The 11th Asia Partnership Conference of Pharmaceutical Associations

Building a platform and delivering valuable innovation for the peoples in Asia – Next decade of APAC

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Accelerating Access to Innovative Medicines at the time of the Pandemic: The FDA Philippines COVID-19 Experience

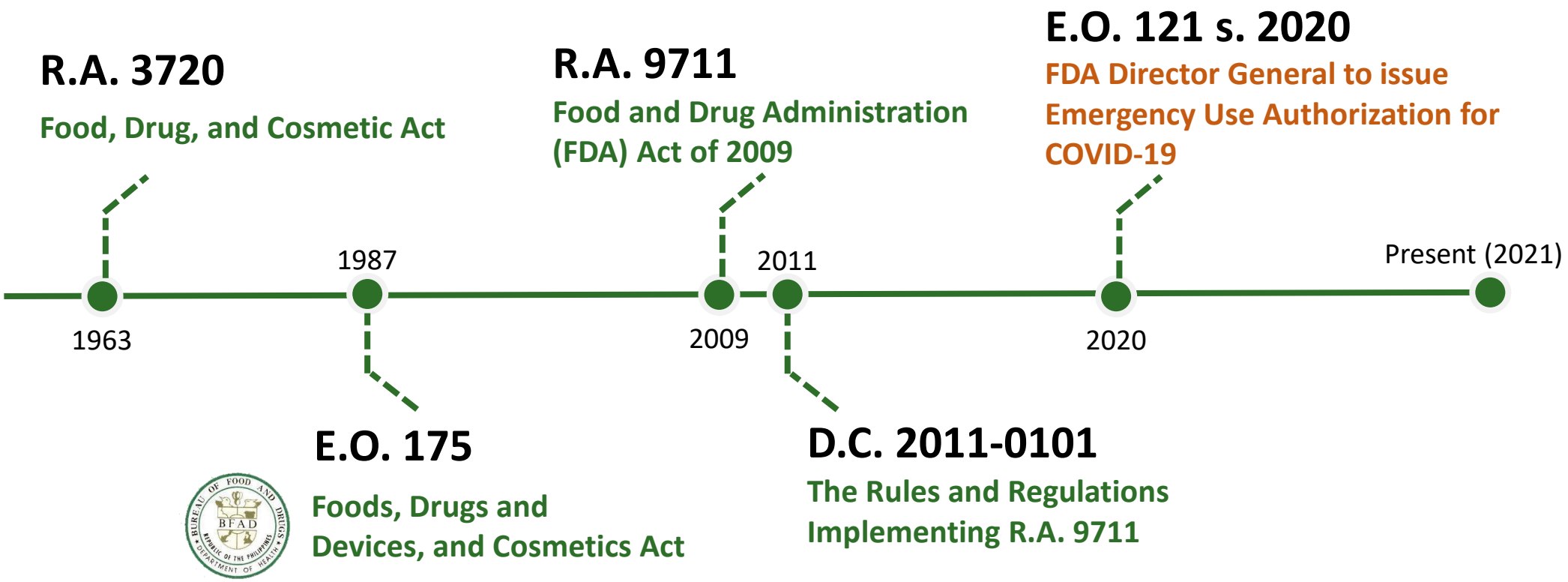
Presentation Outline

I. FDA Overview
II. Regulatory environments to introduce innovative medical products
III. Other topics related to registration
IV. Expectation to Concept Paper & Position Paper

FDA Overview

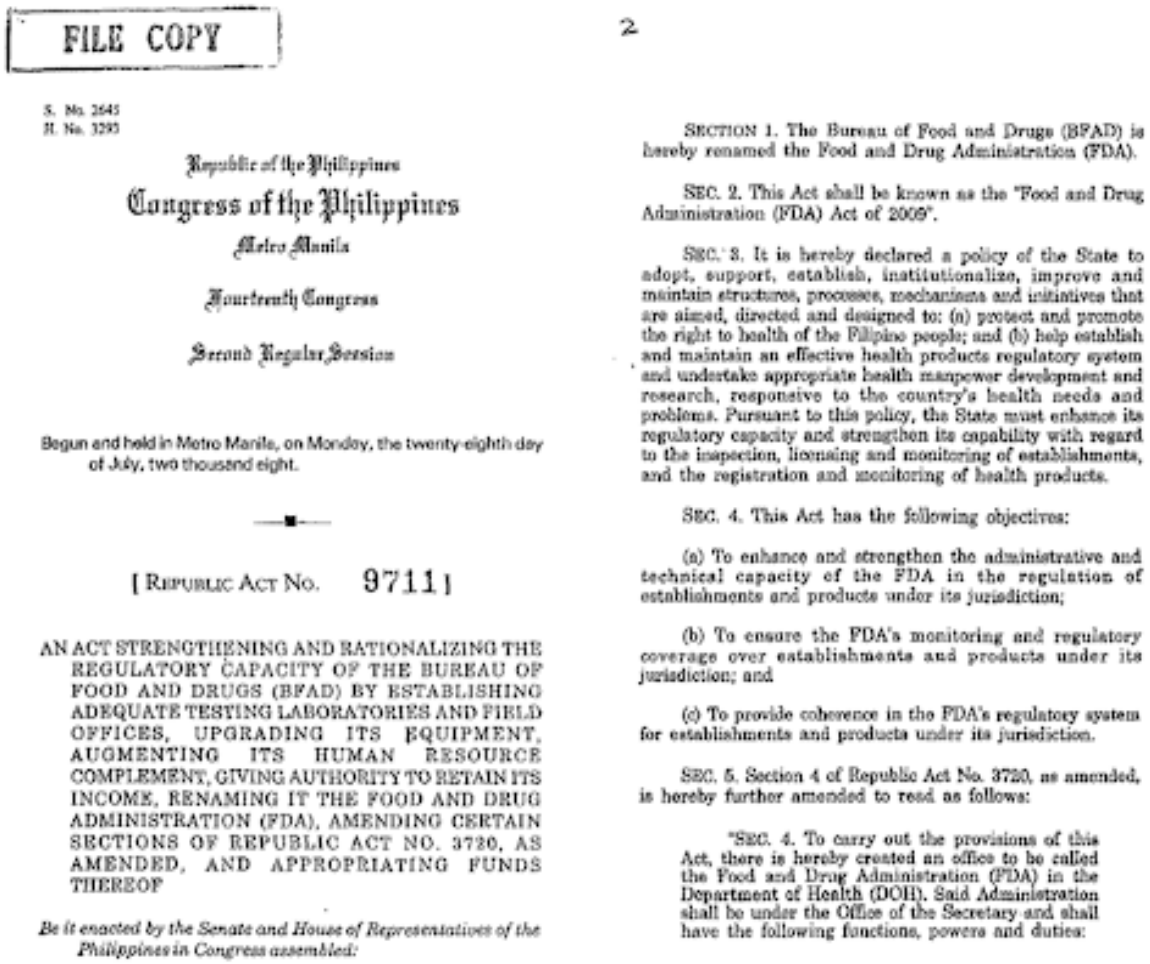
Historical Background

Establishment of FDA Philippines



Republic Act 9711

Regulate all establishments, namely manufacturers, traders, and distributors (importers, exporters and wholesalers), among others, engaged in business and operations involving health products and to issue product market authorization on all health products prior to manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non – consumer use, promotion, advertising, or sponsorship.



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S. No. 2645
H. No. 3293

Republic of the Philippines
Congress of the Philippines
Metro Manila
Fourteenth Congress
Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-eighth day of July, two thousand eight.

[REPUBLIC ACT NO. 9711]

AN ACT STRENGTHENING AND RATIONALIZING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME, RENAMING IT THE FOOD AND DRUG ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND APPROPRIATING FUNDS THEREOF

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

2

SECTION 1. The Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drug Administration (FDA).

SEC. 2. This Act shall be known as the "Food and Drug Administration (FDA) Act of 2009".

SEC. 3. It is hereby 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 regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.

SEC. 4. This Act has the following objectives:

(a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;

(b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and

(c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

SEC. 5. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

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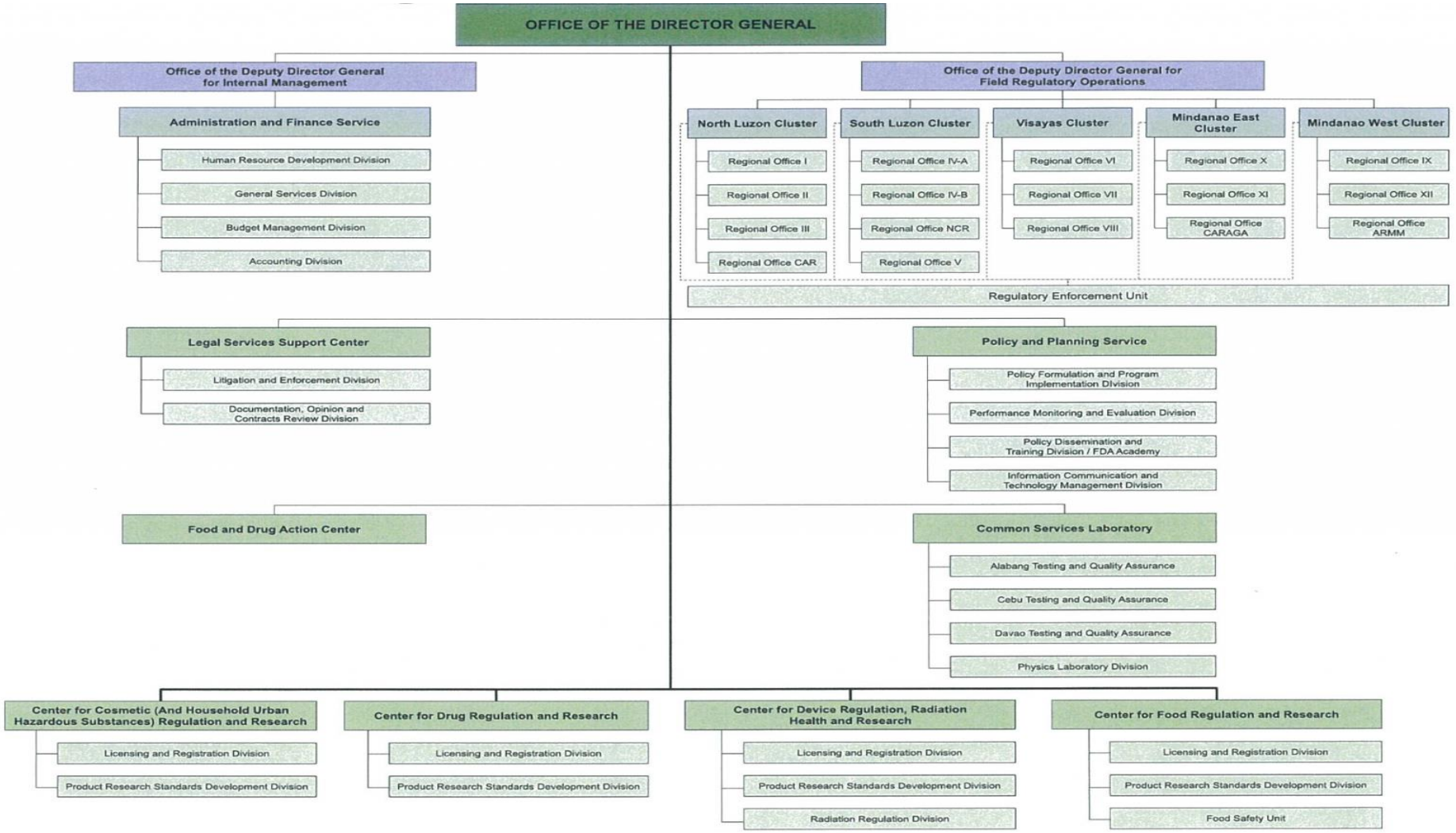
FDA Organogram



The FDA is regulatory agency under the Department of Health responsible for ensuring the safety, efficacy and quality of health products.

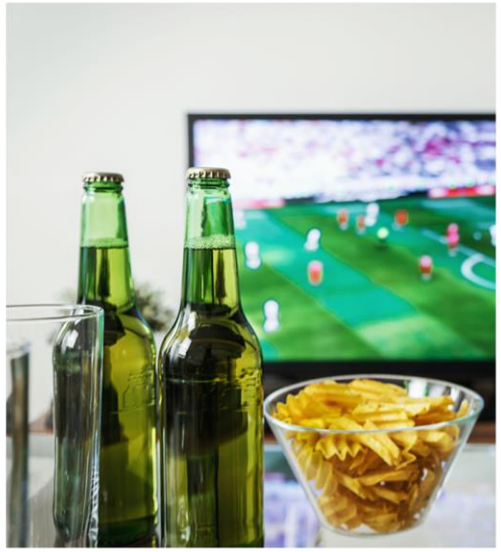
Food and Drug Administration PHILIPPINES

FDA Centers

The FDA is regulatory agency under the Department of Health responsible for ensuring the safety, efficacy and quality of health products.

CDRR

Center for Drug Regulation and Research

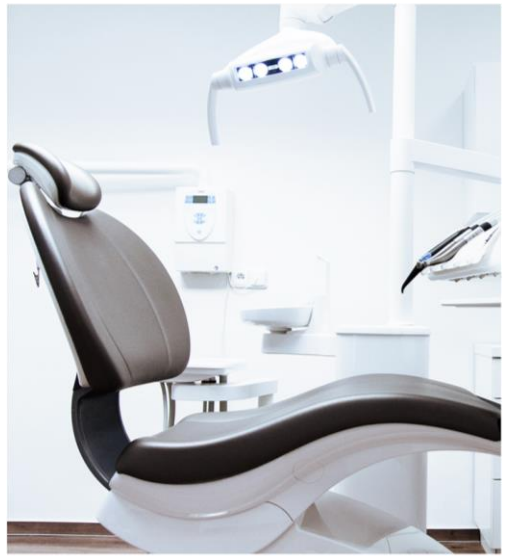


CFRR

Center for Food Regulation and Research

CCHUHSSRR

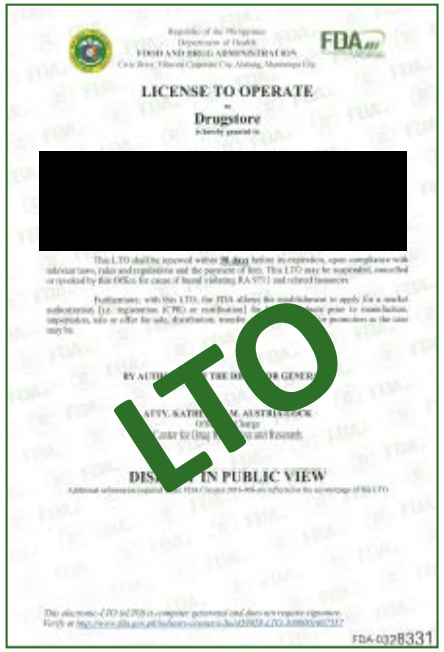
Center for Cosmetic and Household Urban Hazardous Substances Regulation and Research



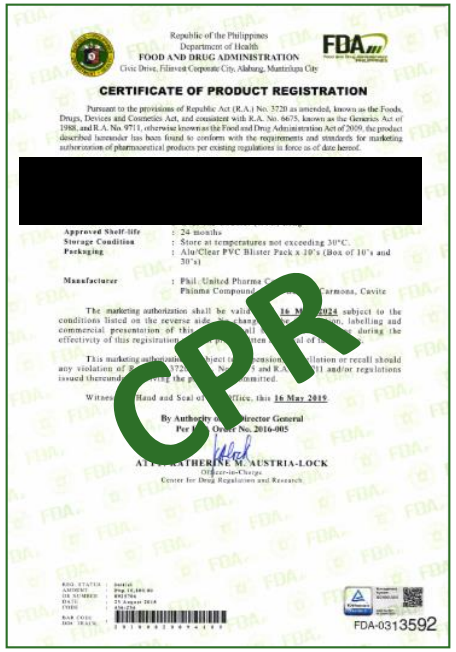
CDRRHR

Center for Device Regulation, Radiation Health and Research

Core Regulatory Process



Licensing of Establishments



Product Registration

Post-Market Surveillance

Republic Act No. 9711: CDRR

The Center for Drug Regulation and Research (CDRR) shall **regulate** the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and testing of **drugs** (to include veterinary medicine, vaccines and biologicals)

Regulatory Environments to Introduce Innovative Medical Products

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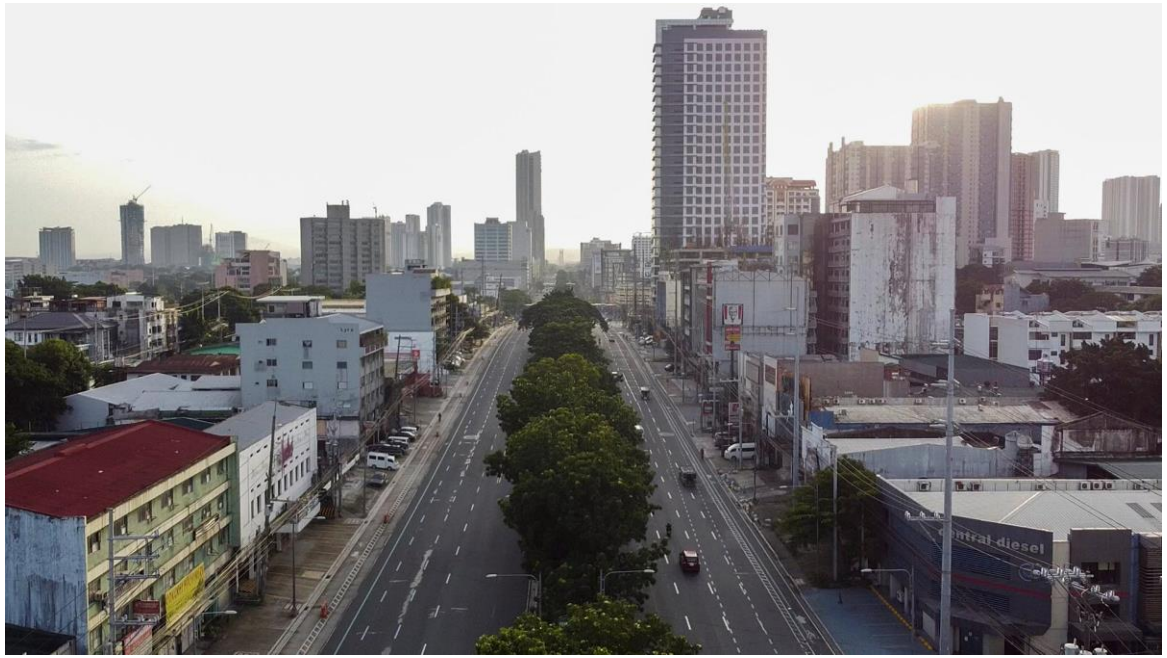
“Longest” and “strictest” lockdown



COVID-19 pandemic posed challenges to regulatory systems

“Longest” and “strictest” lockdown

Travel restrictions and manual systems were hurdles in regulatory submissions

Full review = longer lead times

Aligning with best practices, pre-pandemic

Dialogue and Communications	Consultative Policy Review	Digitalization	Regulatory Reliance
• *Kapihan at Talakayan with the Industry*	• Publishing of policy targets • Public comments and presentation of drafts	• Development of online platforms for regulatory applications • Acceptability of digital documents	• Use of abbreviated, facilitated, and collaborative review procedures • Expanding coverage to post-approval changes • MRA and work-sharing
Recognized Reference DRAs: • **USFDA** • **EMA** • **PMDA** • **TGA** • **HEALTH CANADA** • **MHRA**	**Regional Harmonization** • **APEC** • **ASEAN**	**International standard-making bodies** • **WHO** • **ICH**	**Global and Regional Industry Partners** • **APAC** • **IFPMA**

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Vaccination

To respond to the pandemic, FDA Philippines needed reliance-based policies to accelerate the availability of innovative COVID-19 vaccines and therapies

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Emergency Use Authorization

EMERGENCY USE AUTHORIZATION (EUA)	
Executive Order No. 121	Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization (EUA) for COVID-19 Drugs and Vaccines, Prescribing Conditions therefore and for other Purposes
FDA Circular No. 2020-036	Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19

Early Access saves lives

New regulatory approach is providing early access, saving lives

COVID-19 Vaccines Authorized by the FDA: 9

COVID-19 Drugs Authorized by the FDA: 3

Total Doses Administered

136,863,668

As of 06 March 2022

No. of individuals partly vaccinated

5,473,879 As of 06 March 2022

No. of fully vaccinated individuals

63,690,890 As of 06 March 2022

No. of individuals with booster shots

10,554,093 As of 06 March 2022

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Facilitate Access

The EUA experience showed how regulators can facilitate access to innovative medicines without compromising QSE, saving lives.

This is a valuable learning that we will incorporate in future reforms in the FDA Philippines.

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New Drug Issuances

NEW DRUG (MONITORED RELEASE) REGISTRATION	
(PRE-PANDEMIC)	
Administrative Order No. 67 s. 1989	Revised Rules and Regulations on Registration of Pharmaceutical Products
Bureau Circular No. 5 s. 1997	Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products
Administrative Order No. 2006-0021	Supplemental Guidelines to Administrative Order No. 67 s. 1989
FDA Circular No. 2013-019	Organization of the ASEAN Common Technical Dossier (ACTD) for the Registration of Pharmaceutical Products for Human Use
FDA Circular No. 2020-003	Guidelines for Pharmaceutical Industry on Pharmacovigilance
FDA Circular No.2021-020	**Revised Post-marketing Surveillance Requirements for New Drugs under Monitored Release**

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New Drug Issuances

CLINICAL TRIALS	
(PRE-PANDEMIC)	
FDA Circular No. 2012-007	Reduction of Turn-Around-Time for the Regulatory Review of Clinical Trials and Revised Procedure for the Application of Import License for Investigational Products
FDA Circular No. 2012-007-A	Amending FDA Circular No. 2012-007: Reduction of Turn-Around-Time for the Regulatory Review of Clinical Trials and Revised Procedure for the Application of Import License for Investigational Products
(PANDEMIC)	
Administrative Order No. 2020-0010	Regulations on the Conduct Clinical Trials for Investigational Products
FDA Circular No. 2020-0029	Guidance on Applications for the Conduct of COVID-19 Clinical Trials

Drug for Emergency Use

DRUG PRODUCTS UNDER EMERGENCY USE (DEU)	
FDA Circular No. 2020-012	Guidelines for the Registration of Drug Products under Emergency Use (DEU) for the Coronavirus Disease 2019 (COVID-19)
FDA Circular No. 2021-008, FDA Circular No. 2021-008-A	Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19

Facilitated Availability

COMPASSIONATE SPECIAL PERMIT (CSP)	
Administrative Order No. 2020-0028	Amendment to Administrative Order No. 4 s. 1992 (Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation)

COLLABORATIVE REVIEW PROCEDURE (CRP)	
Administrative Order No. 2020-0044	Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines

FACILITATED REVIEW PATHWAYS (FRP)	
Administrative Order No. 2020-0045	Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals

Other Topics Related to Registration

REGULATORY FLEXIBILITIES	
FDA Circular No.2021-0025	Guidelines for Application of Authorizations at the Food and Drug Administration in Light of the Extended State of Public Health Emergency

ACCESS TO VITAMIN DRUG PRODUCTS	
FDA Circular No. 2020-015	Interim Measures to Ensure Access to Vitamin Drug Products during the Coronavirus Disease 2019 (COVID-19) Pandemic

ACCESS TO ALCOHOLS	
FDA Memorandum Circular No. 2020-001	Interim Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research
FDA Circular No. 2021-004	Revised the Interim Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research

GUIDELINES FOR DONATED HEALTH PRODUCTS	
Administrative Order No. 2007-0017	Guidelines on the Acceptance and Processing of Foreign and Local Donations During Emergency and Disaster Situation
FDA Circular No. 2021-018	Updated Guidelines on the Identification, Notification, Evaluation, Regulatory Enforcement Action, and Review and Monitoring of Donated Health Products Solely Intended to Address Covid-19 Public Health Emergency

Expectation to Concept Paper & Position Paper

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TOPIC #1:	STRUCTURED FRAMEWORK OF REGULATORY CONSULTATION SYSTEM
Goal: To establish structured framework to support regulatory consultation	FDA is aligned with the proposed options and agrees with the expected effects laid out; FDA is open to comments and suggestions from stakeholders to further improve the consultation system in place

TOPIC #2:	TRANSPARENCY TO REVIEW POLICY, STANDARDS, DRAFT REGULATIONS, GUIDELINES, AND NEW INITIATIVE FROM REGULATORY AUTHORITY
Goal: To facilitate transparency to review policy, standards, draft regulations, guidelines, and new initiative from regulatory authority	FDA agrees with the reorganization of previous topics into this topic; FDA is aligned with the proposed options and expected effects

TOPIC #3:	REVIEW PROCESS TRACKING SYSTEM
Goal: To facilitate transparency to review process and status	FDA is aligned with the proposed options and expected effects

TOPIC #4:	COLLABORATIVE TRAINING PROGRAM
Goal: To facilitate collaborative training program and workshop between the regulatory authorities and industry	FDA agrees with the proposed options and continues its review and improvement of its procedures to explore such programs

TOPIC #5:	UTILIZATION OF DIGITAL TOOLS/PLATFORM FOR DRUG REGISTRATION
Goal: To facilitate utilization of digital tools/platform for drug registration	FDA agrees and is aligned with the proposed options, investing in more flexible online platforms

TOPIC #6:	REGULATORY RELIANCE THROUGHOUT THE PRODUCT LIFE CYCLE
Goal: To implement effective regulatory reliance throughout the product life cycle	FDA agrees and is aligned with the proposed options; the implementing guidelines for the adopted facilitated review pathways, i.e. collaborative, abridged, and verification review procedures, are currently being developed in consultation with the industry

END

THANK YOU!

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