ADMINISTRATIVE ORDER
No. _____

SUBJECT : **Guidelines Prescribing the Principle of Reliance for Regulatory Decisions of the Food and Drug Administration**

I. BACKGROUND/ RATIONALE

Reliance is defined by the World Health Organization as *"the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments, and information of others."*

Reliance implies that through the reports collated from Clinical Trial Assessment, Marketing Authorization (MA) assessment, GMP inspection, and Quality Control (QC) related decisions by the reference regulatory Authority, among others, the FDA can use these shared information according to its own scientific knowledge and regulatory procedures while maintaining its own regulatory responsibilities to arrive at a sound decision.

The principle of reliance is not a new concept under the Philippine setting. Republic Act No. 9502 already formally incorporates the idea of reliance in mandating the FDA to take the necessary steps to ensure that all drugs authorized for marketing in the country shall conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia; that imported products in finished dosage forms, should be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce; and the registration for multisource pharmaceutical products should conform to the WHO guidelines on registration requirements to establish interchangeability.

Republic Act No. 10611, on the other hand, expressly directs the DOH that setting of food safety standards shall be established on the basis of science, risk analysis, scientific advice from expert body/bodies, standards of other countries, existing Philippine National Standards (PNS) and the standards of the Codex Alimentarius Commission (Codex), where these exist and are applicable.

Republic Act 9711 or the FDA Strengthening Act of 2009 declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regards to

the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.

On the other hand, Executive Order 292 or the Administrative Code of 1987 mandates the Department of Health to be primarily responsible for the formulation, planning, implementation, and coordination of policies and programs in the field of health. The primary function of the Department is the promotion, protection, preservation, or restoration of the health of the people through the provision and delivery of health services and through the regulation and encouragement of providers of health goods and services. Accordingly, the Department is empowered, among others, to issue orders and regulations concerning the implementation of established health policies.

Therefore, this Administrative Order is hereby issued upon the recommendation of the Food and Drugs Administration, as the policy formulation and sector monitoring arm of the Secretary on matters pertaining to foods, drugs, traditional medicines, cosmetics and household products containing hazardous substances, and the formulation of rules, regulations and standards in accordance with Republic Act No. 3720, as amended by Executive Order No. 175, s. 1987, and other pertinent laws for their proper enforcement. The issuance of this Order is also consistent with Section 4 and Section 19 of Executive Order No. 175, amending, respectively, Section 3 and Section 26 (a) of Republic Act No. 3720, and the declared policies and objectives under Republic Act No. 11223.

II. OBJECTIVES

The FDA, in cognizance of reliance application, shall leverage its review process in accelerate its regulatory decisions of FDA to provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction Effective implementation of reliance will benefit not only the Agency but also the patients/clients, healthcare providers, Marketing Authorization Holders (MAH) and other stakeholders. This will consequently strengthen post-marketing surveillance and promote continuous improvement in building FDA’s institutional capacity towards effectively safeguarding public health.

This Order aims to institutionalize reliance in the regulatory processes covering health products and establishments as determined by the FDA.

Specifically, it shall aim to:

A. Expedite the submission and/or evaluation of authorization applications towards their timely approval;
B. Make greater efficiency to the regulatory process by eliminating duplicative work, strengthen regulatory systems, and optimize resource utilization with a focus on value-added activities without sacrificing product quality, safety, or efficacy; and
C. Optimize innovative and more effective forms of international collaboration or measures by use of available resources/expertise to aid the FDA to address emerging concerns and to be abreast with internationally acceptable norms and standards.

III. SCOPE

This Order shall cover reliance activities in relation to application of authorizations within the FDA. The reliance procedures shall apply, among others, to the registration

and marketing authorization, Good Manufacturing Practice (GMP) Inspections, Clinical Trial, Vigilance and Quality Control (laboratory testing).
In issuing this Order however, it is hereby reiterated that the concept of reliance is resorted to only ~~to~~ aid in reaching regulatory decisions based on consideration of robust scientific evidence that demonstrates a favorable benefit-risk profile and assures the quality of health products and compliance of establishments. It is not meant to replace existing legally mandated requirements. The FDA shall remain independent, responsible, and accountable for the decisions taken.

IV. DEFINITION OF TERMS

A. **Authorization** this refers to a permission embodies 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.

B. **Consistency** this refers to the application of an established specific regulatory process for a well-defined product/ practice in the same predetermined category.

C. **Joint activity** refers to a form of work-sharing whereby a regulatory task is conducted by two or more collaborating regulatory authorities in order to share their assessments, benefit from each other's expertise and discuss any shortcomings of the data being evaluated.

D. **Reference authority** refers to a national or regional regulatory authority or a regional and international entity, being relied upon by the FDA for a more efficient approach at arriving at a decision thereby improving and expediting authorizations.

E. **Regulatory reliance** refers to the act whereby the regulatory authority in one jurisdiction may consider and give significant weight to the regulatory work performed by another regulatory or trusted institution for purposes of reaching its own regulatory decisions.

F. **Recognition** refers to the routine acceptance of the regulatory decision of another regulator or other trusted institution. It indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B.

V. GUIDELINES

A. Development of policies, guidelines, and operating procedures

1. Policies, guidelines, and operating procedures shall be developed and established as necessary in order for the FDA to implement regulatory reliance through adoption of regulatory pathways based on reliance or amending existing pathways to allow the adoption of reliance principles.

2. The Center/Office involved in the regulation of the product/process shall spearhead the development of the reliance policy to be adopted and shall follow the rules and procedures in the preparation and approval of administrative

issuances in the FDA or DOH, whichever is applicable. Complete staff work shall be undertaken which includes the review of existing policies and standards, internal and external consultations, regulatory impact assessment, and the review and endorsement of other Offices involved, among others.

3. The reliance policy shall contain the criteria for eligible applications, the criteria for qualifying the reference authorities, the enumeration of application requirements, the reliance-based evaluation process, and the process turn-around time, among others.

4. Proper dissemination of the reliance policy, preparation of quality work procedures and updating of Citizen's Charter shall be undertaken as necessary to provide guidance to the stakeholders and implementing Offices.

B. Guiding principles (or other term)

1. Regulatory reliance shall be a measure to aid the FDA in arriving at a regulatory decision. It shall not mean to replace existing legally mandated requirements. The FDA shall remain independent, responsible, and accountable for any regulatory decisions taken.

2. Regulatory reliance shall be adopted by the FDA on the basis of science, risk analysis, scientific advice or recommendation from expert body/bodies/organizations, standards of other countries, existing Philippine National Standards (PNS) and internationally recognized standards, where these exist, are applicable, and are not in conflict with what is necessary to protect public health.

3. The FDA shall decide when and how to use reliance and in which circumstances. The Center/Office involved shall formulate the necessary reliance guidelines for health products/ practices under its jurisdiction. Consideration shall be made, among others based on existing capacities, regulatory systems' needs, the availability of an authority that the FDA can rely upon with confidence, and how reliance can complement FDA's own capacities to drive efficiencies and the optimal use of resources.

4. The FDA may use reliance pathways or alternative/non-routine application approval pathways in its regulatory decisions. The approval of any type of authorization application may be accelerated by reliance on prior regulatory decisions from a reference authority.

5. Reliance procedures shall be coherent with the FDA's overall legal frameworks and supported by clear mandates/regulations to ensure effective implementation.

6. Transparent standards and processes shall be used in adopting reliance procedures. Further, the rationale for relying on a specific reference regulatory authority shall be disclosed and understood by all parties.

7. The FDA shall build its own competency for critical decision making and proper implementation. Critical tools are needed for implementation such as information sharing arrangements or information platforms. The reference authorities being

relied on must have and maintain competencies and performance within its jurisdiction as well as prove the use of internationally accepted standards. The competencies should be bench-marked by transparent processes that develop trust on the capacities of these reference authorities.

8. The decision on reliance shall be established for specific and well-defined categories of health products and practices. Consistency shall be applied for all products/practices in the same predetermined category.

9. The FDA shall be open for opportunities for work-sharing which include, but are not limited to, jointly assessing applications for authorization of clinical trials, marketing authorizations or good practices inspections, joint work in the post-marketing surveillance of the health product's quality and safety, joint development of technical guidelines or regulatory standards, and collaboration on information platforms and technology.

10. The Center/Office involved shall use a risk-based approach to reliance and its implementation procedures shall consider the following factors:

    i. type of products;
    ii. public health needs and priorities;
    iii. level of resources and expertise available in the reference regulatory authority; and
    iv. opportunities and confidence for reliance in the country.

C. Areas of reliance

1. Regulatory reliance may be applied in the establishment of regulatory pathways that would expedite the FDA's review and authorization of regulated health products for emergency use during declared public health emergencies.

2. Regulatory reliance may be applied in the adoption of regulatory pathways that would allow reliance or recognition of relevant regulatory decisions, assessment reports, inspection reports, or other information from other reference NRAs, or regional and international bodies in the review of applications of products, processes, or establishments for registration, notification, or licensing.

3. Regulatory reliance may be applied in the establishment of a national vigilance system for health products such as through recognition and/or reliance on vigilance-related information and decisions from other countries or regional or international entities.

4. Regulatory reliance may be applied in the recognition of regulatory decisions of reference authorities in the area of laboratory testing.

5. Regulatory reliance may be applied in the recognition and use of relevant clinical trial decisions, reports, or information from other NRAs, or from regional and international bodies.

6. Regulatory reliance may be applied in establishing acceptance policies and criteria for lot release performed by another NRA.

VII. REPEALING CLAUSE

All issuances, or parts thereof, pertaining to the implementation of reliance covered by this Order are hereby amended. Reliance procedures previously adopted ad implemented by FDA are hereby affirmed in so far as consistent with the guidelines herein prescribed.

VIII. SEPARABILITY CLAUSE

If any provisions in this Order or application of such provision to any circumstances, are held invalid, the remainder in this Order shall not in any way be affected or impaired thereby and continue to be in effect, unless the invalidated provisions totally affect the whole part of this Order.

IX. EFFECTIVITY

This Order shall take effect immediately upon its publication in a newspaper of general circulation and filing with the University of the Philippines – Office of the National Administrative Register.

Secretary of Health