Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

ADMINISTRATIVE ORDER
No. 2024-0013

SEP 20 2024

SUBJECT : General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use

I. BACKGROUND

Article II, Section 15, of the 1987 Constitution provides as a policy of the State to "protect and promote the right to health of the people and instill health consciousness among them". Additionally, Article XIII, Section 12 provides that the State shall establish and maintain an effective food and drug regulatory systems and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Towards this end, Republic Act (RA) No. 3720, otherwise known as "Food, Drug, and Cosmetics Act", as amended by Executive Order No. 175 series of 1987, and further amended by RA No. 9711 or the "Food and Drug Administration (FDA) Act of 2009" were enacted, mandating the FDA to regulate health products through the issuance of appropriate authorizations prior to the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, testing, promotion, advertisement, or sponsorship of any health product.

Administrative Order (AO) No. 67 s. 1989, titled "Revised Rules and Regulations on Registration of Pharmaceutical Products", was issued to provide comprehensive guidelines on the registration of pharmaceutical products with the FDA, consistent with RA No. 6675, otherwise known as the "Generics Act of 1988". However, with the fast-changing technologies and regulatory landscape in pharmaceutical regulations, there is a need to develop responsive policy guidelines for the authorization of pharmaceutical products, and active pharmaceutical ingredients (API). Also, institutionalizing regulatory reliance is necessary to avoid redundancy in regulation particularly products that are already authorized in other countries that passed the stringent regulatory review process. Other health legislations also incorporate timely access to pharmaceutical products and technologies.

Additionally, laws were issued to improve efficiency and adopt digitalization in government regulatory services, such as RA No. 8792 or the "Electronic Commerce Act of 2000" and RA No. 11032 or the *"Ease of Doing Business and Efficient Government Service Delivery Act of 2018"*.

Consistent with these laws, and in line with regional and global developments on regulatory harmonization, this Order is being issued to provide the revised rules and regulations on registration applications of pharmaceutical products and API applied for the FDA authorization, streamlining the covered registration processes, and establishing the general guidelines for different authorizations, application types, and registration pathways.

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II. OBJECTIVES

A. This Order aims to provide the general rules, regulations, and guidelines for the issuance of a Certificate of Product Registration (CPR) reflecting the FDA authorization granted for pharmaceutical products and APIs applied for registration for the following authorizations:

1. Marketing Authorization
2. DOH-Use-Only Authorization
3. Foreign Donation Authorization

B. Specifically, this Order shall provide the regulatory guidelines for the following:

1. Identification of registrable pharmaceutical products and APIs
2. Types of registration applications for pharmaceutical product and API authorizations
3. Regulatory review implemented by the FDA on applications and the applicable registration pathways
4. Regulatory decisions on the applications

III. SCOPE

This Order shall apply to all pharmaceutical products for human use and for which registration applications are submitted by eligible applicants as provided in Section V.A.1 of this Order to the FDA for the following authorizations:

A. Marketing Authorization

B. DOH-Use-Only Authorization

C. Foreign Donation Authorization

This Order shall also apply to APIs for human use intended for distribution and sale, and submitted to the FDA for Marketing Authorization. APIs manufactured or imported exclusively by the pharmaceutical product manufacturer for its production are not covered by this Order.

Furthermore, pharmaceutical products and APIs intended solely for export, are not covered by this Order.

IV. DEFINITION OF TERMS

All the terms or words, and phrases used herein that are already defined under RA No. 3720 as further amended by EO No. 175 and RA No. 9711, and other related FDA-implemented laws and their respective Implementing Rules and Regulations (IRRs), for the purpose of implementing this Order, shall have the same meaning as defined therein.

The following terms or words and phrases, as used in this Order, are defined or clarified to be understood as follows (*Annex A* provides additional definitions of a non-exclusive list of terms and phrases):

A. Active Pharmaceutical Ingredient (API) or drug substance refers to any substance or combination of substances intended to be used in the manufacture of a pharmaceutical product. Such substances are intended to furnish pharmacological activity or to otherwise have a direct effect in the diagnosis, cure, mitigation, treatment, or prevention

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of disease, or to have direct effect in restoring, correcting, or modifying physiological functions of the body.

B. **Applicant** refers to any private company or government institution that submits a registration application for a pharmaceutical product or API authorization, or a post-registration application for an update to, a variation to, or the renewal of an existing authorization.

C. **Authorization** refers to a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document. An FDA-authorized product refers to an FDA-registered product that has a valid or active FDA authorization.

D. **Authorization Holder** refers to the local company, government institution, or legal entity duly licensed by the FDA in whose name the authorization for a pharmaceutical product or API has been granted. Such holder is responsible for all aspects of the product, including safety, efficacy, quality and compliance with the conditions of the authorization.

E. **Certificate of Product Registration** (CPR) refers to the certificate issued by FDA for a pharmaceutical product or API that has been applied for and has successfully complied with the standards and requirements for FDA authorization. The type of authorization granted shall be indicated in the CPR.

F. **DOH-Use-Only Authorization** refers to the authorization granted by FDA to the Department of Health (DOH), allowing them to exclusively use a specific pharmaceutical product. Only pharmaceutical products with no valid marketing authorization, to be procured locally or internationally, and used by the DOH may be applied for this authorization. Pharmaceutical products with valid marketing authorization are not required to apply for this authorization since they are already deemed suitable for DOH use.

G. **Foreign Donation Authorization** refers to the authorization granted by FDA to allow the importation of finished pharmaceutical products to provide the actual expressed needs of target recipients based on approved distribution list endorsed by the DOH.

H. **Marketing Authorization** (MA) refers to the approval granted by FDA to a marketing authorization holder allowing a pharmaceutical product and API to be legally marketed in the Philippines after having undergone a process of evaluation to determine the safety, efficacy and quality of the product and the appropriateness of the product information.

I. **Pharmaceutical Products** refer to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/specialties. It is the finished dosage form that contains an API, generally, but not necessarily in association with other active or inactive ingredients.

J. **Registration** refers to the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. An FDA-registered product refers

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to a product that has been applied for and has successfully complied with the necessary requirements for FDA authorization.

V. GUIDELINES

A. General Conditions

1. Eligibility requirements
   a. For the marketing authorization:
      i. For the marketing authorization of locally manufactured pharmaceutical products and APIs, only applications from establishments with a valid License to Operate (LTO) as drug manufacturer or trader and a drug manufacturer Certificate of Good Manufacturing Practice (GMP) Compliance from FDA are acceptable.
      ii. For the marketing authorization of imported pharmaceutical products and APIs, only applications from establishments with a valid LTO as a drug distributor/importer and a Certificate of GMP Compliance of the Foreign Drug Manufacturer issued by FDA are eligible.
      iii. For the marketing authorization of identical pharmaceutical products, only applications for generic pharmaceutical products with principal pharmaceutical products from establishments with a valid LTO as a drug manufacturer, trader, or distributor (importer/exporter/wholesaler) are eligible.
   b. For DOH-use-only authorization, only applications for pharmaceutical products submitted by the DOH shall be eligible and authorized for their exclusive use.
   c. For pharmaceutical products donated by foreign entities, applications shall be eligible if they meet the following conditions:
      i. with endorsement from the DOH;
      ii. from individuals, organizations, institutions, both public and private, and all levels of government engaged in the importation, facilitation, and management of all regular donations of foreign origin covering pharmaceutical products; and
      iii. for use during non-emergency situations.

      For pharmaceutical products used in times of emergencies and disasters, AO No. 2023-0001 titled, "Guidelines on the Acceptance, Processing, and Distribution of Foreign and Local Donations During Emergency and Disaster Situations", or any amendment or latest issuance thereafter, and/or other relevant existing guidelines shall apply.
2. For pharmaceutical products, the registration application for the marketing authorization, DOH-use-only authorization, or foreign donation authorization of pharmaceutical products entails seeking FDA authorization to allow the use of a finished pharmaceutical product by patients or healthcare providers in the Philippines.

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Through the approval of the application, the FDA signifies that the pharmaceutical product is safe, efficacious, and of good quality when manufactured according to approved specifications and used as intended.

3. For API, the registration application for the marketing authorization for APIs entails seeking FDA authorization to allow the marketing of the API as a raw material to pharmaceutical manufacturing companies. Through the approval of the application, it is ensured that the API, when manufactured according to approved specifications, is of good quality for use in the manufacture of pharmaceutical products. Authorization is not required in the manufacture and importation of APIs for the manufacturer's use in the production of its pharmaceutical products covered by a separate authorization prior to sale.

4. Pharmaceutical products and APIs authorized by FDA for local use are also authorized for export, subject to the importing country's regulations authorizing local use implemented by their national drug regulatory authority (NDRA), and authorized FDA-licensed activity for exportation.

5. For pharmaceutical products and APIs found in recognized pharmacopeias (*Annex B*), the specifications outlined in the relevant pharmacopeia shall be adhered to as one of the bases for the assessment of the pharmaceutical product or API. For innovator pharmaceutical products and APIs not yet listed in any pharmacopeia, or when setting in-house specifications that differ from those in a recognized pharmacopeia, applicants must submit validated specifications along with justifications backed by comprehensive scientific data.

6. When applying for the registration of a pharmaceutical product or API, the applicant must ensure that all information contained in the application is true, correct and is not misleading.

   It shall be the responsibility of the applicant to inform the FDA and any other concerned government agency of any emerging information that may affect the risk-benefit assessment of the pharmaceutical product or API as soon as the applicant becomes aware of such information. Failure to fully disclose material information about the pharmaceutical product or API is a ground for disapproval of registration application and/or a basis for cancellation of the establishment's LTO as provided in Book II, Article 1, Sec. 4-A of the Implementing Rules and Regulations (IRR) of RA 9711.

7. Upon the approval of pharmaceutical products applied through New Pharmaceutical Product Application (NPPA) or New Biological Pharmaceutical Product Application (NBPPA), the authorization holder shall submit a reference standard to FDA, upon request. The reference standard must be of sufficient purity, stability, and quantity to support the development and validation of analytical methods and the assessment of the quality of pharmaceutical products by the FDA.

8. Upon the approval of pharmaceutical products applied through Identical Pharmaceutical Product Application (IPPA)-1, the pharmaceutical product shall have an independent marketing authorization as a generic pharmaceutical product.

   Upon the approval of pharmaceutical products applied through IPPA-2, the marketing authorization of the identical pharmaceutical product shall remain dependent on the authorization of the principal, i.e., any post-approval changes to

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the principal pharmaceutical product must be applied by the authorization holder of the identical pharmaceutical product to FDA to maintain its validity.

9. For the standards of the pharmaceutical product and API authorizations, the application requirements and the evaluation procedures shall be established and updated for all covered pharmaceutical products and APIs through appropriate FDA issuances.

10. The Annexes of this Order may be subject to amendment, modification, revision, or supplement by the FDA, through the proper FDA issuance, subject to its internal rules on policy development and coordination with the DOH.

B. Types of applications

1. Authorization applications

   a. Marketing Authorization

      i. New pharmaceutical product application (NPPA) / New biological pharmaceutical product application (NBPPA)

         (1) NPPA/NBPPA-1: For the first strength of a product containing a new chemical or biological entity. This means the entity is currently not registered in the country or with any reference drug regulatory authority (RDRA).

         (2) NPPA/NBPPA-2: For the first strength of a product containing:

            (a) New fixed-dose combination of registered chemical or biological entities. This means the fixed-dose combination is currently not registered in the country or with any RDRA.

            (b) Registered chemical or biological entities with any of the following conditions or changes not previously approved for any reference pharmaceutical product and do not fall under post-approval changes/variations:

               (i) in new dosage forms, such as tablets, capsules, and injectables;

               (ii) in new presentation, such as single-dose vials and pre-filled syringes;

               (iii) in new formulation, such as preservative-free;

               (iv) for use by a new route of administration; and

               (v) for a new indication, dosage recommendation, or patient population.

            (c) For products that do not fall under NPPA/NBPPA-1, NPPA/NBPPA-3, or generic pharmaceutical product application (GPPA).

         (3) NPPA/NBPPA-3: For subsequent strengths of a product that has been registered through an NPPA/NBPPA-1 or NPPA/NBPPA-2. The product name, dosage form, presentation, indication, dosing regimen, and patient population should be the same as that for the NPPA/NBPPA-1 or NPPA/NBPPA-2 submission.

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ii. Biosimilar product application: Biosimilar products are required to be submitted via NBPPA-2 or NBPPA-3.

(1) NBPPA-2: For the first strength of a biosimilar product with the same dosage form and route of administration as the reference biological pharmaceutical product.

(2) NBPPA-3: For subsequent strengths of a biosimilar product that has been registered through an NBPPA-2. The product name, dosage form, indication, dosing regimen, and patient population should be the same as that for the NBPPA-2 submission.

iii. Generic pharmaceutical product application (GPPA)

(1) A pharmaceutical product shall undergo GPPA provided that:

(a) it has the same dosage strength and form, route of administration, and conditions of use (e.g., indication, dosing regimen, and patient group) as the reference pharmaceutical product, and

(b) it exhibits interchangeability with a reference pharmaceutical product.

iv. Identical pharmaceutical product application (IPPA)

(1) In order to streamline the processing of registration applications for marketing authorization of pharmaceutical products which are identical to those with valid FDA marketing authorization based on the identity of the manufacturer and of the drug formulation, such products may be applied for IPPA and shall undergo the identical pharmaceutical product review.

(a) IPPA-1, Independent identical pharmaceutical product application: For a pharmaceutical product to be applied for an independent marketing authorization. While the registration review pathway makes use of reliance on the previous assessment conducted on the principal pharmaceutical product, once approved, FDA shall issue an independent CPR reflecting the product's marketing authorization.

(b) IPPA-2, Principal-dependent identical pharmaceutical product application: For a pharmaceutical product to be applied for marketing authorization that is dependent on the marketing authorization of the principal pharmaceutical product. The registration review procedure makes use of reliance on the previous assessment conducted on the principal pharmaceutical product. Once approved, the FDA shall issue a CPR reflecting the product's marketing authorization as an identical pharmaceutical product.

v. Active Pharmaceutical Ingredient (API) Application

(1) APIs applied for registration shall be issued the appropriate FDA authorization specific for use in the manufacture of pharmaceutical products.

(2) It is important to note that this does not apply to precursors, which are intermediate chemical compounds used in the synthesis of an API.

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b. DOH-Use-Only Authorization

Only pharmaceutical products with no valid marketing authorization, to be procured locally or internationally and used by the DOH, may be applied for DOH-use-only authorization. All pharmaceutical products applied for DOH-use-only authorization shall undergo a review process similar to Marketing Authorization (refer to Section V.B.1.a).

c. Foreign Donation Authorization

i. All donations shall adhere to the core principles reflected in the World Health Organization (WHO) Guidelines on Medicine Donations, namely:

(1) maximum benefit to the recipient,

(2) respect for the wishes and authority of the recipient,

(3) no double standards in quality, and

(4) effective communication between donor and recipients

ii. Foreign donations comprising pharmaceutical products shall be accepted if these conform with the following acceptance criteria:

(1) Must have a counterpart product with a marketing or DOH-use-only authorization;

(2) Must not be classified under experimental/investigational pharmaceutical product registration of FDA;

(3) Must not be a dangerous drug listed in the schedules annexed to RA No. 9165, otherwise known as "Comprehensive Dangerous Drugs Act of 2002" or its amendments; and

(4) Must have a shelf-life of at least twelve (12) months at the expected date of arrival.

iii. Due consideration to the following instances may be given by the FDA in the issuance of the authorization, subject to the approval of the Secretary of Health:

(1) Pharmaceutical products not listed in the current edition of the Philippine National Formulary but duly registered in other countries, and needed for treatment by a patient;

(2) Pharmaceutical products which have valid FDA authorization but are not available, or without any available drug substitute, and specifically requested and justified by the recipient;

(3) Orphan drugs;

(4) Other critically needed drugs, including dangerous drugs, as justified; and

(5) Pharmaceutical products with a shelf-life less than twelve (12) months, provided that:

(a) an undertaking under oath from the recipient of the donation, that the pharmaceutical product shall be consumed before the expiry date and the DOH/FDA shall not be held liable for any adverse events that may occur, shall be submitted; and

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(b) must satisfy at least one of the following conditions:

(i) The product has a total shelf life of less than 2 years AND has a remaining at least one-third (1/3) of its shelf-life at the expected date of arrival which in no case shall be less than six (6) months; or

(ii) Must be recommended as suitable for distribution as per case assessment by the DOH Technical Working Group on Foreign Donations and approved by the Secretary of Health despite the limited product shelf-life remaining.

2. Post-Authorization Applications

a. Post-Approval Change (PAC) Application

i. Changes to a pharmaceutical product or API throughout the validity of its authorization must be submitted to FDA through PAC application. These include administrative/editorial, quality, and clinical/non-clinical changes, and are categorized as follows:

(1) Major Variation (MaV) – Variation to a registered pharmaceutical product or API that may affect significantly and/or directly the aspects of safety, efficacy, and quality and it does not fall within the definition of minor variation and new registration.

(2) Minor Variation (MiV) – Variation to a registered pharmaceutical product in terms of administrative data and/or changes with minimal/no significant impact on the aspects of safety, efficacy, and quality. There are two types of minor variations:

(a) MiV-Notification (MiV-N or Do & Tell) – If the notification fulfills the requirements (conditions and supporting documents) for MiV-N, the FDA shall acknowledge receipt of a valid notification. The MAH may already implement the change even before notifying the FDA, up to a maximum of one year.

(b) MiV-Prior Approval (MiV-PA or Tell & Do) – If the application fulfills the requirements (conditions and supporting documents) for MiV-PA, the FDA shall issue an approval for the proposed change. Thereafter, the MAH shall implement the change after receiving the approval of the FDA.

ii. No PAC application shall be filed together with the registration application for renewal of authorization of a pharmaceutical product or API.

iii. The submission and processing of applications, including the bundling of PAC applications into a single submission (for instance, when the same post-approval change affects multiple products or a principal pharmaceutical product and its principal-dependent identical pharmaceutical products, multiple/simultaneous/ consequential post-approval changes affect a single product, or other similar cases wherein PAC applications may be combined), shall follow the current implemented guidelines as laid out in the FDA Citizen's Charter.

b. Registration Application for the Renewal of Authorization

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i. A pharmaceutical product or API with a valid authorization applied for renewal before the expiration of the CPR validity shall be eligible for automatic renewal.

ii. A pharmaceutical product or API with a lapsed authorization may be applied for renewal of authorization within one hundred twenty (120) calendar days from the expiration of the CPR validity with a surcharge or penalty equivalent to twice the renewal registration fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application. For applications for renewal filed within one hundred twenty (120) days from its original expiry the CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal. Beyond this period, and to ensure adherence to current standards and regulations that impact the product's safety, efficacy, and quality, the pharmaceutical product or API shall be considered not eligible for the renewal registration application and shall be required to undergo a new registration application for authorization if sought again for the product.

iii. No registration application for renewal of authorization shall be filed together with a PAC application. Separate application(s) shall be submitted for all changes to the pharmaceutical product or API registration.

c. Notification for the Cancellation of Authorization

The authorization holder shall submit a notification for cancellation of a pharmaceutical product or API authorization voluntarily anytime during its validity stating the reason for cancellation and the latest distribution following the procedures, requirements, and schedule prescribed in the covering implementing guidelines as laid out in the FDA's Citizen's Charter pursuant to this Order.

C. Product Categories

1. Product Types

The types of pharmaceutical products and APIs covered in this guideline are as follows:

a. Chemical drug
b. Biological drug
c. Radiopharmaceutical
d. Homeopathic drug
e. Medical gas
f. Herbal medicine
g. Traditional Medicine
h. Orphan drug

In view of the foregoing enumeration, the FDA is not precluded from determining the inclusion of all other types of pharmaceutical products and APIs as it may deem necessary.

2. Pharmaceutical Product Classification

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a. In general, all products are classified according to the safety of the API and the finished pharmaceutical product and how it may be accessed by patients/consumers in the market. Pharmaceutical products may be classified as prescription pharmaceutical products or non-prescription pharmaceutical products. Non-prescription pharmaceutical products are further classified as pharmacist-only non-prescription pharmaceutical products or general sales non-prescription pharmaceutical products:

i. Prescription Pharmaceutical Product

(1) A pharmaceutical product shall be classified as prescription pharmaceutical product if it fulfills any of the following criteria:

(a) is likely to present a risk either directly or indirectly, even when used correctly if utilized without medical supervision;

(b) is frequently used incorrectly, likely to present a direct or indirect risk to human health;

(c) contains substances or preparations thereof, the activity and/or adverse reactions of which require further investigation or additional monitoring;

(d) is prescribed for parenteral administration;

(e) produces dependency and has a tendency for abuse, illicit use, or misuse even at an established therapeutic dosage level;

(f) emits radiation;

(g) shall be obtained only from a licensed pharmacist of a licensed retail pharmaceutical establishment upon presentation of a valid prescription from a licensed physician, or dentist and for which a pharmacist's advice is necessary.

(2) Prescription pharmaceutical product with special requirements:

(a) Dangerous drug preparation requiring an S-2 License and Dangerous Drugs Board (DDB) Prescription as listed in the latest version of the Updated List of Scheduled Controlled Substances released by DDB.

(b) Radiopharmaceuticals administered to patients for diagnosis and/or therapy. Only Authorized Nuclear Pharmacists are allowed to prepare and dispense radiopharmaceuticals.

ii. Non-Prescription Pharmaceutical Product

(1) Pharmacist-Only Non-Prescription Pharmaceutical Product

A pharmaceutical product shall be classified as pharmacist-only non-prescription pharmaceutical product if:

(a) the contraindications, drug interactions, precautions or warnings need reinforcement by a licensed pharmacist or are not easily recognized by the patient; or special precautions are needed in the storage and handling of the product; or the use of the pharmaceutical product may mask symptoms or delay diagnosis of a condition;

(b) it does not conform with any of the conditions for a prescription medicine [See Section V.C.2.a.i.(1)]; and

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(c) to be obtained only from licensed retail pharmaceutical establishments under the direct supervision of a licensed pharmacist, and advice from a pharmacist is necessary to confirm the appropriate choice of medication to avoid misuse and abuse of such medication.

(2) General Sales Non-Prescription Pharmaceutical Product

A pharmaceutical product shall be classified as general sales non-prescription pharmaceutical product if:

(a) the contraindications, drug interactions, precautions and warnings are easily recognized by the patient;

(b) the hazard to health, the risk of misuse, the risk of misdiagnosis, the need to take special precautions in the storage and handling of the product is minimal;

(c) it does not conform with any of the conditions for a prescription medicine [See Section V.C.2.a.i.(1)] and pharmacist-only non-prescription medicine [See Section V.C.2.a.ii.(1)]; and

(d) the product is reasonably safe and can be sold or supplied without the need for supervision by a licensed physician, dentist, or pharmacist.

(e) Additionally, a general sales non-prescription pharmaceutical product shall be further classified as household remedy if, in addition to the above criteria for general sales non-prescription medicine, the preparation contains APIs of common or ordinary use to relieve common physical ailments.

b. The FDA shall provide and publish an updated list of APIs with corresponding pharmaceutical product classifications.

c. Products with API(s) not yet included in the list shall be assigned with pharmaceutical product classifications prior to the issuance of CPR. Assigning the classification shall be part of the registration process.

d. Products in fixed-dose combination should be classified with reference to the list of API considering the API content. A pharmaceutical product shall be classified conservatively based on the following conditions:

i. If the pharmaceutical product contains any API listed as prescription medicine, then the product shall be classified as prescription medicine.

ii. If the pharmaceutical product contains an API not listed as prescription medicine but has an API listed as pharmacist-only non-prescription medicine, then the product shall be classified as pharmacist-only non-prescription medicine.

iii. If the pharmaceutical product contains an API neither listed as prescription medicine nor pharmacist-only non-prescription medicine and both are general sales non-prescription medicine, then the product shall be classified as general sales non-prescription medicine.

iv. If the pharmaceutical product contains a new fixed-dose combination that is a first of its class and in which both APIs have the same classification, the pharmaceutical product will be conservatively classified into the appropriate

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pharmaceutical product classification in accordance with Section V.C.2.a. of this Order.

e. The authorization holder may request a reclassification to a stricter or lower classification of a pharmaceutical product by filing a corresponding application for post-approval change following the currently implemented guidelines on pharmaceutical product classification of pharmaceutical products for human use.

f. The FDA has the authority to reclassify a pharmaceutical product without requests from the authorization holder whenever appropriate as supported by scientific evidence. Appropriate issuance, notice, or announcement to the authorization holders shall be made accordingly. Whenever a pharmaceutical product is reclassified to another classification, the MAH shall apply for a post-approval change to reflect the new classification status of the product. Specifically, when seeking a post-approval change to reclassify to a stricter classification, the supplementary requirements outlined for the new classification will have to be complied with.

g. Only non-prescription pharmaceutical products are allowed for advertisements and promotions to the general public. Except through medical journals, publications, literature, or scientific events like symposia or conventions exclusively meant for medical and associated professionals, no pharmaceutical product categorized as prescription pharmaceutical product shall be advertised or promoted in any form of mass media.

D. Registration Pathways

1. Full review

   Full review shall apply to registration applications not covered nor eligible by any facilitated registration pathway.

2. Abridged review

   Abridged review shall apply to a pharmaceutical product approved by at least one of FDA's RDRA at the time of submission. Application, requirements, and recognized RDRAs shall follow the existing implementing guidelines of AO No. 2020-0045 and future amendments.

3. Verification review

   Verification review shall apply to a pharmaceutical product with similar indication(s), dosing regimen(s), patient group(s), and/or direction(s) for use that has been approved by at least two of FDA's RDRAs. Application, requirements, and recognized RDRAs shall follow the existing implementing guidelines of AO No. 2020-0045 and future amendments.

4. Collaborative review

   Collaborative review shall apply to a pharmaceutical product that is the same as the product prequalified by the WHO Prequalification Team (WHO/PQT). All aspects of the pharmaceutical product's quality, including but not limited to the formulation, manufacturing site(s), release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission. The proposed indication(s), dosing regimen(s), patient group(s), and/or direction(s) for use should be the same as those

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approved by the WHO/PQT. Application and requirements shall follow the existing implementing guidelines of AO No. 2020-0044 and AO No. 2020-0045 and future amendments.

5. Joint Assessment

   Formal procedure in which the same application is simultaneously submitted to all participating NDRAs.

   For the ASEAN Joint Assessment procedure for pharmaceutical products, notes announcing priority therapeutic areas and indications will be periodically posted on ASEAN NDRAs websites inviting expressions of interest from applicants for the submission of applications for joint assessment candidate product selection. In addition, products should be manufactured in a Pharmaceutical Inspection Co-operation Scheme (PIC/S)-GMP compliant site (documentary verification only, no inspections foreseen).

   The FDA is not precluded from participating in other joint assessment schemes as it may deem necessary.

6. Identical Product Review

   Identical product review shall apply to an application for marketing authorization of a pharmaceutical product that is identical in terms of the manufacturer and of the pharmaceutical formulation vis-à-vis the principal pharmaceutical product. Application and requirements shall follow the current implementing guidelines.

   In view of the foregoing enumeration, the FDA is not precluded from determining the inclusion of any alternative registration pathways as it may deem necessary.

E. Registration Overview

1. Filing of application

   a. Only a duly licensed drug manufacturer, trader, or distributor-importer/exporter may file an application for registration of a pharmaceutical product or API.

   b. The FDA shall require a declaration under oath by the applicant verifying all information contained in or relating to the application to be true and correct.

   c. For pharmaceutical product registration, separate applications shall be required for the following conditions:

      i. Distinct APIs

         (1) different salt or isomer form of the API

         (2) additional API to a single component or multicomponent product

         (3) removal of API from a multicomponent product

         (4) different strength of one or more APIs

         (5) higher overage than previously applied

      ii. Various pharmaceutical dosage forms

      iii. Different routes of administration (exception for parenteral route)

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iv. Modifications in the pharmaceutical product formulation (added and/or removed excipients)

v. Different cell substrate/viral or bacterial seeds that are unrelated to the licensed master cell bank (MCB)/master seed lot (MSL) or pre-MCB/MSL material for biological pharmaceutical products

vi. Distinct components for drug kits

d. For branded pharmaceutical products, the brand name(s) proposal shall be submitted with the registration application and shall be processed simultaneously following the current implemented guidelines governing brand names of pharmaceutical products for registration with FDA.

2. Pre-assessment

a. All registration applications shall undergo pre-assessment by the FDA to ensure the completeness of submitted applications and documentary requirements, as stated in this Order and its subsequent implementing guidelines. No pre-assessment shall be conducted by the FDA without proof of payment of the pre-assessment fee.

b. Applications with incomplete documentary requirements and/or incorrect data entry or format shall not be accepted and will not proceed to the next step of the process.

c. If an application is identified to be more appropriately submitted under a different authorization type, application type, or review route, the application will not be accepted.

d. The FDA shall inform the applicant of the result of the pre-assessment through the provided e-mail address of the applicant. If the application passes the pre-assessment step, the applicant shall receive the Order of Payment with a reference number indicating the fees to be paid. If the application does not pass the pre-assessment step, the FDA shall notify the reason(s) for non-acceptance (e.g., deficiency(ies)) and prompt the applicant to submit a new application.

e. Payment shall be made within the time stipulated in the current implemented guidelines on FDA applications payments platforms. If payment has not been made, the application shall not be accepted, and a new application must be re-submitted.

f. The pre-assessment process only checks for the completeness of the application documentary requirements for evaluation, correctness of entries on the application form, and compliance with the prescribed submission format. Successfully passing the pre-assessment step does not denote the adequacy of the data for regulatory approval.

3. Evaluation

a. The complete document submission, in accordance with the list of requirements based on the current implemented guidelines as laid out in the FDA Citizen's Charter, shall be reviewed and evaluated.

b. The FDA shall assess the suitability of use under local conditions and regulatory requirements relative to the FDA Authorization applied and consider the benefits

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and risks as they apply to the Philippine context based on the available data provided by the applicant.

c. The FDA, during the evaluation of the application, may require clarifications, or additional information through a Notice of Deficiency (NOD) issued to the applicant who will be required to comply within a specified timeframe. Evaluation shall resume upon the receipt of compliance from the applicant.

d. The FDA, during the evaluation of the application, may consider engaging external consultants/experts and advisory committees in the fields related to drug evaluation such as pharmaceutical, medical, and public health sciences, when necessary. All external consultants/experts shall be screened and required to adhere to confidentiality/non-disclosure agreements and disclose any conflicts of interest pursuant to Section 35 of RA No. 11223 to safeguard the confidentiality of the information made available to them and uphold professional integrity and impartiality in the evaluation. The identity of these consultants/experts, comprising scientists and clinicians from both local and overseas institutions, shall remain confidential.

4. Regulatory decision

a. Upon evaluation, the FDA shall arrive at a final decision on the registration application based on compliance with existing standards set by FDA. An application can be considered either "approved" or "disapproved."

b. Approved

i. An approved application means that the pharmaceutical product or API has been evaluated as conforming to the standards required for the authorization being sought and has been successfully registered with the FDA.

ii. A Certificate of Product Registration (CPR) shall be issued to the applicant and the registered pharmaceutical product or API shall be included in the FDA's Drug Registry *(Annex C)*.

iii. The CPR shall reflect the type of authorization granted by the FDA, its validity, and restrictions, among others, as applicable.

c. Disapproved

Any of the following or similar instances shall be a ground for the disapproval of a registration application the authorization sought:

i. The application requirements submitted show that the applicant does not meet the required technical requirements or appropriate standards;

ii. The applicant 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. The holder or owner has violated any of the terms and conditions of its previous authorization in case of renewal applications; or

iv. Such other analogous grounds or causes as determined by the FDA through specific implementing guidelines pursuant to this Order.

5. Post-approval change / Variation

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a. The authorization holder is responsible for ensuring that any variation made to their FDA authorized pharmaceutical product or API satisfies manufacturing and validation according to generally accepted scientific methods. They shall keep up with the latest technical and scientific progress and propose changes or variations based on best available evidence throughout the pharmaceutical product's or API's life cycle.

b. The authorization holder shall inform the FDA of any changes or any variation to the dossier which may affect the safety, efficacy, and/or quality of the pharmaceutical product or API.

c. For products applied through IPPA-1, any post-approval changes on the principal product shall be treated as information on the independent pharmaceutical products or vice-versa. If, upon review, the post-approval change has an impact on the safety, efficacy, or quality of the pharmaceutical product, the FDA shall require all pharmaceutical products linked to the said product through approved IPPA-1 application(s), regardless of whether it was the principal or identical pharmaceutical product, to apply for the post-approval change.

d. For products applied through IPPA-2, any post-approval changes to the principal pharmaceutical product must be applied by the authorization holder of the identical pharmaceutical product to FDA to maintain its validity.

e. An application for post-approval change may be filed within the validity of the CPR and shall follow procedures, requirements, and schedule prescribed in the current implemented guidelines as laid out in the FDA Citizen's Charter.

f. In general, once the application has been approved/processed, the changes should be implemented.

For post-approval changes affecting the labeling materials, the authorization holder may continue to use the previously approved labeling materials at the manufacturing level within one (1) year from the receipt of approval or acknowledgment of the post-approval change application. Upon conclusion of the one-year exhaustion period and following approval, the authorization holder shall exclusively use the updated labeling materials.

6. Renewal of authorization (for Marketing Authorization and DOH-Use-Only Authorization)

a. In order for a pharmaceutical product or API authorization to remain valid, an application for renewal shall be submitted by the authorization holder before expiry or within 120 days after expiry of the CPR.

b. All applications for renewal of authorization shall be submitted following the procedures, requirements, and schedule prescribed in the current implemented guidelines as laid out in the FDA Citizen's Charter.

c. Applications for the renewal of authorization shall be reviewed and evaluated on the basis of the pharmaceutical product or API meeting the current FDA implemented standards of safety, efficacy, and quality, as applicable.

7. Voluntary Cancellation of authorization

a. Voluntary cancellation of the authorization holder of its existing CPR shall be allowed through the filing of a formal notification before the FDA, provided the voluntary cancellation is not intended to defraud the government, or escape

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regulatory accountability. Provided further that any act of voluntary cancellation shall not remove the FDA of jurisdiction or preclude it in pursuing acts of ensuring the safety of the public or regulatory, enforcement, or other actions as a result of violation or non-conformance of the authorization holder with FDA-implemented laws, standards, rules and regulations.

b. No clearance or affirmation of the voluntary cancellation of the existing CPR shall be made unless any FDA-related obligation of the authorization holder has been settled or unless restrained by the Secretary of Health or the Court.

c. Once canceled, the pharmaceutical product or API registration status shall be updated in the FDA Drug Registry. Any requests for reinstatement of pharmaceutical product or API authorization shall not be accommodated by the FDA. A new application shall be submitted for the pharmaceutical product or API to be authorized again.

d. It shall be the responsibility of the authorization holder to discontinue the supply of the pharmaceutical product or API with canceled authorization. Any recall proceedings shall be the responsibility of the authorization holder following the guidelines stipulated in the current implemented guidelines on the recall of health products regulated by the FDA.

F. Validity

For marketing authorization and DOH-use-only authorization, the CPR issued by FDA shall have an initial validity of six (6) years. The CPR may be renewed for another six (6) years or twelve (12) years upon the discretion of the applicant. Qualifications for the applicable validity periods shall follow the implementing guidelines. The validity of the authorization is contingent upon the possession of a valid CPR and a valid LTO by the authorization holder.

For foreign donation authorization, the CPR shall have a validity period of one (1) year. The product may be used by the recipient of the donation until the end of the product's shelf-life.

G. Drug Registry

The FDA Drug Registry, which shall contain all registered pharmaceutical products and APIs issued with FDA authorization shall be made available and officially accessed through the FDA-available online platforms. This registry shall reflect the latest information on the pharmaceutical products and APIs including its registration and authorization status, and approved product information.

H. Fees and Charges

The appropriate fees and charges as specified under existing regulations shall apply, including a Legal Research Fee (LRF), or any amendment or latest issuance thereafter.

I. Processing Time

The processing time or prescribed turn-around time per type of application shall follow the current implemented guidelines as laid out in the FDA Citizen's Charter posted on the FDA website.

J. Reconsideration and Reapplication

All applications for authorizations covered in this Order that are disapproved due to non-compliance with the requirements for registration can submit either a one-time request for reconsideration or reapplication.

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1. Reconsideration

   a. 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 Center for Drug Regulation and Research (CDRR), a formal request for reconsideration within fifteen (15) calendar days after receipt of a copy of the Letter of Disapproval (LOD) and paying the required reconsideration fees as provided in the current FDA's schedule of fees and charges.

   b. The applicant shall point specifically to the findings or conclusions stipulated in the LOD which are not supported by facts, rules, or technical standards.

   c. The FDA shall resolve the request for reconsideration within sixty (60) working days from receipt of the request for reconsideration.

2. Reapplication

   a. The applicant may opt for a re-application following the disapproval of the application by submitting a request for re-application together with the additional supporting documents, if necessary, in compliance with the deficiencies listed in the LOD within forty (40) calendar days after receipt of a copy of the LOD and paying the required re-application fees as provided in the current FDA's schedule of fees and charges.

   b. The applicant shall point specifically to the findings or conclusions stipulated in the LOD which the additional supporting documents intend to answer or clarify.

   c. The FDA shall resolve the re-application within the same turn-around time as the original application.

3. No extension for filing of the request for reconsideration or re-application shall be entertained.

4. No request for reconsideration or re-application shall be entertained unless the required fees are paid. The procedure for payment of fees shall be followed as far as applicable.

VI. ROLES AND RESPONSIBILITIES

A. The FDA shall exercise its regulatory powers in the implementation and enforcement of this Order. Specifically, the FDA shall:

1. Issue guidelines, including but not limited to the application procedure, forms, documentary requirements, and such other requirements as may be prescribed by regulations to ensure the safety, efficacy, and good quality of pharmaceutical products and APIs through issuances;

2. Endeavour to incorporate digitization and digitalization initiatives such as transition to electronic or other forms of labeling and other reengineering and streamlining activities to ensure the efficiency of the registration process.

B. For the purposes of complying with the guidelines including rules and regulations under this Order, the applicant shall:

1. Undertake responsibility for the submission of complete and correct application documents to this Office in accordance with the list of requirements and acceptable

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equivalent documents in the current implemented guidelines as laid out in the FDA Citizen's Charter and ensure unrestricted access to the e-mail address and other contact information declared in the submission;

2. Assume accountability for scrutinizing the pharmaceutical product or API they are applying, determining the application type and evaluation pathway (as guided through *Annex D*), and understanding the requirements and procedures (as guided through *Annex E*) prior to submission of application; and

3. Ensure consistent adherence to FDA rules and regulations throughout the validity of the authorization.

VII. PENALTY

A. Violations of this Order shall deem the pharmaceutical product or API either unregistered, adulterated, and/or misbranded and shall warrant the application of the sanctions and penalties under the applicable provisions of RA No. 3720, as amended by Executive Order No. 175 and RA No. 9711 and its Implementing Rules and Regulations.

B. Grounds for Suspension or Revocation:

1. Except in cases of willful violation of FDA-implemented laws, rules, and regulations, or when public health or safety require otherwise, no authorization issued pursuant to this Order may be suspended or revoked without notice and hearing.

   In any of the instances in the preceding paragraph not requiring prior notice and hearing, an automatic suspension or revocation shall be ordered by the FDA. The authorization holder shall, within forty-eight (48) hours from receipt of the order suspending or revoking the issued authorization without notice and hearing, show cause as to why the said order should not remain in force. Thereafter, if the authorization holder 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 authorization holder will be sustained, or the initial regulatory action will be maintained, and further appropriate penalty shall be imposed.

2. In other instances, any issued authorization shall be suspended or revoked, after notice and hearing, based on any of the following grounds:

   a. The application requirements submitted show that the authorization holder does not meet the required technical requirements or appropriate standards;

   b. 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;

   c. The authorization holder has violated any of the terms and conditions of its authorization; and

   d. Other analogous grounds or causes.

   The proceedings in the above cases shall follow the Uniform Rules of Procedures under Book III of the IRR of RA No. 9711, and the appropriate penalty imposed as provided by the same law and its IRR.

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3. Any suspended or revoked authorization shall have the effect of non-possession of an authorization by the establishment. Thus, the use of the pharmaceutical products and APIs covered by the authorizations under the scope of this Order is deemed prohibited.

C. Nothing in this section shall restrict the FDA, the DOH, or other concerned agencies from imposing other sanctions for administrative violations of any other relevant laws or their implementing rules and regulations.

VIII. SEPARABILITY CLAUSE

The provisions of this Order are hereby declared separable and in the event that any such provision(s) is/are declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions that are not affected by such declaration shall remain in full force and in effect.

IX. REPEALING CLAUSE

In so far as issuance of authorization for registration applications of pharmaceutical products and APIs for human use by the FDA, provisions of the issuances listed in *Annex F* are repealed or modified accordingly.

X. TRANSITORY CLAUSE

All current CPR holders of pharmaceutical products for marketing and foreign donations approved under the existing guidelines shall be valid until expiration. Renewal and variation applications shall follow and be covered by the rules of this Order through its implementing guidelines.

Pending the issuance of the implementing guidelines, the existing regulations shall continue to be followed.

XI. EFFECTIVITY

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

TEODORO J. HERBOSA, MD
Secretary of Health

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ANNEX A
DEFINITION OF TERMS

The following terms or words and phrases, as used in this Administrative Order, shall mean or be understood as follows:

A. **Advanced Therapy Medicinal Products (ATMPs)** for human use refer to any cell or gene therapy product or tissue engineered product that has been substantially manipulated and/or performs a different function in the recipient than in the donor. Although typically produced from substantially manipulated or genetically modified somatic cells or tissues, ATMPs may also include nucleic acids, and viral and non-viral vectors, as well as recombinant bacterial cells and recombinant oncolytic viruses.

B. **Biological Drug** or biological, biologic, or biotherapeutic product refers to any product of biological origin, prepared with biological processes, derived from blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular weight whose purity, potency, and composition cannot readily and reliably be determined by chemical or physicochemical analysis. This shall include but not limited to vaccines, blood products, modified animal tissues, high molecular weight hormones, allergens, the products of genetic engineering or other newer biotechnological techniques and ATMPs. This definition does not include antibiotics and substances that, although of biological origin, are of low molecular weight and can be isolated as pure substances, such as purified steroids and alkaloids.

C. **Blood Product** refers to any therapeutic substance derived from human blood, including whole blood and other blood components for transfusion, and plasma-derived medicinal products.

D. **Brand Name** refers to the proprietary name given by the marketing authorization holder to distinguish its product from those of competitors.

E. **Bundling** refers to the consolidation of multiple applications for post-approval changes into a single submission.

F. **Chemical Drug** also referred to as conventional drug, refers to a pharmaceutical product or API containing any chemical element, naturally occurring chemical material or chemical product obtained by chemical change or synthesis (including macromolecules produced by chemical synthesis, such as peptides/oligo-nucleotides), or any metabolites from a micro-organism (such as antibiotics).

G. **Collaborative Registration Procedure** refers to an assessment process recognized by the Food and Drug Administration (FDA) through reliance, work-sharing, or joint reviews with other international organizations, like the World Health Organization (WHO) Prequalification Team (WHO/PQT), or other drug regulatory agencies as may be identified by the FDA.

H. **Drug** refers to chemical compound(s) or biological substance(s), other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals, including the following:
   1. any article recognized in official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA;

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2. any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
3. any article, other than food, intended to affect the structure or any function of the body of human beings or animals; or
4. any articles intended for use as a component of articles, specified in clauses (1), (2), or (3) not including devices or their components, parts or accessories.
5. herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:
   a. recognized in the Philippine National Formulary;
   b. intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;
   c. other than food, intended to affect the structure or any function of the human body;
   d. in finished or ready-to-use dosage form; and
   e. intended for use as a component of any of the articles specified in clauses a, b, c, and d.

I. **Drug Combination Pack** refers to a pharmaceutical product, packaged in combination with another pharmaceutical product, that may or may not have corresponding individual Certificate of Product Registration (CPRs) intended to be authorized together under a single CPR. The combination pack shall be differentiated from a fixed-dose combination such that the former exists in separate dosage forms while the latter is in a single pharmaceutical dosage form.

J. **Drug Kit** refers to a packaged set of a pharmaceutical product and its delivery system(s) or device(s) used for a particular medical activity or procedure involving the pharmaceutical product including required documentation for the kit components and the entire kit. This does not include a packaged set of a pharmaceutical product, and other items not related to the use of the pharmaceutical product but for other purposes such as promotional materials or emergency kits.

K. **Drug Registry** refers to the official centralized database containing current and comprehensive information regarding pharmaceutical products and APIs that have been registered and authorized by the FDA.

L. **Facilitated Registration Pathway** refers to an alternative registration process whereby the FDA takes into account and gives significant weight to assessments performed by a reference drug regulatory agency (RDRA) in reaching its own decision. The FDA remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments, and information of others.

M. **Fixed-Dose Combination** refers to a pharmaceutical preparation containing two or more pharmacologically active ingredients in a single formulation or dosage form.

N. **General Sales Non-Prescription Pharmaceutical Product** or GS Non-Rx refers to a non-prescription pharmaceutical product for human use that may be dispensed without a prescription from a licensed physician or dentist, and advice from a licensed pharmacist. General sales non-prescription medicines include non-prescription medicines not classified as pharmacist-only and those classified as household remedies.

O. **Generic Pharmaceutical Product** refers to a pharmaceutical product created to be the same as the innovator pharmaceutical product or a generic equivalent serving as a reference pharmaceutical product, in terms of dosage form, safety, strength, route of administration,

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quality, performance characteristics, and intended use. These similarities help to demonstrate interchangeability, which means that a generic pharmaceutical product works in the same way and provides the same clinical benefit as its reference pharmaceutical product.

P. **Generic Pharmaceutical Product Application (GPPA)** refers to a registration application for a generic pharmaceutical product that contains one or more chemical entities and is the same as the reference pharmaceutical product in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Q. **Herbal Medicine** refers to finished, labeled, medicinal product that contain as active ingredient(s) aerial or underground part(s) of a plant or multiple plants, other materials, or combination(s) thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and other substances of this nature.

R. **Homeopathic Drug** refers to any substance used in the system of therapeutics in which a disease is treated by the use of minute amounts of one or more substances which are capable of producing, in a healthy human being, symptoms similar to those of the disease being treated. It is prepared following a homeopathic manufacturing procedure described by a pharmacopeia in official use or other officially recognized documents. A homeopathic pharmaceutical product may contain a number of active substances.

S. **Household Remedy** refers to any preparation containing pharmaceutical substances of common ordinary use to relieve common physical ailments, and which may be dispensed without a medical prescription in original packages, bottles or containers, of which the nomenclature has been duly approved by the FDA.

T. **Identical Pharmaceutical Product** refers to a pharmaceutical product that is identical to a principal pharmaceutical product in terms of the manufacturer of the finished product and the pharmaceutical formulation. The registration of an identical pharmaceutical product may be applied through an **identical pharmaceutical product application (IPPA)**, further categorized to either **independent** identical pharmaceutical product application (IPPA-1) or **principal-dependent** identical pharmaceutical product application (IPPA-2).

U. **Joint Assessment** refers to the formal procedure in which the same application is simultaneously submitted to two or more National Drug Regulatory Authorities (NDRAs) so that they can conduct their evaluations in parallel and share their scientific assessments. This includes submission to all participating NDRAs in the Association of Southeast Asian Nations (ASEAN) Joint Assessment Procedure, or any other similar procedure that will be instituted by FDA.

V. **Labeling Materials** refer to the label on the immediate container, and the other printed or electronic materials that are made available with the pharmaceutical product and API at the time of purchase and/or when the product is used, such as the outer wrapper cartons, package insert/leaflet accompanying the product, which provide the accurate and necessary detailed information for the identification and proper use of the product.

W. **Manufacturer** refers to an establishment engaged in any and all operations involved in the production of pharmaceutical products and APIs including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies.

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X. **Medical Gas** refers to any gas or mixture of gases intended for administration to patients for anesthetic, therapeutic, diagnostic, or prophylactic purposes, which may be manufactured in a liquefied, non-liquefied, or cryogenic state and administered as a gas.

Y. **New Pharmaceutical Product** refers to any pharmaceutical product the composition of which is such that said pharmaceutical product is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use and efficacious under the conditions prescribed, recommended, or suggested in the labeling thereof.

Z. **New Pharmaceutical Product Application (NPPA)** or **New Biological Pharmaceutical Product Application (NBPPA)** – refers to a registration application for a pharmaceutical product that contains:
   1. a new chemical and/or biological entity proposed to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
   2. new dosage forms, dosage strengths, routes of administration, and/or indications, which have not been previously approved for the reference pharmaceutical product.

AA. **Non-Prescription Pharmaceutical Product** also referred to as non-Rx drug or over-the-counter (OTC) pharmaceutical product, refers to a pharmaceutical product for human use that can be dispensed without a prescription from a licensed physician or dentist for the symptomatic relief of minor or self-limiting ailments.

BB. **Notice of Deficiency (NOD)** refers to the official notification to the applicant outlining specific deficiencies, deviations, and/or discrepancies identified during the evaluation of the application that require clarification.

CC. **Orphan Drug** refers to any drug or medicine used to treat or alleviate the symptoms of persons afflicted with a rare disease and declared as such by the DOH upon recommendation of the National Institutes of Health (NIH).

DD. **Pharmacist-Only Non-Prescription Pharmaceutical Product** also referred to as pharmacist-only non-Rx drug or pharmacist-only OTC pharmaceutical product, refers to a non-prescription pharmaceutical product classified by FDA to be obtained only from a licensed pharmacist, with mandatory pharmacist's advice on their selection and proper use.

EE. **Precursor** refers to any substance that is intended to be used in the manufacture of an API and that can be converted into such through chemical, biochemical, or other means. Precursors may include, but are not limited to, starting materials, intermediates, reagents, catalysts, solvents, and any other substance that contributes to the production of an API.

FF. **Prescription Pharmaceutical Product** also referred to as Rx drug, prescription-only pharmaceutical product, or ethical medicines, refers to a pharmaceutical product that can only be dispensed by a licensed pharmacist to a patient, upon the presentation of a valid prescription from a licensed physician or dentist and for which a pharmacist's advice is necessary.

GG. **Principal Pharmaceutical Product** refers to the FDA-authorized pharmaceutical product against which the review of an identical pharmaceutical product application shall be assessed.

HH. **Radiopharmaceutical Product** or radiopharmaceutical preparation or radioactive drug refers to a finished dosage form that contains a radioactive substance in association with one or more ingredients and that is intended to diagnose, stage a disease, monitor treatment, or

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provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. Since radiopharmaceuticals contain radioactive materials, these products are regulated by the Philippine Nuclear Research Institute (PNRI) which is mandated to undertake the licensing and regulation of the peaceful applications of nuclear and radioactive materials and nuclear facilities for its radioactivity, and by FDA for its quality, safety, and efficacy as a pharmaceutical preparation.

II. **Reapplication** refers to the filing of an application as a result of disapproval of a previous application, submitting compliance documents to satisfy the listed deficiencies in the Letter of Disapproval (LOD) and paying the required fees.

JJ. **Request for Reconsideration** refers to the process where an applicant formally requests and seeks a review or re-evaluation of a decision disapproving an application for initial registration, renewal, or post-approval change for FDA authorization.

KK. **Reference Biotherapeutic Product** refers to a product used as the comparator for head-to-head comparability studies with a similar biotherapeutic product in order to show similarity in terms of quality, safety, and efficacy. Only an originator product that was licensed on the basis of a full registration dossier can serve as a reference biotherapeutic product. The term does not refer to measurement standards such as international, pharmacopeial, or national standards or reference standards.

LL. **Reference Drug Regulatory Authority (RDRA)** refers to a national or regional regulatory authority for drugs, vaccines, and biologicals being relied upon by the FDA for a more efficient approach to arriving at a decision thereby improving and expediting quality assured, effective, and safe products.

MM. **Reference Pharmaceutical Product** refers to a pharmaceutical product that has a valid marketing authorization granted by FDA or by a reference drug regulatory authority recognized by FDA. The reference pharmaceutical product may be the innovator or a generic equivalent (as determined by FDA), in cases wherein the innovator product does not hold a valid marketing authorization.

NN. **Similar Biotherapeutic Product** or biosimilar refers to a biotherapeutic product that is similar in terms of quality, safety, and efficacy to an already licensed reference biotherapeutic product.

OO. **Traditional Medicine** refers to any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals, and/or minerals) used in the system of traditional practice.

PP. **Vaccine** refers to a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins.

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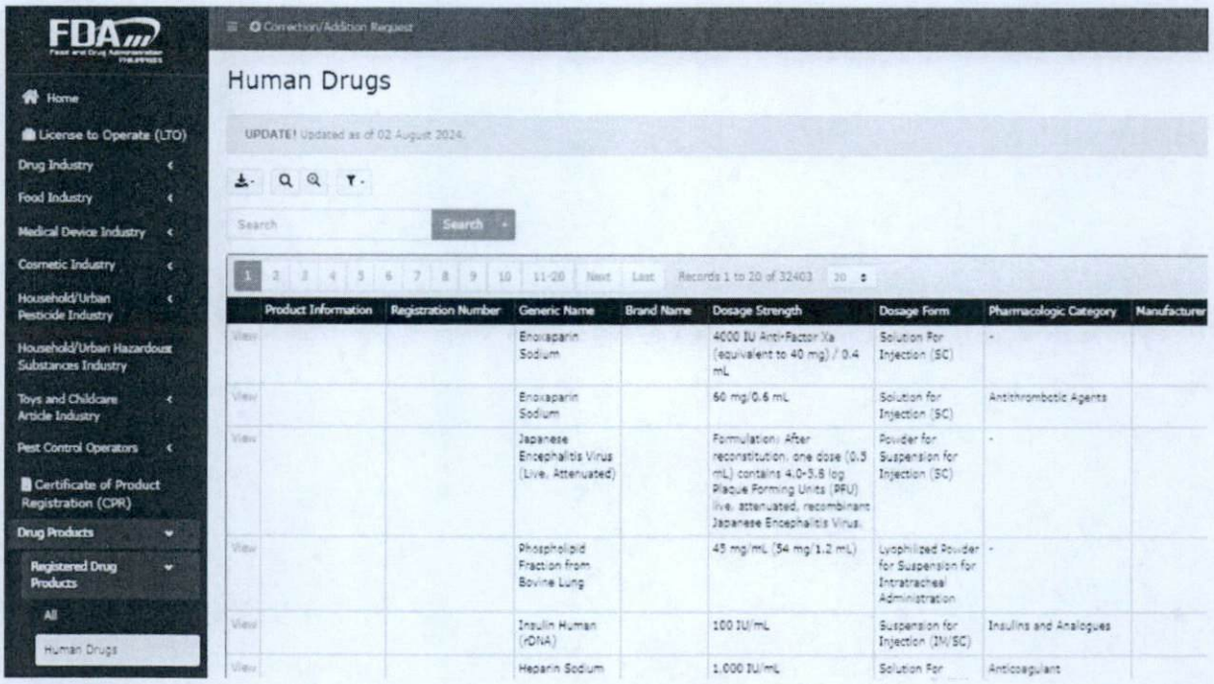
ANNEX B
LIST OF RECOGNIZED PHARMACOPEIAS

1. Philippine Pharmacopeia (PP)
2. British Pharmacopeia (BP)
3. European Pharmacopeia (Ph. Eur)
4. Japanese Pharmacopeia (JP)
5. International Pharmacopeia (Ph. Int.)
6. United States Pharmacopeia-National Formulary (USP-NF)
7. Official Homeopathic Pharmacopeia of the United States (HPUS)

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ANNEX C
FDA DRUG REGISTRY

A. FDA Drug Registry as seen on the FDA Website (Verification Portal)



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FDA DRUG REGISTRY

B. Content of registered pharmaceutical product-specific webpage

FDA
Food and Drug Administration
PHILIPPINES

Registration No.	<data>
Generic Name	<data>
Brand Name (if any)	<data>
Dosage Strength and Form	<data>
Indication	<data>
Classification	<data>
Approved Shelf-life	<data>
Storage Condition	<data>
Packaging	<data>
Manufacturer	<data>
Importer	<data>
Distributor	<data>
Authorization Type	<data>
Valid Until	<data>
Date Issued	<data>
Status	<data>
Special Conditions	<data>
Package Insert/Patient Information Leaflet	<data>

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FDA DRUG REGISTRY

C. Content of registered active pharmaceutical ingredient-specific webpage

FDA
Food and Drug Administration
PHILIPPINES

Registration No.	<data>
Generic Name	<data>
Approved Shelf-life	<data>
Storage Condition	<data>
Packaging	<data>
Manufacturer	<data>
Importer	<data>
Distributor	<data>
Authorization Type	<data>
Valid Until	<data>
Date Issued	<data>
Status	<data>
Special Conditions	<data>

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ANNEX D
APPLICATION TYPE AND REGISTRATION PATHWAY GUIDE

A. Application Matrix

Registration Objectives and Applicant Eligibility	FDA Authorization	Application-relevant Conditions	Application Type
The product is a pharmaceutical product or active pharmaceutical ingredient (API) and is intended for commercial use by patients or healthcare providers in the Philippines. The applicant is an establishment with a valid License to Operate (LTO) as drug manufacturer or trader or distributor/ importer/exporter. The manufacturer has a valid Certificate of GMP Compliance from FDA.	Marketing Authorization	- The innovator or first strength of a pharmaceutical product containing a new chemical or biological entity that is not a currently registered entity in the country	New Pharmaceutical Product Application (NPPA)-1 / New Biological Pharmaceutical Product Application (NBPPA)-1
		- The first strength of a registered pharmaceutical product containing any of the following new characteristics or elements which have not been previously approved for a reference pharmaceutical product: • fixed-dose combination; • dosage form • presentation • formulation • route of administration • indication • dosage recommendation • patient population	NPPA-2 / NBPPA-2
		- A subsequent strength of a registered pharmaceutical product applied through NPPA-1 / NBPPA-1 or NPPA-2 / NBPPA-2 with the following same characteristics or elements: • product name • dosage form • presentation • indication • dosing regimen • patient population	NPPA-3 / NBPPA-3
		- The first strength of a similar biotherapeutic product (SBP) with the following same characteristics	NBPPA-2

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Registration Objectives and Applicant Eligibility	FDA Authorization	Application-relevant Conditions	Application Type
		or elements as the reference biological pharmaceutical product: • dosage form • route of administration	
		- A subsequent strength of an SBP that has been registered through an NBPPA-2 with the following same characteristics or elements: • product name • dosage form • indication • dosing regimen • patient population	NBPPA-3
		- The pharmaceutical product has the following same characteristics or elements as that of the reference pharmaceutical product from which it should exhibit interchangeability: • dosage strength • dosage form • route of administration • conditions for use	Generic Pharmaceutical Product Application (GPPA)
		- The pharmaceutical product is identical to a principal pharmaceutical product in terms of having the following same characteristics or elements: • manufacturer • drug formulation - The pharmaceutical product is intended to have an **independent** marketing authorization	Identical Pharmaceutical Product Application (IPPA)-1
		- The pharmaceutical product is identical to a principal pharmaceutical product in terms of having the following same characteristics or elements: • manufacturer • drug formulation	IPPA-2

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Registration Objectives and Applicant Eligibility	FDA Authorization	Application-relevant Conditions	Application Type
		- The pharmaceutical product is intended to have a **principal-dependent** marketing authorization (identified as an identical pharmaceutical product)	
		- The product is an API or combination thereof intended to be marketed as a raw material to pharmaceutical manufacturing companies in the Philippines for use in the manufacture of a pharmaceutical product	Active Pharmaceutical Ingredient (API) Application
The product is a pharmaceutical product and is intended for use only by the Department of Health (DOH) for patients in the Philippines. The applicant is the DOH.	DOH-Use Only Authorization	- The pharmaceutical product has no valid FDA marketing authorization	DOH-Use Only Authorization Application
The product is a pharmaceutical product donated by foreign entities and is intended for use on patients and by healthcare providers in non-emergency situations in the Philippines. The applicant (endorsed by the DOH) is any individual, organization, institution (public	Foreign Donation Authorization	- The donation is in accordance with the core principles stipulated in the current implemented WHO Guidelines on Medicine Donations - The pharmaceutical product has a counterpart product with a valid FDA marketing authorization - The pharmaceutical product must satisfy at least one (1) of the following conditions: • contains the same active ingredient(s), dosage form, and strength as the products with a valid FDA authorization • is an orphan drug	Foreign Donation Authorization Application

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Registration Objectives and Applicant Eligibility	FDA Authorization	Application-relevant Conditions	Application Type
or private), and any level of government.		• is a pharmaceutical product for compassionate use • is a critically needed pharmaceutical product - The pharmaceutical product is not classified as an investigational pharmaceutical product - The pharmaceutical product has a shelf-life of at least twelve (12) months at the expected date of arrival or satisfies at least one (1) of the following conditions: • the product has a total shelf life of less than two (2) years AND has a remaining at least one-third (1/3) of its shelf-life at the expected date of arrival, with a minimum of six (6) months; or • is recommended as suitable for distribution as per case assessment by the DOH Technical Working Group on Foreign Donations and approved by the Secretary of Health despite the limited product shelf-life remaining	

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B. Registration Pathway Matrix

Application Type	Review pathway-relevant Conditions	Pathway	Processing Days
- Marketing Authorization • NPPA/NBPPA-1/2/3 • GPPA	- Product status or conditions is not covered nor eligible by any of the succeeding review pathways	Full	120 working days
- DOH-Use Only Authorization Application	- The pharmaceutical product has been approved by at least one (1) reference drug regulatory authority (RDRA) at the time of submission and complies other eligibility requirements as applicable	Abridged (pursuant to Administrative Order [AO] No. 2020-0045)	45 working days
	- The pharmaceutical product has similar indication(s), dosing regimen(s), patient group(s), and/or direction(s) for use that has been approved by at least two (2) RDRAs at the time of submission and complies other eligibility requirements as applicable	Verification (pursuant to AO No. 2020-0045)	30 working days
	- The pharmaceutical product has the following same characteristics or elements as that of a product prequalified by the World Health Organization Prequalification Team (WHO/PQT) at the time of submission: • formulation • manufacturing site • release and shelf-life specifications • primary packaging • commercial presentation • indication • dosing regimen • patient group • direction for use	Collaborative (pursuant to AO No. 2020-0044 and AO No. 2020-0045)	65 working days

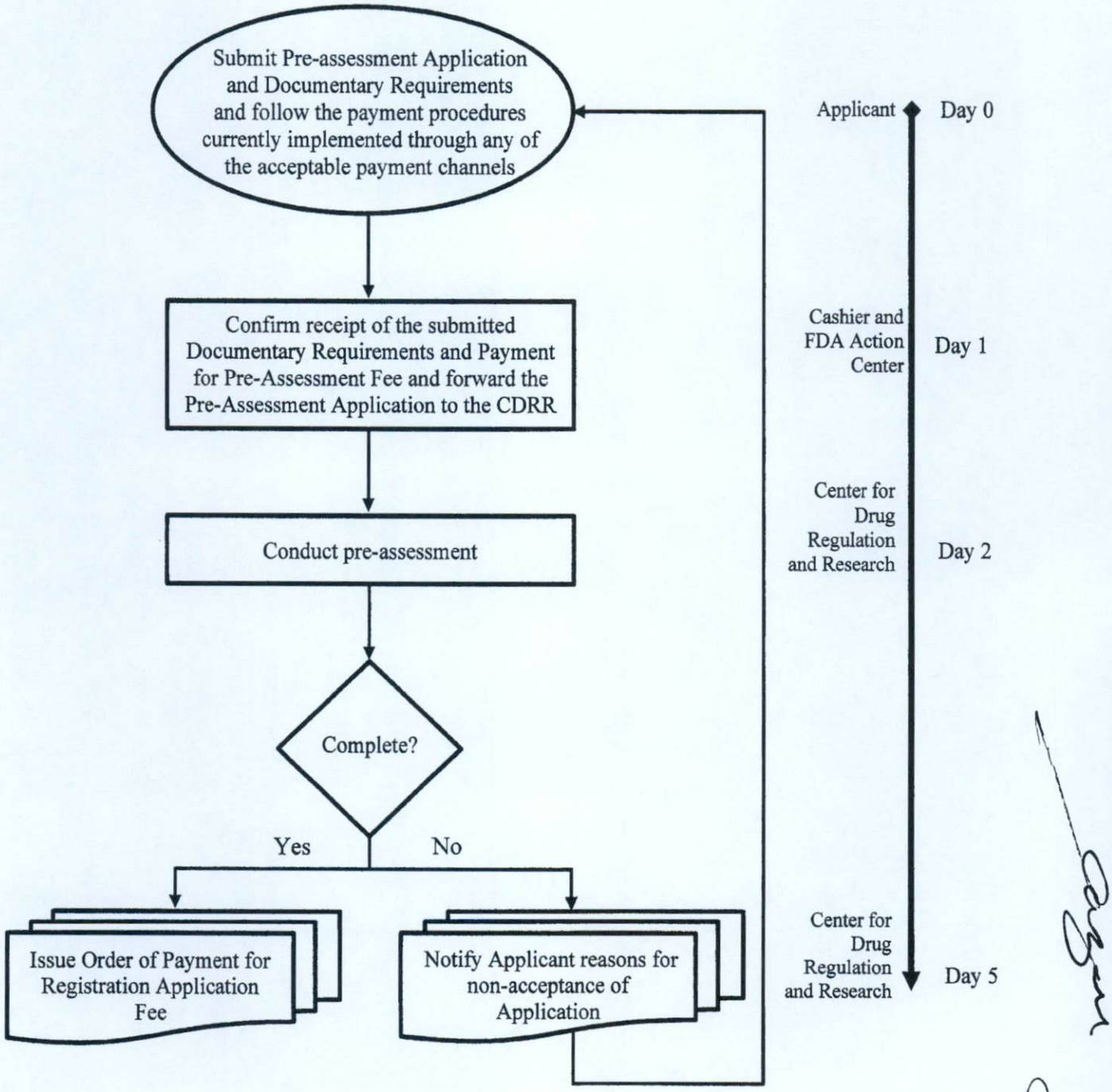
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	- The pharmaceutical product has been applied to any of the joint assessment procedures participated by the FDA and complies other eligibility requirements as applicable	Joint Assessment	
- Foreign Donation Authorization	- Product status or conditions is not covered nor eligible by any of the succeeding review pathways	Full	20 working days
- Marketing Authorization • IPPA-1/2	- The pharmaceutical product is eligible and applied through IPPA-1 or IPPA-2	Identical Product	30 working days

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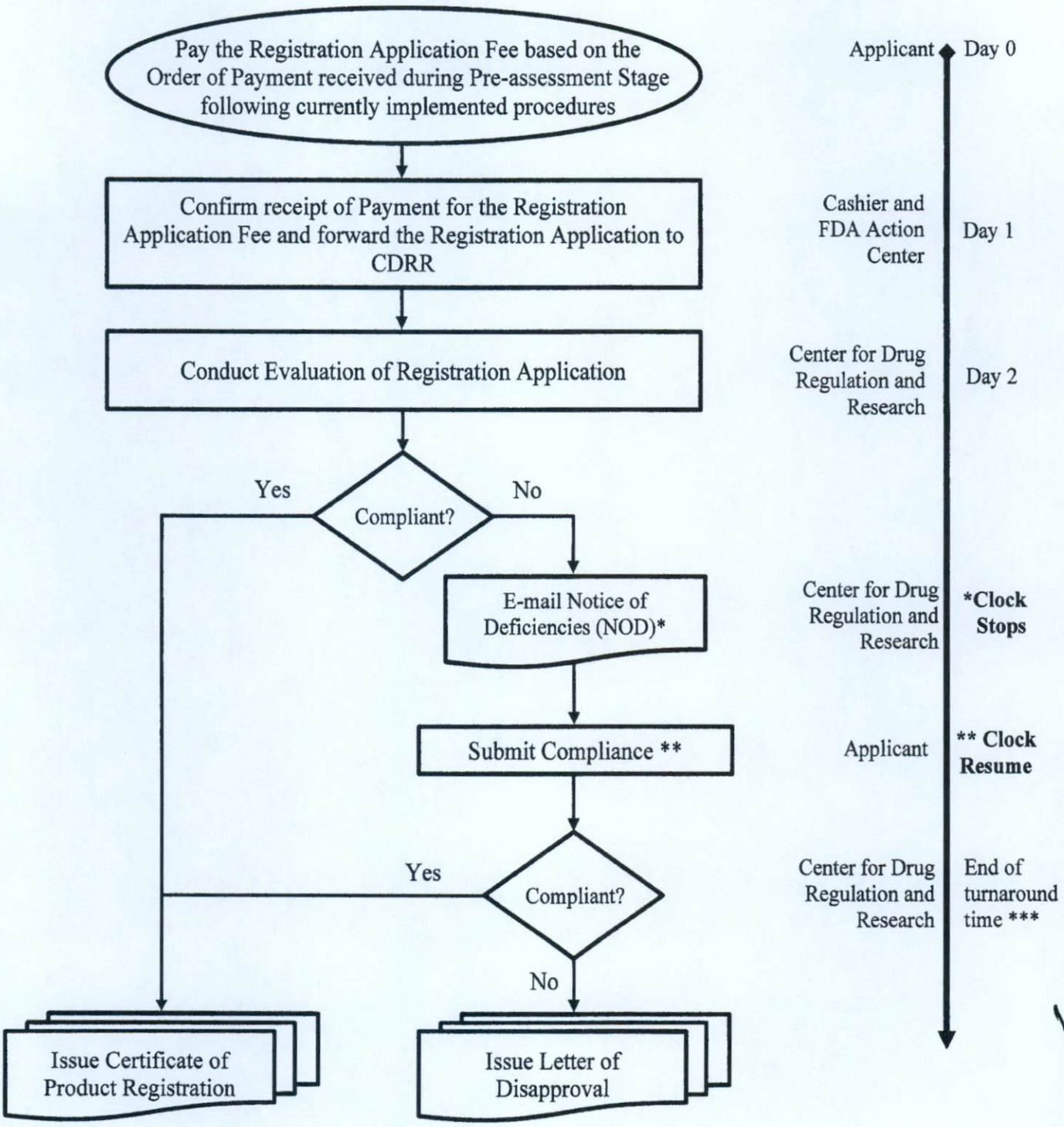
ANNEX E
REGISTRATION – APPLICATION PROCESS FLOWCHART

A. PRE-ASSESSMENT PROCESS



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B. EVALUATION PROCESS



*** Turnaround time shall be based on the current implemented guidelines covering the specific application and laid out in the FDA Citizen's Charter.

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ANNEX F
LIST OF MODIFIED OR REPEALED ISSUANCES

Issuance	Status
A. Administrative Order No. 67 s. 1989: Revised Rules and Regulations on Registration of Pharmaceutical Products (subject to the transitory provision)	Modified: The effectivity of AO No. 67 s. 1989, in so far as its applicability on the issuance of authorizations for registration applications of pharmaceutical products and APIs for human use, is hereby repealed and deemed ineffective. The effectivity of the issuance in so far as its applicability in the rules and regulations for veterinary pharmaceutical shall not be affected.
B. Administrative Order No. 96 s. 1990: Guidelines on the Registration of Fixed-Dose Combination Drug Products	Repealed
C. Administrative Order No. 117 s. 1992: Providing for the Classification of Household Remedies	Repealed
D. Administrative Order No. 41 s. 1994: Supplemental Rules and Regulations in Registration of Pharmaceutical Products, entitled to a Conditional Certificate of Product Registration	Repealed
E. Administrative Order No. 23-c s. 2000: Policies and Guidelines on Over-the-Counter (OTC) Drug Products	Repealed
F. Administrative Order No. 47-a s. 2001: Rules and Regulations on the Registration, including Approval, and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products	Repealed
G. Administrative Order No. 142 s. 2004: Bureau of Food and Drugs (BFAD)'s issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological products Procured by and/or delivered to the Department of Health	Modified: Provisions of AO No. 142 s. 2004 regarding the exemption of all foreign donated pharmaceutical and biological products from the requirement of CPR are hereby repealed.

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Issuance	Status
	The exemption from the requirement of CPR for foreign donated invasive medical devices shall not be affected.
H. Administrative Order No. 172 s. 2004: Guidelines on the Registration of Herbal Medicines	Repealed
I. Administrative Order No. 184 s. 2004: Guidelines on the Registration of Traditionally-Used Herbal Products	Repealed
J. Administrative Order No. 2005-0007: Amending Administrative Order No. 142, s. 2004 by providing exemption from the requirement of Certificate of Product Registration for all goods procured through UNICEF, UNDP, WHO, and GDF	Modified Provisions of AO No. 2005-0007 regarding the exemption of all foreign donated pharmaceutical and biological products from the requirement of CPR are hereby repealed. The exemption from the requirement of CPR for foreign donated invasive medical devices shall not be affected.
K. Administrative Order No. 2005-0016: General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drugs	Modified The effectivity of AO No. 2005-0016, in so far as its applicability on the issuance of authorizations for registration applications of pharmaceutical products for human use, is hereby repealed and deemed ineffective. The effectivity of the issuance in so far as its applicability in the governing of brand names of the covered products other than pharmaceutical products and APIs shall not be affected.
L. Administrative Order No. 2005-0030: Guidelines and Procedure for the Automatic Renewal of the Certificate of Product Registration issued by the Bureau of Food and Drugs	Repealed
M. Administrative Order No. 2005-0031: Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation	Repealed

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Issuance	Status
N. Administrative Order No. 2006-0021: Supplemental Guidelines to Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in evaluating New Drug Application	Repealed
O. Administrative Order No. 2012-0011: Further Amendment to Administrative Order No. 142, s. 2004 regarding the "Bureau of Food and Drugs (BFAD)'s issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological products Procured by and/or delivered to the Department of Health (DOH)"	Modified Provisions of AO No. 2012-0011 regarding the exemption of all foreign donated pharmaceutical and biological products from the requirement of CPR are hereby repealed. The exemption from the requirement of CPR for foreign donated invasive medical devices shall not be affected.
P. Administrative Order No. 2016-0008: Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use	Modified The effectivity of AO No. 2016-0008, in so far as governing the generic labeling requirements of pharmaceutical products for human use Marketing Authorization, shall not be affected. The applicability of the issuance is being modified to also apply to DOH-Use-Only Authorization and Foreign Donation Authorization, and to allow incorporation of digitization and digitalization initiatives such as transition to electronic or other forms of labeling.
Q. Administrative Order No. 2019-0041: Implementing Guidelines in Assuring the Efficacy, Quality and Safety of Pharmaceutical Product in the Public Health Facilities	Modified The following provision of AO No. 2019-0041 under Section VI.A.2 is repealed: *'(a copy of the expiring CPR which is stamped with an "extension of validity" shall be submitted as proof)'*
R. Administrative Order No. 2020-0001: Guidelines in the Importation, Facilitation, and Management of Foreign Donations involving Health and Health-Related Products	Modified Provisions of AO No. 2020-0001 regarding the conditions and requirements on foreign donated pharmaceutical and biological products from the requirement of CPR are hereby repealed. The provisions covering other foreign donated products shall not be affected.

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Issuance	Status
S. Bureau Circular No. 12 s. 1991: Clarification of New Registration when there is a Change of Manufacturer	Repealed
T. Bureau Circular No. 5 s. 1997: Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products	Modified The effectivity of BC No. 5 s. 1997, in so far as its applicability on the issuance of authorizations for registration applications of pharmaceutical products and APIs for human use, is hereby repealed and deemed ineffective. The effectivity of the issuance in so far as its applicability in the rules and regulations for veterinary pharmaceutical shall not be affected.

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