Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

ADMINISTRATIVE ORDER:
No. _____

SUBJECT : **Guidelines on Food and Drug Administration's Regulatory Responses During Declared National or State of Public Health Emergencies**

I. RATIONALE

In upholding the people's constitutional rights to life, health, and property in times of public health emergencies or disasters, there is a need to strengthen the country's institutional capacity, together with partner stakeholders, to build the disaster resilience of the country, and to institutionalize measures for addressing public health threats especially those that endanger our national security, reducing disaster risks, and enhancing emergency and disaster preparedness and timely and appropriate response capabilities at all levels.

Pursuant to Republic Act (RA) No. 11517 or the ""An Act Authorizing the President to Expedite the Processing and Issuance of National and Local Permits, Licenses and Certifications in Times of National Emergency", RA No. 11332 or the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concerns"; Republic Act or (RA) No. 10121 or "The Philippine Disaster Risk Reduction Management Act of 2010"; and the mandate and powers of the Department of Health under Executive Order No. 292 or the "Administrative Code of 1987", this guideline is hereby promulgated as part of the country's public health emergency-related responses.

II. OBJECTIVES

The objective of this Order is to provide the guideline for the implementation of the authority of the President pursuant to RA No. 11517 to either suspend the Food and Drug Administration's requirements for Licenses, Registrations, Certifications and other authorizations covering health products and establishments, or to streamline and expedite the process for their issuance thereof following the conditions provided under RA No. 11517 and RA No. 11332.

III. SCOPE

This Order shall cover FDA's regulatory requirements and activities in response to national public health emergencies declared as such by the President of the Philippines. It shall apply to FDA Centers/Offices and concerned stakeholders with respect to applications for licensing, registration or other required authorizations.

IV. DEFINITION OF TERMS

A. **Disaster** – refers to a serious disruption of the functioning of a community or a society involving widespread human, material, economic or environmental losses and impacts, which exceeds the ability of the affected community or society to cope using its own resources.

B. **Emergency** – refers to unforeseen or sudden occurrence, especially danger, demanding immediate action.

C. **Emergency Use Authorization** – refers to an authorization issued for unregistered drugs and vaccines in times of a public health emergency.

D. **Epidemic/outbreak** – refers to the occurrence of more cases of disease than normally expected within a specific place or group of people over a given period of time.

E. **Health event of public health concern** - refers to either a public health emergency or a public health threat due to biological, chemical, radio-nuclear and environmental agents.

F. **Health products** - means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

G. **National Security** – refers to a state or condition wherein the people's welfare, well-being, ways of life; government and its institutions; territorial integrity; sovereignty; and core values are enhanced and protected.

H. **Public Health Emergency** – refers to an occurrence or imminent threat of an illness or health condition that;

1) Is caused by any of the following

a) Bio-terrorism;
b) Appearance of a novel or previously controlled or eradicated infectious agent or biological toxin;
c) A natural disaster;
d) A chemical attack or accidental release; and
e) A nuclear attack or accident.

2) Poses a high probability of any of the following

a) A large number of deaths in the affected population;
b) A large number of serious injuries or long-term disabilities in the affected population;

c) Widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of people in the affected population;
d) International exposure to an infectious or toxic agent that poses a significant risk to the health of citizens of other countries; or
e) Trade and travel restrictions.

(For purposes of implementing RA No. 11517 and in so far as the DOH and FDA are concerned, the term emergency used under the law is deemed referring to public health emergency applied under RA No. 11332.)

I. **Reliance -** shall refer to the act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision.

J. **Response** – refers to the regulatory or non-regulatory interventions during or after a public health emergency or disaster to ensure the availability in the country of essential health products needed by the public for their basic subsistence/survival.

K. **Risk -** refers to the combination of the probability of an event and its negative consequences.

L. **State of Calamity-** a condition involving mass casualty and/or major damages to property, disruption of means of livelihoods, roads and normal way of life of people in the affected areas as a result of the occurrence of natural or human-induced hazard.

V. GENERAL GUIDELINES AND LEGAL BACKGROUND

A. Republic Act RA No. 11517 expressly authorizes the President, *in times of national emergency*, to:

i. accelerate and streamline regulatory processes and procedures for new and pending applications and renewals of permits, licenses, clearances, certifications or authorizations, including fixing or shortening the periods provided for under existing laws, regulations, issuances, ordinances;

ii. suspend or waive the requirements in securing such permits, licenses, clearances, certifications or authorizations; and

iii. in consultation with or upon the recommendation of the affected government agencies, may prescribe to be permanent the streamlined regulatory processes and procedures, and the suspension or waiver of the requirements in securing permits, licenses, clearances, and certifications or authorizations.

B. Republic Act No. 11332, on the other hand, empowers the Secretary of Health to declare epidemics of national and/or international concerns except when the same threatens national security. In which case, the President of the Republic of the Philippines shall declare a State of Public Health Emergency and mobilize governmental and non-governmental agencies to respond to the threat.

C. The President of the Philippines, pursuant to Republic Act No. 10121 may also declare a State of Calamity upon the recommendation of the National Disaster Risk Reduction Management Council.

D. In order to establish preparedness and ensure efficient government response to assess, monitor, contain, control, and prevent the spread of any potential epidemic in the Philippines, the Inter-Agency Task Force for the Management of Emerging Infectious Disease created pursuant to Executive Order No. 168 s. 2014, to which the Department of Health is the designated chairperson, may also trigger the application of RA No. 11517.

E. For the President to exercise his authority granted under RA No. 11517, the following conditions must concur:

i. A public health emergency exists;
ii. The public health emergency is national in scope, and requires unrestricted access to emergency health products to respond to the threat;
iii. The national public health emergency threatens the national security;

F. The application of RA No. 11517 maybe invoked simultaneous with the declaration of a national or a state of public health emergency or thereafter of such declaration through an appropriate issuance. In either case however, the Secretary of Health, upon the direction of the President of the Republic of the Philippines and in consultation with the FDA, will assess the application of RA No. 11517, the measures to be exercised by the President as provided therein, including but not limited to, the covered products, establishments, other activities and responsibilities of the FDA, and provide the appropriate recommendation to the President.

Once any of the measures provided under Section 2 of RA No. 11517 is formally directed by the President, the FDA shall immediately formulate and issue the appropriate guidelines covering either streamlining regulatory processes and procedures, or suspending or waiving the requirements in securing authorizations and other regulatory activities, subject to any conditions as may be provided under such directive.

If the measure will affect the validity of an existing issuance previously issued by the Secretary of the Department of Health, the FDA may prepare the proposed measure and recommend to the Secretary of Health for approval and signature. The requirement of prior public consultation may likewise be dispensed with due to the nature of the threat which the measure seeks to address.

G. The said issuance(s) on the streamlining of regulatory processes or suspending/waiving the requirements shall take effect as long as the national public health emergency exists or the declaration of it is sooner lifted by the President. Notwithstanding any declaration of suspension or waiving of regulatory requirements, the liability of covered establishment over the safety, quality, efficacy, and purity of their health product is not waived. Other regulatory tools, such as, but not limited to, seizure and product recall are likewise not waived.

H. The President, in consultation with or upon the recommendation of the DOH and/or the FDA, may prescribe to be permanent the streamlined regulatory processes and procedures, or the suspension or waiver of the requirements in securing permits, licenses, clearances, and certifications or authorizations.

I. The preceding provisions shall not affect the current regulations to accelerate approval of health products (e.g. Emergency Use Authorization, Compassionate Use , Regulatory Reliance) including other regulatory measures like Risk-based Inspections and Extension of Validity of Certain FDA Authorizations.

J. The DOH and the FDA shall not be precluded from pursuing other public health emergency measures designed to enhance accessibility of emergency health products as may be allowed under other existing laws.

(Note: See Annex 1 for the process flow of the guidelines)

VI. SPECIFIC GUIDELINES

1. Within 24 hours, upon the declaration of a national public health emergency and any of the measures provided under Section 2 of RA No. 11517 is directed by the President Republic of the Philippines, the Director General shall convene the FDA Crisis Management Committee for the proper implementation of such directive. Creation of a Task Force may be pursued.

2. The Task Force shall be composed of respective Centers/Offices. They will be tasked to formulate action plans that will be articulated and communicated to the concerned stakeholders, including the appropriate implementing issuance for the Director General's approval. Coordination with other national and local agencies shall be observed as necessary.

3. The guideline shall be issued not later than 15 calendar days upon the effectivity of the issuance of the directive from the President of the Republic of the Philippines. Any rules or guidelines issued by FDA pursuant to this Order shall take effect as long as the national public health emergency exists or the declaration of it or the directive is sooner lifted by the President.

4. As far as necessary and appropriate, the Director General shall ensure budgetary provisions for efficient deployment/mobilization of material, human and

organizational resources in accordance with existing applicable laws, rules, and regulations.

5. The Task Force shall initiate coordination meetings with both concerned internal (FDA Offices) and external stakeholders (e.g Local Government Unit, Law Enforcement Agencies and other national agencies) to ensure effective communication of priorities, strategies, and timelines; and facilitate discussion of challenges encountered and resolutions to address the same.

6. The Task Force shall also develop a communication and monitoring and evaluation plan. The Task Force shall likewise promptly provide updates, reports and recommendations to the Crisis Management Committee. After deliberation on the reports and recommendations, the Committee shall submit its recommendation to the Director General for his/her final approval.

7. The Director General shall submit to the President, through the Secretary of Health, a regular report on the implementation of any of the measures under RA No. 11517 as directed by the President.

VII. REPEALING CLAUSE

All issuances, or parts thereof, inconsistent with the any of the provisions of this Order are hereby deemed amended or modified.

VIII. SEPARABILITY CLAUSE

If any provision in this Order or application of such provision to any circumstances are held invalid, the remaining provisions in this Order shall remain in effect.

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