FDA: Safeguarding Public Health towards Universal Health Care

The Manila Times Health Forum: "Innovative Keys to Universal Health"
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DECLARATION OF CONFLICT OF INTEREST

DISCLOSURE: NONE

I am NOT connected in any way to an establishment or health product being regulated by the Food and Drug Administration (FDA).

I have NO financial relationship whatsoever to any member of the industry registered with the FDA.

OUTLINE

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II. Accomplishments

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FDA
Food and Drug Administration
PHILIPPINES

Brief History

1963

RA 3720

(Food, Drug, and Cosmetic Act)

Creation of FDA

1982

EO 851

FDA was changed to BFAD

1987

EO 175

Amending 3720 Food, Drugs and Devices, and Cosmetics Act

Inclusion of medical device

2009

RA 9711

Food and Drug Administration Act

Strengthening regulatory capacity of the FDA

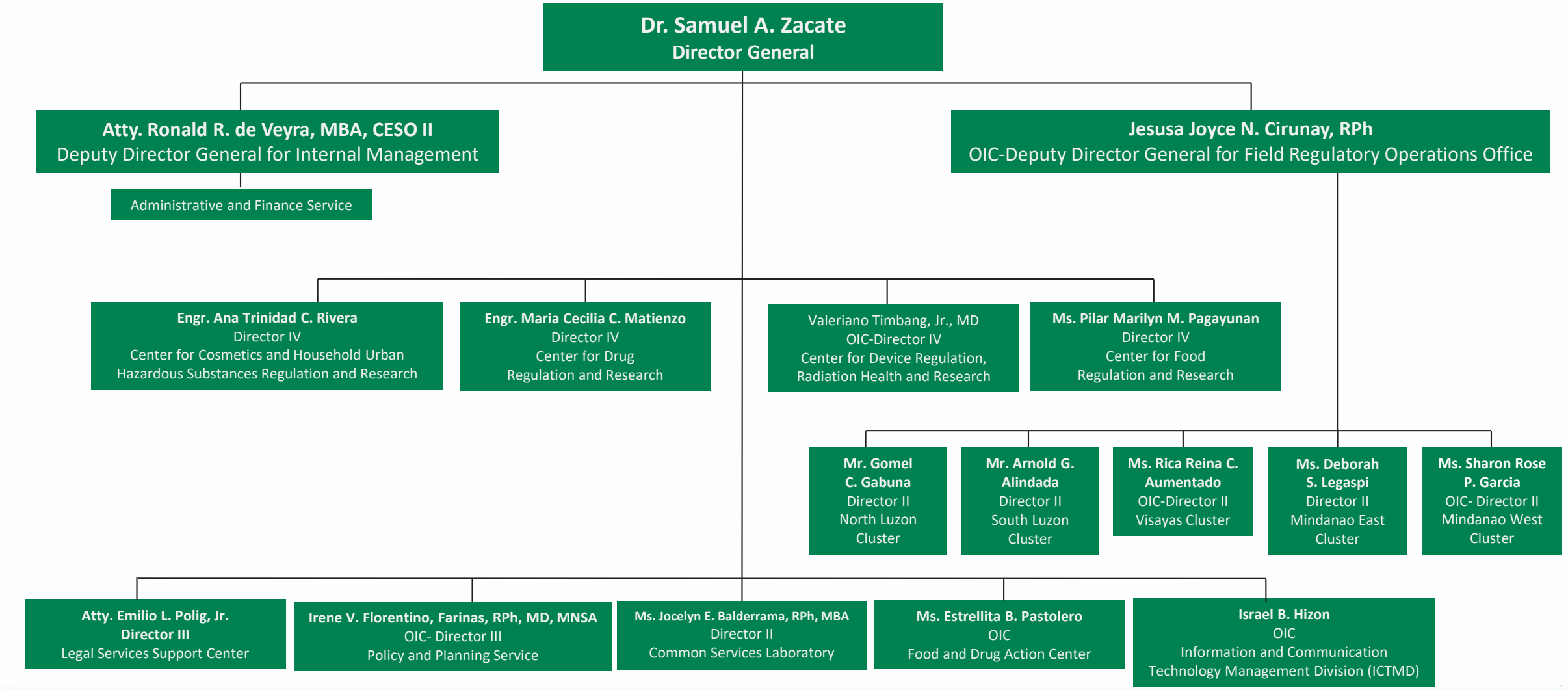
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PROTECT
THE GENERAL PUBLIC

by ensuring the safety, efficacy, purity, and quality
of health products



FDA Organogram



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FDA Centers



Center for Drug Regulation and Research



Center for Food Regulation and Research



Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research



Center for Device Regulation, Radiation Health and Research

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Center for Drug Regulation and Research



Traditional Medicines, Herbal Medicines and Home Remedies



Vaccines, and biological products



Veterinary drug products



Drug products



Medical Oxygen

Center for Food Regulation and Research



Prepackaged and
Processed food products



Food
Supplements



Raw materials for Food



Food Additives



Cosmetics

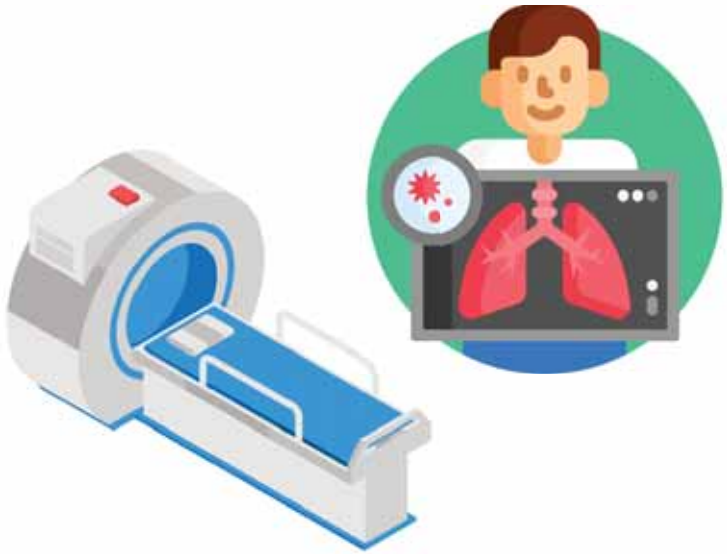


Household Urban Hazardous Substances, and Household Pesticides



Toys and Childcare Articles (TCCA)

Center for Device Regulation, Radiation Health, and Research



Radiation-Emitting Devices,
and Radiation Facilities



Medical Devices and Health-Related Devices



In-vitro diagnostics

FDA Core Functions



Licensing of Establishments

- *Manufacturers*
- *Traders*
- *Distributors/ Importers/ Exporters/ Wholesalers*
- *Retailers/ (Drugstores)*
- *Contract Research Organization*
- *Sponsors*

Registration of Health Products

- *Drug*
- *Vaccines, Biologicals*
- *Prepackaged & Processed Food*
- *Food Supplements*
- *Medical Devices*
- *Radiation-Emitting Devices*
- *Cosmetics (Notification)*
- *Household Urban Hazardous Substances/Pesticides*
- *Toys and Childcare Articles (Notification)*

Post-Marketing Surveillance

- *Inspection*
- *Health Product Vigilance*
- *Enforcement*
- *Advertisements and Promotions Regulation*

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Project Bigyang-Halaga, Bangon MSMEs (BBMSMEs) and Bagong Negosyante Program (BNP)

The FDA implemented several initiatives to support MSMEs in the food and cosmetics industries, focusing on helping them **develop market-oriented products that meet domestic and international standards.**

- Current Good Manufacturing Practices (cGMP)
- Quality and Safety Management.

Project Bigyang-Halaga, Bangon MSMEs (BBMSMEs) and Bagong Negosyante Program (BNP)

Key programs include:

1. **Bigyang-Halaga, Bangon MSMEs (BBMSMEs):** A pilot project in collaboration with LGUs to support selected MSMEs in food and cosmetics manufacturing (FDA Order No. 2023-1419) forged by a MOA.

2. **Bagong Negosyante Program (BNP):** Offers training and advocacy campaigns to MSMEs, cooperatives, and academic institutions on FDA regulations and application processes for required authorizations.

Objectives

A. enhancing capacity for food and cosmetic manufacturing establishments;

B. free training for quality and safety compliance;

C. upgrading capacity and operation of the FDA for training, advocacy, and with the goal of promoting exports of the MSMEs;

D. revisiting, revising or establishing the requirements of relevant regulations, codes and principles for good practices, including application processes for appropriate authorizations specific to supporting MSMEs.

Project Bigyang-Halaga, Bangon MSMEs (BBMSMEs) and Bagong Negosyante Program (BNP)

Activity	Total Number
Memorandum of Agreement/ Understanding (MOA/U)	**16**
Total Number of Trainees	**447**
Engagement with Other National Government Agencies	**8**
Participation with LGUs and NGAs MSME Activities	**4**

Upcoming Activities - 2025

FDA Cluster	LGU/PGU	SUC
North Luzon Cluster	- Provincial Government of La Union (Q1 2025) - City Government of Malolos (Q1 2025)	
Visayas Cluster	- Provincial Government of Bohol (Q1 2025) - Capiz Provincial Government (Q1 2025)	- Capiz State University (Q1 2025)

Oplan Katharos

The FDA remains steadfast in its mission to protect public health by combating the spread of **counterfeit, adulterated, misbranded, and unregistered health products.**

Through rigorous enforcement of its regulatory responsibilities, the FDA **aims to shield the public from the risks posed by violative health products in the market**

Oplan Katharos

Unregistered Health Products (Monitored and Enforced Takedown Measure	CDRR	576
	CDRRHR	330
	CFRR	1,328
	CCHUHSR	708
	Total	**2,942**
FDA issued Advisories (Unregistered Health Products)	CDRR	52
	CDRRHR	107
	CFRR	1,116
	CCHUHSRR	453
	Counterfeit Drug Products	41
	Total	**1,769**

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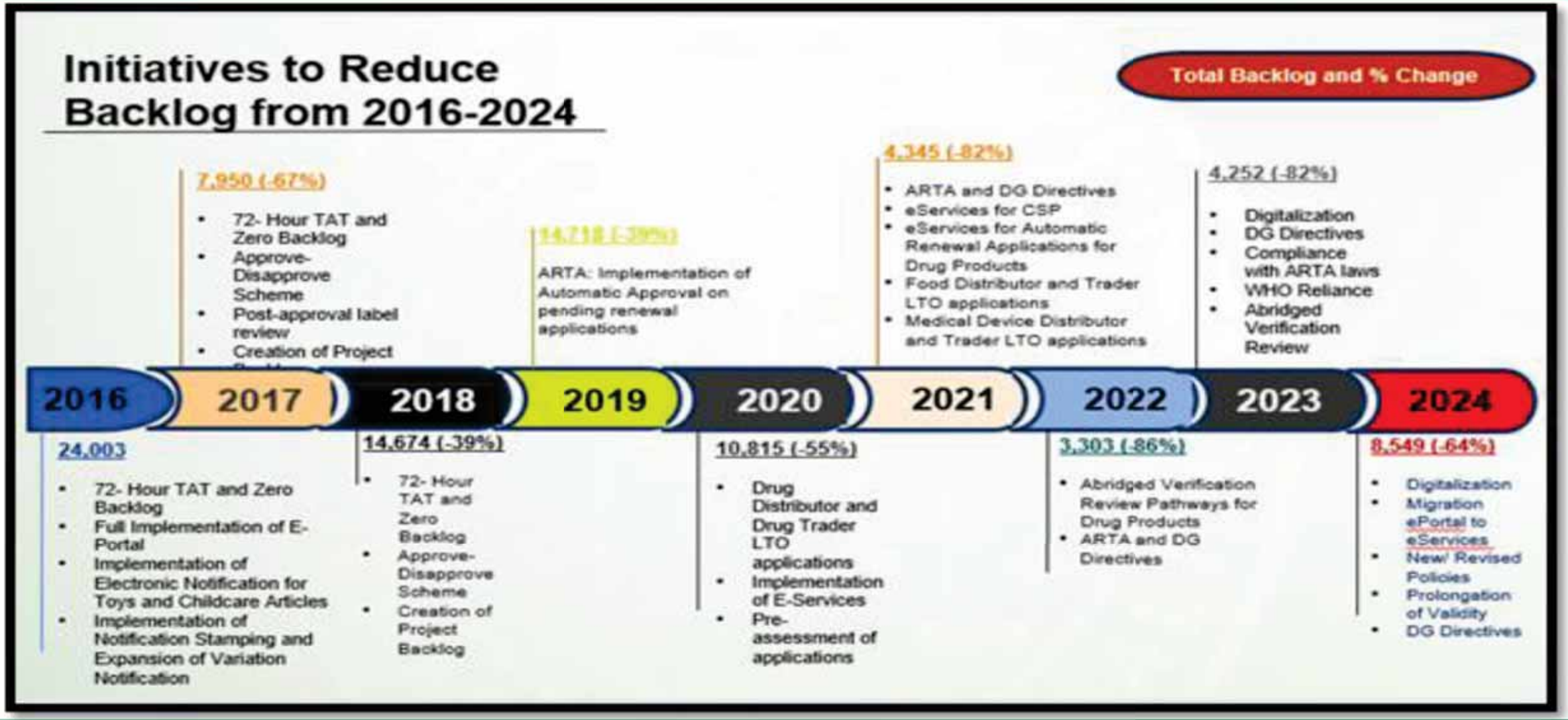
Oplan Katharos

Total estimated amount of Seized Counterfeit Drug Products		**Php 20,925,720.00**
Total estimated amount of Seized Unregistered Health Products		**Php 9,395,451.00**
Estimated Amount of Seized Violative Health Products	CDRR	Php 23,996,730
	CDRRHR	Php 142,200.00
	CFRR	Php 5,345,679.00
	CCHUHSRR	Php 711,762.00
	Total	**Php 30,196,371.00**

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Addressing Backlogs



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Addressing Backlogs

a. DOH Administrative Order 2024-0015: Prescribing the Rules, Requirements and Procedures in the Application for License to Operate

One of the key policy measures under DOH A.O. 2024-0015 focuses on **extending the validity period** of certain licenses, certificates, and registrations issued by the FDA. By prolonging validity, the agency reduces the frequency of renewal applications, which, in turn, alleviates the administrative burden on both the FDA and the regulated industries.

Validity of LTO	Micro and Small Enterprises	Medium and Large Enterprises
Initial LTO	3 Years	6 Years
Renewal LTO	6 Years	12 Years

Addressing Backlogs

b. Administrative Order 2024-0016: New Schedule of Fees and Charges

Complementing the extension of validity periods, DOH A.O. 2024-0016 signifies the updating of the FDA's fees and charges.

These adjustments **are necessary to sustain and enhance the quality of services provided to stakeholders and to meet the growing demand for efficient regulatory processes.**

Addressing Backlogs

c. Facilitated Pathway Review: Expedited Processing of Applications

1. **Abridged Review**: A limited local assessment relying on RDRA evaluations to ensure the product meets local suitability and regulatory standards.
2. **Verification Review**: A validation process for products approved by at least two RDRAs, ensuring conformity with their established standards and requirements.
3. **Collaborative Procedure**: An assessment involving reliance, work-sharing, or joint reviews with international organizations like WHO-PQP or other identified RDRAs.

Addressing Backlogs

d. Administrative Order (A.O.) 2024-0012: Registration of Export-Only and Human Use Products

Administrative Order (A.O.) 2024-0012 prescribes rules for the registration of pharmaceutical products and APIs intended solely for export.

It streamlines requirements for export-focused registrations, promoting the competitiveness of local manufacturers in the global market.

Addressing Backlogs

e. Administrative Order (A.O.) 2024-0013: General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use

Administrative Order (A.O.) 2024-0013 establishes comprehensive regulations for the registration of pharmaceutical products and APIs intended for human use.

Green Lane and Pharma-Dev Zone

Pharma-Dev Zones will serve as **specialized hubs for local and foreign companies** involved in drug and medical manufacturing, including research and development (R&D), clinical testing, and trials

- Support the **production of affordable generic drugs**, bolstering local supply and **reducing medicine costs**
- Empower Filipino SMEs by **fostering opportunities** to manufacture and toll medical products, food supplements, and drugs.

Green Lane and Pharma-Dev Zone

05 October 2023	Issued FDA Personnel Order No. 2023-0924 "Creation of the Technical Working Group on the Development of the FDA Green Lane Guidelines"
14 March 2024	Initial Coordination with FDA, PEZA, and Office of the Special Assistant to the President for the Investment and Economics Affairs
16 July 2024	Meeting with PEZA to finalize draft MOA
31 July 2024	Signing of MOA
1st week of Aug 2024	Endorsement of proposed policy for review/approval prior routing to Centers/Offices

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Green Lane and Pharma-Dev Zone

Aug to Sept 2024	Internal Consultation
October 2024	External Consultation via FDA Website Posting
November 2024	2nd Internal Consultation
December 2024	External Consultation of the Draft Policy with PEZA and BOI
1st Quarter of 2025	Finalize Policy Public Consultation
2nd Quarter of 2025	Approval

Infrastructure and Laboratory

The FDA is dedicated to **strengthening its regulatory capabilities** through targeted investments in **infrastructure and laboratory modernization.**

Infrastructure and Laboratory

North Luzon Cluster

•Letter request sent to administrators of Mariano Marcos State (MMSU) University, after negotiations with Board of Regents for Usufruct agreement for land within their campus in **Batac, Ilocos Norte.**

•Recently concluded site visit for possible Satellite Laboratory in MMSU with personnel of CSL and FDA Engineers. Currently in the process of negotiations and drafting of Usufruct agreement.

Status as of 2024

•Congressional insertion **120 million** for the phase 2 construction of the **Tarlac Regional Office and Laboratory**

•Board of Regents of the **MMSU has granted the request of the FDA,** and the MOA is currently being reviewed.

Infrastructure and Laboratory

North Luzon Cluster

•Letter request submitted to the Office of Governor Ortega- David in La Union, along with talks for inclusion in the Local Government Center of Regional Office.

•Ongoing transfer of subject lot to the Local Government, which will eventually be donated to the FDA for the construction of a mini- laboratory and regional office.

•**Deed of Donation** signed and notarized from the LGU of **Victoria Tarlac.** Future site of Regional Office with laboratory.

Status as of 2024

•**MOA** with DOH RFO II for the construction of the fence for **Tuguegarao property.**

•Letter submitted to Subic Bay Metropolitan Authority (SBMA), with response of the request of the FDA being placed under consideration.

Infrastructure and Laboratory

South Luzon Cluster/NCR	Status as of 2024
• Draft Letter for signature of Director General, to express intent in availing of the proposed lot from the National Government Center Administration Committee (NGCAC)	•Currently in talks with ARTA for a possible partnership to avail the allotment in the NGCAC.
•Letter submitted to the NGCAC for deliberation and approval of specific lot allotment of lot within the NGCAC.	

Infrastructure and Laboratory

Visayas Cluster	Status as of 2024
•Prospective lot has already been identified, and awaiting finalization	•Letter submitted to Governor Garcia requesting for allotment of land in NGCAC in Cebu.
•Allotment for regional office in land donated to the DOH in Cebu.	•Letter request submitted to Governor Aumentado for allotment of land in the Government Center in Bohol for the Testing and Quality Assessment Lab.
•Prospective property in Iloilo currently being worked out with DOH	

Infrastructure and Laboratory

Mindanao East Cluster	Status as of 2024
•Grant from Bureau of Plant Industry of usufruct of real property for Regional Office. Deed of Usufruct in the process of drafting by BPI.	•Deed of Usufruct signed. However, land was subject to agrarian reform as well. Issue currently being worked out with Department of Agriculture.
•Usufruct agreement approved by the BPI and routing for signature of parties on going. Ceremonial signing will be on a later date, subject to availability of heads of agencies that are party to the agreement.	

Infrastructure and Laboratory

Mindanao West Cluster

•Deed of Donation of Real Property in Pagadian City, with area of 2,500 sq. meters, signed by head of LGU of Pagadian and of the FDA. Notarized and with MWC for processing and titling of land into the name of the FDA.

•Fencing of property pending, in compliance with stipulations provided in the Deed of Donation.

•Possible Donation of current site of Regional Office XII being processed and issuance of SPA for transfer of property to FDA's name.

Status as of 2024

•Pagadian property is slotted for fencing.

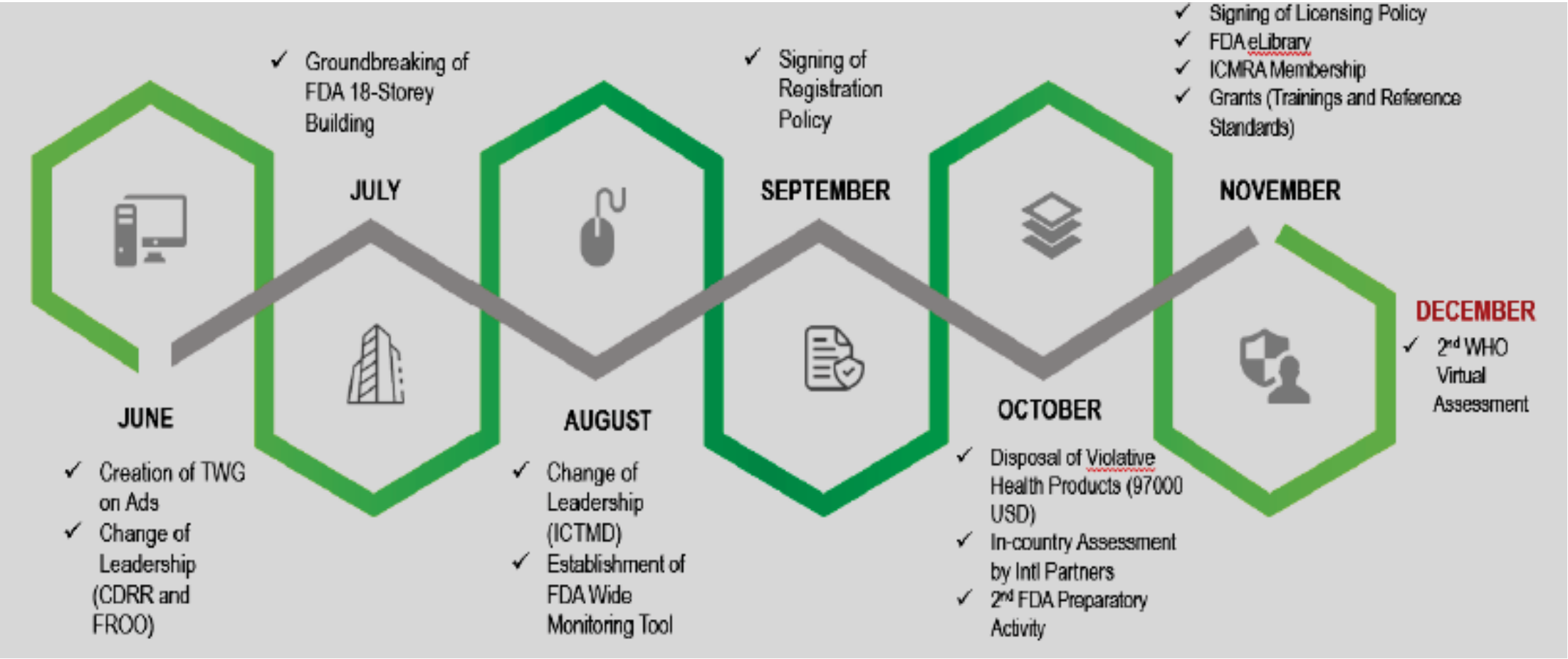
•Transfer of title for RFO XII currently being processed.

The Southern Cross Initiative

- to decrease the number of unregistered products by creating a pathway
- to explore the full potential of the FDA by streamlining all the processes
- to strengthen the post-marketing surveillance (PMS)
- to proceed with the Northern Cross Initiative, i.e., the full implementation monitoring

International Commitment
1. WHO-Global Benchmarking Tool

- **May 21-23, 2024 -** First World Health Organization (WHO) Global Benchmarking Tool (GBT) Virtual Follow-up



International Commitment
1. WHO-Global Benchmarking Tool

On **2-4 December 2024**, FDA Philippines have successfully undergone the 2nd WHO GBT virtual assessment in Tagaytay, City. The agency committed to presenting the status of the IDP and its associated CAPA status. This effort aims to showcase the agency's regulatory progress in its efforts to strengthen regulations, aligning with WHO standards.

International Commitment
2. **Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

PIC/S Indicators:

- **67 of 78 Indicators are Implemented**
- 10 of 78 are Partially Implemented
- 1 of 78 is Not yet Implemented

Objectives:

- Promotes regional trade
- Ensures food safety
- Strengthens cooperation among ASEAN member states

International Commitment
3. **Mutual Recognition Agreements (MRA)**

- Reduces technical barriers
- Streamlines trade processes
- Aligns with the ASEAN Economic Community's (AEC) goal of a single market.

International Commitment
3. **Mutual Recognition Agreements (MRA)**

Objectives:

Facilitate Trade

Protect Consumers and Build Trust

Harmonize Standards

Enhance Regional Cooperation

International Commitment
Mutual Recognition Agreements (MRA)

11 May 2023
Notification of participation to be Party to MRA on PF.

06 June 2023
ASEC acknowledged the receipt of our notification and informed JSC of this matter.

17 October 2023
Submission of Information and Evidence of Compliance to MRA on PF (Annex 1.3 and 1.4 and its attachments).

International Commitment
Mutual Recognition Agreements (MRA)

13 November 2023

ASEC's confirmed that Philippines has complete the required documents as stipulated in Annex 1.3 and 1.4. Submitted documents forwarded to JSC for their information and reference. Then, JSC assigned POE to evaluate the documents and conduct the onsite audit.

11-12 April 2024

Assessment of Submitted Documents for the application to the ASEAN Mutual Recognition Agreement for Inspection and Certification Systems on Food Hygiene for Prepared Foodstuff Products (MRA on PF)

CFRR Cross Regulation with Other Agencies

Bureau of Animal Industry (BAI) and National Meat Inspection Service (NMIS)

Animal diseases that may impact public health, such as African Swine Fever (ASF), Highly Pathogenic Avian Influenza (HPAI), and Bovine Spongiform Encephalopathy (BSE).

Bureau of Fisheries and Aquatic Resources (BFAR)

Fisheries and aquaculture products, including potential risks of contaminants or diseases affecting aquatic species that may pose health risks to humans.

Bureau of Plant Industry (BPI)

Plant products, with attention to risks such as pests or contaminants in dried herbs, spices, and other plant-based food items.

Digitization and Digitalization

Objectives of Digitization and Digitalization:

- To improve regulatory efficiency and safeguard public health
- To streamline its processes, enhance service delivery
- To strengthen regulatory oversight and improve collaboration with stakeholders
- To modernizing operations of FDA

Digitization and Digitalization

Goals of the Digitization and Digitalization

- Digitizing manual records and systems
- Enabling easier access to data
- Promotes transparency
- Effective decision-making
- Facilitating timely access to essential health products

Digitization and Digitalization

Digitalization	
Center	**Percent**
CDRR	47%
CDRRHR	44%
CFRR	57%
CCHUHSRR	46%
Total	**48%**

Migration to eServices	
Center	**Percent**
CDRR	45.65%
CDRRHR	76.27%
CFRR	82.50%
CCHUHSRR	95.60%
Total	**73.40%**

Ways Forward

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Ways Forward – Oplan Katharos

Ongoing and future policies include:

- PMS Inspection and Motu Propio
- Borderline Health Products
- Functional Cosmetics

Ways Forward – **World Health Organization – Global Benchmarking Tool (GBT)**

- **15 September 2025** - Submission of Progress Report:

- Focus Group Discussion with Teams will still be conducted to further discuss sub indicators evidence (policies, guidelines, reports, among others) critical in reaching the target Maturity Level.

- The WHO GBT TWG remains dedicated to working collaboratively and harmoniously maximizing its resources to achieve this international undertaking.

Ways Forward – **Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

- **PIC/S Audit**

  During the 54th PIC/S Committee Meeting on 4-5 November 2024, Virginie Waysbuam from the Agence Nationale de Se curite du Me dicament et des Produits de Sante (ANSM), France, was designated as the lead rapporteur for the Philippines' PIC/S audit.

  The inspection is tentatively scheduled for the fourth (4th) quarter of 2025.

Ways Forward – **Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

- **PIC/S training**

  PIC/S Expert Circle on Quality Risk Management (QRM) Training Event on ICH Q9(R1) hosted by EMA in Amsterdam (The Netherlands) on **28-30 January 2025**, to be attended by GMP Inspectors.

- **Audit Preparations**

  An IOM for the TWG members, detailing the meeting dates for 2025 and preparations for the upcoming audit, was disseminated on 02 January 2025.

Ways Forward – **Mutual Recognition Arrangement (MRA)**

- Finalization of AO on Food Hygiene

- **Q4 2025** – Schedule of On-Site Assessment/Audit

Digitization and Digitalization Initiatives

- Integration of PAYMAYA as an additional payment channel.
- Digitalization of CDRR Initial Prescription Application Process [Manual to Automated] pilot implementation ended 07 August 2024.
- Drug Clearance for Customs Release application in eServices
- X-Ray Clearance for Customs Release application in eServices

THANK YOU

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