In other instances above, any issued Certificate of GMP Compliance shall be suspended, canceled, or revoked, after notice and hearing, based on any of the following grounds:
    a. The correctness and substance of the specified documentary evidence supplied by the applicants, either during at the time of application, during the conduct of inspection, or subsequent thereto when requested by the FDA, show that the establishment (manufacturer) does not meet the required technical requirements or appropriate standards**.** Non-submission of the required CAPA if any or non-implementation of the FDA-accepted CAPA within the approved timeline is deemed not meeting the requirements for appropriate standards;
        i. The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the FDA-implemented laws, their IRR, or appropriate standards
        ii. The manufacturer and, in case of foreign manufacturer, including the importer or distributor, has violated any of the terms and conditions of its Certificate of GMP Compliance;
        iii. Other analogous grounds or causes, such as but not limited to:
            (1) Non-existence of the physical site at the declared address;
            (2) The applicant refuses entry of FDA inspection officers or access to pertinent records upon request, or caused fear, force, intimidation, threat, violence, before or during the conduct of inspection or immediately thereafter.
            (3) Findings that the manufacturer or in case of foreign including the importer or distributor, or their officers connive with other establishments or the inspection or evaluation officer or other FDA officer related to findings during the conduct of evaluation or inspection, which may result in health product safety risks to the consumers.
            (4) Findings of violation of any of the prohibited acts identified under Republic Act No. 3720, as amended by Executive Order No. 175 and Republic Act No. 9711 or other FDA-implemented laws, rules and regulations that affects the regulatory compliance of the applicant;
        iv. The suspension of the validity of the Certificate of GMP Compliance shall not exceed one (1) year.
        v. The Uniform Rules of Procedures under Book III of the IRR of RA No. 9711 shall apply unless a particular rules of procedure is provided by the other FDA-implemented laws.
        vi. Nothing in this section shall restrict the FDA in enforcing the other imposable penalties provided under the applicable FDA-implemented laws, rules, and regulations.

P. **Effect of CGMP Suspension, Cancellation, or Revocation**

1. Any suspended, canceled, or revoked CGMP shall have the effect of non-possession of a valid CGMP. Thus, the validity of any issued and existing

Certificate of Product Registration and License to Operate shall be automatically affected and any further manufacture, importation, distribution, wholesale of covered pharmaceutical products, and retail (in the case of drugs and devices) are deemed prohibited.

2. When the CGMP is canceled, either through an inspection verification or voluntarily, the FDA shall retain jurisdiction over violations committed by the establishments while it was in operation.

VII. TRANSITORY PROVISIONS

All pending applications received by the FDA prior to the effectivity of this issuance shall follow the procedures stipulated in AO 2013-0022 and its related issuances.

VIII. SEPARABILITY CLAUSE

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

IX. EFFECTIVITY

This Administrative Order shall take effect after fifteen (15 days) following its publication in a newspaper of general circulation and upon filing with the University of the Philippines of the National Administrative Register.

TEODORO J. HERBOSA, MD
Secretary of Health