ADMINISTRATIVE ORDER
No. _____

SUBJECT : **Prescribing the Rules and Regulations on the Registration of Pharmaceutical Products, including Drug Substances, Intended Solely for Export**

I. RATIONALE

Section 15 of Executive Order (EO) No. 175 s. 1987, adding new sections to Republic Act (RA) No. 3720 provides in part that*: "No drug or device shall be manufactured, sold, offered for sale, imported, exported, distributed or transferred, unless registered by the manufacturer, importer or distributor thereof in accordance with rules and regulations promulgated by the Secretary pursuant to this Act. The provision of Section 21 (b), (d) and (e), to the extent applicable, shall govern the registration of such drugs and devices."* RA No. 9711, further amending RA No. 3720 and EO No. 175, also prohibits the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product (which includes drugs) that is adulterated or misbranded or the adulteration or misbranding of any health product. Thus, the current rules on registration of pharmaceutical products contemplates those that are manufactured intended for both local and foreign market and not those exclusive for exports.

However, Section 23 of EO No. 175 s. 1987, which amended Section 30 of RA No. 3720, states that drugs, among other health products *"shall not be deemed to be adulterated or misbranded under this Act if it (1) conforms with the specification of the foreign purchaser, (2) is not in conflict with laws of the country to which it is intended for export, and (3) is labelled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act."*

RA No. 11981 or the "Tatak Pinoy (Proudly Filipino) Act" reiterated the policy of the State to encourage, support, and promote the production and offering of the Philippine products and services of increasing diversity, sophistication, and quality by domestic enterprises that are globally competitive.

Hence, aligned with the foregoing and the policies adopted under RA No. 11981 with emphasis on the policy of promoting and safeguarding the quality of Philippine products and services in both the domestic and global market as means for encouraging economic growth and consumer and business confidence in Philippine industries, as well as, pursuant 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 41 IX, Book IV of Executive Order No. 292, this AO is hereby issued to prescribe the specific rules covering the authorization of pharmaceutical product including drug substance exclusively intended for export markets.

II. OBJECTIVE

This Order aims to establish the rules, requirements, and procedure for the issuance of Export-Only Authorization for registration applications of pharmaceutical products including drug substances intended solely for export.

In promulgating this Order, the Department of Health (DOH) and the Food and Drug Administration (FDA) hereby consistently reiterate the responsibility of manufacturers and traders in ensuring safe, efficacious and good quality pharmaceutical products.

III. SCOPE OF APPLICATION

This AO shall cover pharmaceutical products and drugs substances wholly manufactured in the country, intended exclusively for export, and not for distribution, sale, offer for sale, transfer, promotion, advertising, or sponsorship in the country.

This AO shall apply to manufacturers and traders, with eligible pharmaceutical products and drug substances intended exclusively for export.

This AO shall not apply to pharmaceutical products and drug substances manufactured abroad and subsequently imported for re-exportation, pharmaceutical products for investigational use, clinical trials, product development, and/or research, samples for registration, and products for personal use.

IV. DEFINITION OF TERMS

As used in this AO:

A. **Applicant** refers to any establishment that submits a registration application for authorization of a pharmaceutical product and/or drug substance, or the renewal of an existing authorization.

B. **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;
   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 article 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 Drug 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.

C. **Drugs Substance** refers to any substance or combination of substances intended to be used as component in the manufacture of a pharmaceutical product. The drug substance in a finished product dosage form is the active ingredient or **active pharmaceutical ingredient (API)** of that 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 of disease, or to have direct effect in restoring, correcting, or modifying physiological functions of the body.

D. **Export-Only Authorization** refers to a permission granted by the FDA for the export of locally manufactured pharmaceutical products and drug substances exclusively intended for overseas markets. This authorization is embodied in the issued Export Only Registration Certificate and indicates that the product is not authorized for sale, offer for sale, use, promotion, advertising, or sponsorship within the Philippines. The evaluation of the product's quality, safety, and efficacy is deferred to the national drug regulatory authority (NDRA) of the importing country.

E. **Export Only Registration Certificate** refers to a certificate embodying the authorization granted by FDA for a pharmaceutical product including drug substance that has successfully complied with the registration application requirements and procedure for Export-Only Authorization provided under this Order.

F. **Manufacturer** refers to any establishment engaged in all operations involved in the production of pharmaceutical products, including drug substances, including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing, and labeling.

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

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

I. **Trader** refers to an establishment that is a registered owner of a pharmaceutical product, including drug substance, 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 Manufacturer.

V. GENERAL GUIDELINES

A. Pharmaceutical products, including drug substances, authorized solely for export under this Order shall not be equivalent as being registered or authorized for local use within the Philippines. Should an applicant intend to seek authorization for local use of a pharmaceutical product that has been granted export-only authorization, the rules and regulations governing authorizations for local use shall apply and be complied with.

B. Consistent with RA No. 11981, the FDA shall establish an export green lane facility for qualified local pharmaceutical manufacturers, and traders in the processing of their export-only registration. The prescribed processing period under the FDA's Citizens Charter applicable for exports-only shall not be longer than the periods prescribed under RA No. 9485 or the Anti-Red Tape Act of 2007, as amended by RA No. 11032 or the Ease of Doing Business and Efficient Government Service Delivery Act of 2018.

C. In availing these guidelines, it is expected that the local pharmaceutical product and drug substance manufacturers, and traders must evaluate the impact that the exportation of their pharmaceutical product including drug substance would have on the country's drug supply.

D. In case of a declared public health emergency in the country or in anticipation of an actual critical shortage of pharmaceutical product or drug substance covered in this Order, which may affect the country's pharmaceutical supply and health care system, local manufacturers and traders of pharmaceutical products and/or drug substances shall prioritize the country's pharmaceutical needs. During these circumstances, priority in the registration shall be accorded should they apply for an appropriate local use authorization and the requirements for registration applications for such authorization must be complied with.

E. The DOH and the FDA reserve the right to suspend *motu proprio* the granted Export-Only Authorization if there is a reasonable ground to believe that the exportation will cause or aggravate a shortage of the pharmaceutical product supply in the country. The suspension shall be lifted once the pharmaceutical product or drug substance supply in the country normalizes as determined by the DOH in coordination with the concerned government agencies and stakeholders.

F. Pharmaceutical products and drug substances covered by an Export-Only Authorization are prohibited to be distributed, sold for consumption, used, offered for sale, transferred, promoted, advertised, or for sponsorship in the country. Once exported, they shall also be prohibited from being re-imported back into the country including any opportunity to re-label the pharmaceutical product and drug substance previously exported for purposes under any of the above activities including for donation.

G. The local pharmaceutical manufacturers, and traders covered under this Order shall be a holder of a valid License to Operate, and in addition, the local manufacturer shall be a holder of a Certificate of Good Manufacturing Practice (GMP) Compliance, both secured pursuant to the existing rules on licensing and GMP.

H. The local pharmaceutical manufacturers and traders in availing these rules and as part of the application requirements, executes and submits a notarized affidavit affirming that their pharmaceutical product or drug substance solely intended for export: (1) conforms with the specification of the country of destination; (2) is not in conflict with the laws of the country to which it is intended for export; and (3) is labeled on the outside of the shipping package to show that it is intended exclusively for export and is manufactured in the Philippines

I. Export-Only Authorization holders are required to report immediately to the FDA any incident that reasonably indicates that the product exported has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person. Reporting shall also include events wherein the exported pharmaceutical product and drug substance is found substandard or declared banned in the importing country including the risk management or controls instituted responsive to such case or regulatory decision of the importing country.

J. The NDRA of the Member States of the Association of Southeast Asian Nations (ASEAN) require that pharmaceutical products to be imported in their respective countries should possess approval for marketing in their country of origin. Pharmaceutical products intended for export to ASEAN Member States must apply and comply with the registration application requirements for FDA marketing authorization.

VI. SPECIFIC GUIDELINES

A. Eligibility Criteria

1. Applicants for Export-Only Authorization, shall be a holder of valid License-to-Operate (LTO), issued by the FDA;

2. The manufacturer of the pharmaceutical product or drug substance shall be a holder of valid Certificate of GMP Compliance issued by the FDA;

3. The pharmaceutical product or drug substance is wholly manufactured in the country. This shall not include bulk or semi-finished pharmaceutical products imported for the purpose of filling, packing, repacking, altering, ornamenting, finishing, and/or labeling.

B. Documentary Requirements

1. The following are the documentary requirements for an initial or renewal application for Export-Only Authorization:
    a. Complete and notarized Application Form containing the following:
        i. Undertaking that the pharmaceutical product or drug substance intended solely for export: (1) conforms with the specification of the

country of destination; (2) is not in conflict with the laws of the country to which it is intended for export; and (3) is labeled on the outside of the shipping package to show that it is manufactured in the Philippines and is intended exclusively for export;

ii. Undertaking that the applicant shall prioritize the country's pharmaceutical supply and shall apply and comply with the requirements for registration applications for a local use authorization in case of declared public health emergency or in anticipation of an actual critical shortage and there is a need for the covered pharmaceutical product or drug substance, affecting the country's pharmaceutical supply and health care system;

iii. Statement of Responsibility accomplished and signed by the Head of Regulatory Office of the product owner stating that: (1) the sole responsibility and accountability for the product shall be on the Export-Only Authorization Holder and (2) the Export-Only Registration Certificate issued shall not be construed as an endorsement by the FDA and/or an authorization for local use of the product, or any claims made for it;

b. Valid LTO as pharmaceutical manufacturer and trader (as applicable), issued by the FDA;
c. Valid Certificate of GMP Compliance issued by the FDA to the manufacturer of the pharmaceutical product or drug substance;
d. Proof of Payment;
e. Master Formula (Unit dose and batch formulation); and
f. Valid Contract Agreement of Trader with Manufacturer, as the case may be.

2. All the requirements identified above are continuing during the validity of the Export-Only

C. **Application Procedure**

1. The eligible applicant shall submit the complete and correct documentary requirements for initial or renewal application, as stipulated by this issuance, through the FDA eServices Portal System. Only one (1) e-mail address of the applicant shall be used for online applications, communications, compliances and/or notification, as the case may be. 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 address.

2. All applications for Export-Only Authorization shall undergo pre-assessment. The pre-assessment stage shall be conducted to determine the completeness of the requirements specific to each submitted application. Incomplete submission and incorrect data entry or format shall not be accepted, and the application shall not proceed to the next step.

3. Applications that passed the pre-assessment stage shall be issued an Order of Payment with the reference number. Applications that did not pass the pre-assessment, the applicant shall be informed of the reason/s for non-acceptance and prompt the applicant to submit a new application.

4. The application shall be evaluated based on the documents submitted. The FDA may require clarification or additional information to ensure the compliance of the drug to the rules and regulations for authorization for export-only pharmaceutical product or drug substance.

5. Approved applications shall be issued an Export Only Registration Certificate while disapproved application shall be issued a Letter of Disapproval (LOD).
6. The Export-Only Authorization shall be specific to one pharmaceutical product or drug substance and one manufacturer. Pharmaceutical products with different dosage form and/or dosage strength shall require separate applications.
7. A registration number shall be assigned to a pharmaceutical product or drug substance with an approved application.

8. Pharmaceutical products and drug substances with a valid Export Only Authorization shall be posted in the FDA Verification Portal System identified as **"For Export-Only."**

D. **Review of Application**

1. The approval of the authorization ensures that the pharmaceutical product or drug substance is manufactured by an FDA licensed and GMP compliant drug manufacturer in the Philippines. The evaluation of the product's quality, safety, and efficacy is deferred to the National Regulatory Authority (NRA) of the importing country.

2. The processing period shall not be longer than the periods prescribed under RA No. 9485, as amended by RA No. 11032 which shall be provided expressly under the FDA's Citizens Charter

3. In case where the cause of delay is due to force majeure or fortuitous events which result to 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.

E. **Decision on the Application**

1. Approval

   Only upon a determination by the FDA of satisfactory compliance to the requirements after evaluation shall the application be granted. An Export-Only Registration Certificate shall be issued or renewed with a corresponding validity.

2. Disapproval

   Any of the following or similar instances shall be a ground for the disapproval of an application to Export-Only Authorization:

   a. The application requirements submitted show that the establishment 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 applicable FDA-implemented laws, Rules, and Regulations or appropriate standards;
c. The holder or owner has violated any of the terms and conditions of its authorization;
d. The holder or owner of the authorization, without legitimate reason fails to export the health product or fails to cause it to be marketed during an uninterrupted period of at least three (3) years from date of issuance or renewal of the registration or the last date of operation or marketing;
e. Such other analogous grounds or causes as determined by the FDA.

F. **Post-Approval Responsibilities**

1. The Export-Only Authorization holder shall provide notification to the FDA identifying the pharmaceutical product or drug substance when it shall begin for export to the country of destination and all subsequent exportation. The notification procedure shall follow the latest implementing issuance adopted by FDA.

2. At the time of exportation, the pharmaceutical product or drug substance shall be labeled on the outside of the shipping package that it is intended solely for export and manufactured in the Philippines.

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3. All manufacturers of products granted Export-Only Authorization shall ensure compliance to the principles Current Good Manufacturing Practice (cGMP) at all times.

4. All Export-Only Authorization holders shall maintain records of all its export-only pharmaceutical products and drug substances and its country of destination. Manufacturers shall also retain samples of all pharmaceutical products and drug substances it has exported. Authorization holders shall also notify the FDA of any updates or changes in the pharmaceutical product and drug substance in the country of destination. Notifications shall be filed through the FDA eServices Portal System, upon the approval of the change or any updates in the country of destination.

5. In the event of cancellation or expiry of the authorization, un-exported quantity of the pharmaceutical product or drug substance shall be destroyed by the Export-Only Authorization holder with notice to the FDA for witnessing. The destruction of the pharmaceutical product or drug substance shall be in accordance with the latest implementing guidelines.

G. **Validity**

1. The validity of the issued Export-Only Authorization shall be as follows:

Registration	Validity
Initial	6 years
Renewal	12 years

2. It is subject to the authority of the DOH and FDA to suspend the validity in case where there is reasonable ground to believe that the exportation will cause or aggravate a shortage of the pharmaceutical product supply in the country.

3. Pharmaceutical products and drug substances with lapsed authorization may be applied for renewal of authorization within one hundred twenty (120) calendar days from the expiration of the Export-Only Authorization 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.

H. **Suspension or Cancellation of the Issued Authorization**

1. Grounds for Suspension or Cancellation:
   a. Except in cases of willful violation of FDA-implemented laws, rules, and regulations, or when public health or safety require otherwise, or when the authorization holder with previously issued Export-Only Authorization failed to file an application for renewal after one-hundred and twenty (120) days from the date of expiration, no Export-Only Authorization may be suspended, cancelled, or revoked without notice and hearing.

      In any of the instances in the preceding paragraph, the Export-Only Authorization may be automatically suspended, cancelled or revoked and the authorization holder shall, within forty-eight (48) hours from receipt of the order suspending, cancelling, or revoking the Export-Only Authorization 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.

   b. In other instances, any issued Export-Only Authorization shall be suspended, cancelled, or revoked, after notice and hearing, based on any of the following grounds:
      i. The application requirements submitted show that the establishment 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 FDA-implemented laws, their IRR, or appropriate standards;
      iii. The owner has violated any of the terms and conditions of its authorization;
      iv. Other analogous grounds or causes

c. Nothing in this section shall restrict the FDA in enforcing the other imposable penalties provided under the applicable FDA-implemented laws, rules, and regulations.

2. Voluntary Cancellation of Existing Authorization
   a. Voluntary cancellation of the authorization holder of its existing authorization may be allowed through the filing of a formal notification before the FDA and the payment of appropriate fees. Provided the voluntary cancellation is not intended to defraud the government, the authorization holder's creditors, and/or its workers. 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 Export-Only Authorization shall be made unless any FDA-related obligation of the authorization holder is settled or unless restrained by the Secretary of Health or the Court.

I. **Fees**
The appropriate fees and charges shall follow the latest implementing guidelines and its amendment.

VII. PENALTY

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

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

VIII. REPEALING CLAUSE

Provisions in existing administrative orders, circulars, and memoranda inconsistent with this Order are hereby repealed and amended accordingly.

IX. SEPARABILITY CLAUSE

If any provision in this Order, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Administrative Order shall not be affected.

X. EFFECTIVITY

This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines Law Center-Office of the National Administrative Register.

TEODORO HERBOSA, MD
Secretary, Department of Health