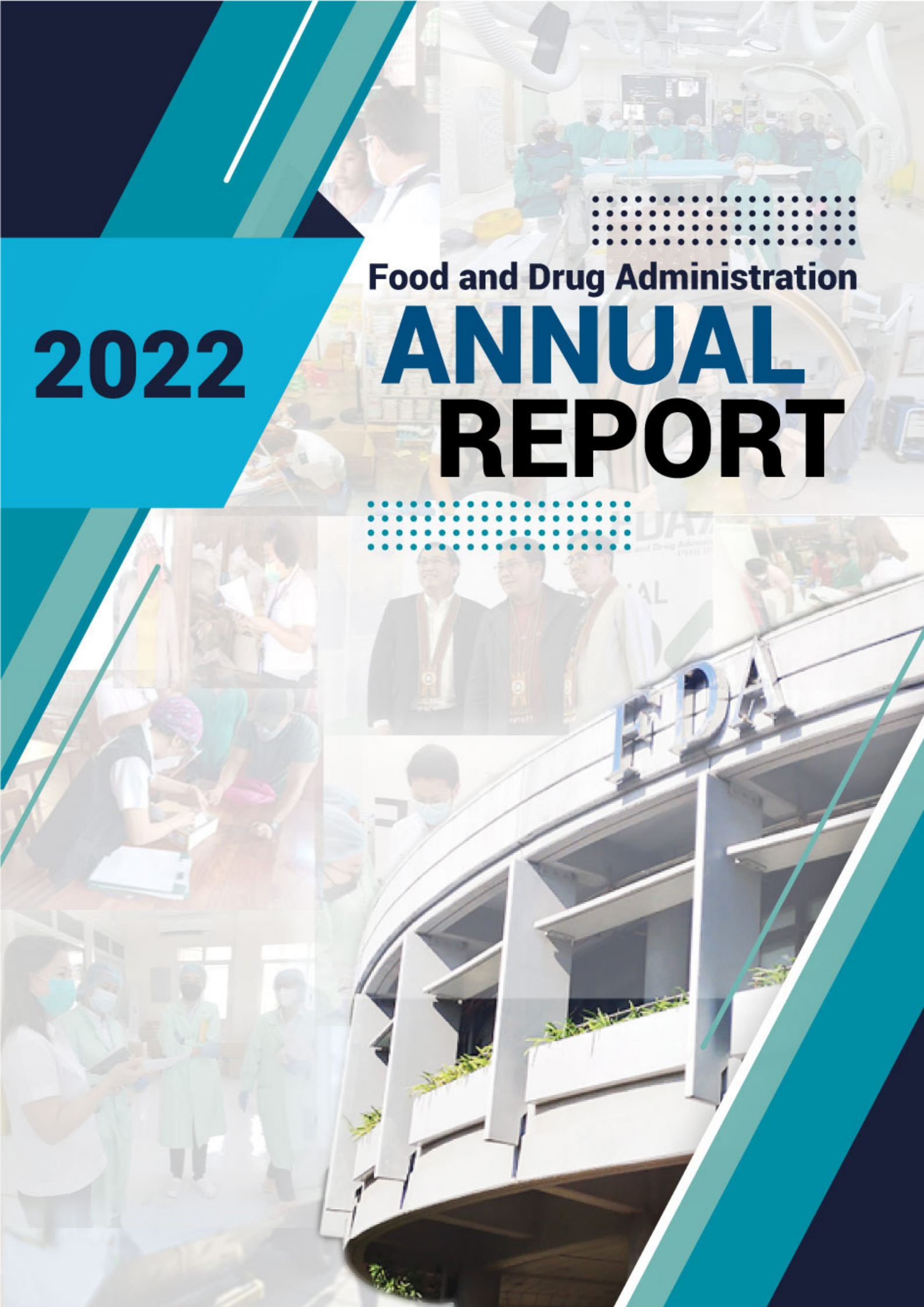
2022

Food and Drug Administration

ANNUAL REPORT



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MESSAGE FROM THE DIRECTOR GENERAL

I am pleased to present the Food and Drug Administration's Annual Report for the year 2022. As the head of the FDA, I am proud to report that our agency has made significant progress in ensuring the safety efficacy and quality of food, drug, cosmetic products, and medical devices.

Throughout the year, our dedicated staff and regulatory experts have worked tirelessly to carry out our mission of protecting and promoting public health. We have achieved several important milestones, including:

- Conducting rigourous safety evaluations of new drugs and medical devices before they are made available to the public.
- Implementing new policies and regulation to provide accessibility to affordable but quality health products to address diseases of public health concern.
- Ensuring the safety of our nation's food supply by monitoring for contaminants and implementing new rules to improve food safety.
- Advancing research and development of innovative treatments for serious and life-threatening diseases.

These accomplishments would not have been possible without the support of our stakeholders, including industry partners, patient advocates, and healthcare professionals. We are greateful for their continued collaboration and commitment to our shared goal of improving public health.

Looking ahead, we remain dedicated to our mission of protecting and promoting public health through science-based regulatory actions. We will continue to work closely with our stakeholders to adddress emerging pulbic health challenges and to ensure that safe and effective products are available to those who need them.

Thank you for your continued support of the FDA.

Sincerely,

Dr. SAMUEL A. ZACATE
Director General

VISION

To be an internationally recognized center of excellence in health product regulation by 2026.

MISSION

To guarantee the safety, quality, purity, and efficacy of products in order to protect and promote the right to health of the general public.

QUALITY POLICY

Ensure the safety, efficacy, quality, and purity of health products by fostering integrity, transparency and excellence; developing and maintaining evidence-based standards and policies, in a healthy and safe work environment.

FDA CORE VALUES

EXCELLENCE - Pagiging Mahusay refers to our Highest degree of professionalism and superior work standard in discharging one's duty

LEADERSHIP - Mahusay na Pamumuno refers to the management thinking that all employees in all levels of public service who, at their best, care and do something about the challenges faced by the FDA

INTEGRITY - Pagiging Matapat refers to our consistent adherence to strong and ethical principles, whether alone or in public

PATRIOTISM - Pagiging Makabayan refers to our love for our country and fellowmen

SPIRITUALITY - Pagiging Maka-Diyos refers to our belief, love and faith for a Higher Being

EXECUTIVE SUMMARY

The Calendar Year (CY) 2022 is a critical year for the Food and Drug Administration since restrictions are starting to loosen, following the country's new normal guidelines. After (2) two-years since the start of the Covid-19 pandemic, the FDA has been continuously evolving, adapting to the use of technologies to improve its services and at the same time, complying with global standards to ensure that health products in the market are safe, effective, and of quality.

Program Expenditure Classification (PrExC) Performance Indicator

The FDA has been consistently performing well, achieving 100% of the agency's Congress approved PrExC performance indicator targets for the CY 2022, utilizing 74.28% of its allocated budget for Maintenance and Other Operating Expenses (MOOE) and Capital Outlay (CO) amounting to 567,938,000.00. With a disbursement rate of 85.34%, the FDA to attained the highest possible score of 5 in one of the criteria on the Performance-Based Bonus, pursuant to Inter-Agency Task Force on the Harmonization of National Government Performance Monitoring, Information, and Reporting Systems based on Memorandum Circular (MC) No. 2022-1 dated 24 March 2022. In the said MC, the highest financial result for Fiscal Year (FY) 2022 is between 80-100% Disbursement Budget Utilization Rate. The table below summarizes the financial accomplishment of the Agency for FY 2022.

Object of Expenditure	Allocation	Utilization	% Utilization
MOOE	527,368,000.00	421,716,841.18	**79.97%**
CO	40,570,000.00	160,000.00	**0.39%**
Total Fund	567,938,000.00	421,876,841.18	**74.28%**

Table 1. FDA Budget Performance for FY 2022

As the agency adapts to new technologies, there has been a 21,000 increase in applications received in CY 2022 compared to the previous year. However, with a slight decrease in the human resource complement from last year, along with the increase in coverage of regulated health products, specifically for medical devices, which significantly contributed to the total number of applications FDA receives, there was an expected decrease in the total percentage of applications processed within the Citizen's Charter timeline from 92.64% to 86.57%. Despite these challenges, the agency achieved its target of 85%, with a variance of above 1.57%.

COVID-19 Response

Adverse Events Following Immunization to COVID-19 Vaccines

As of 31 December 2022, the FDA received 111,639 cumulative reports on Adverse Event Following Immunization (AEFI). This is 0.07% of the total doses administered (169,627,564). The Philippines remains to be one of the top countries with the most reported AEFIs to COVID-19 vaccines.

The agency, together with other public health partners, is continuously monitoring the safety of COVID-19 vaccines. Reports of Suspected Adverse Reactions to COVID-19 Vaccines are published monthly and posted on the FDA website.

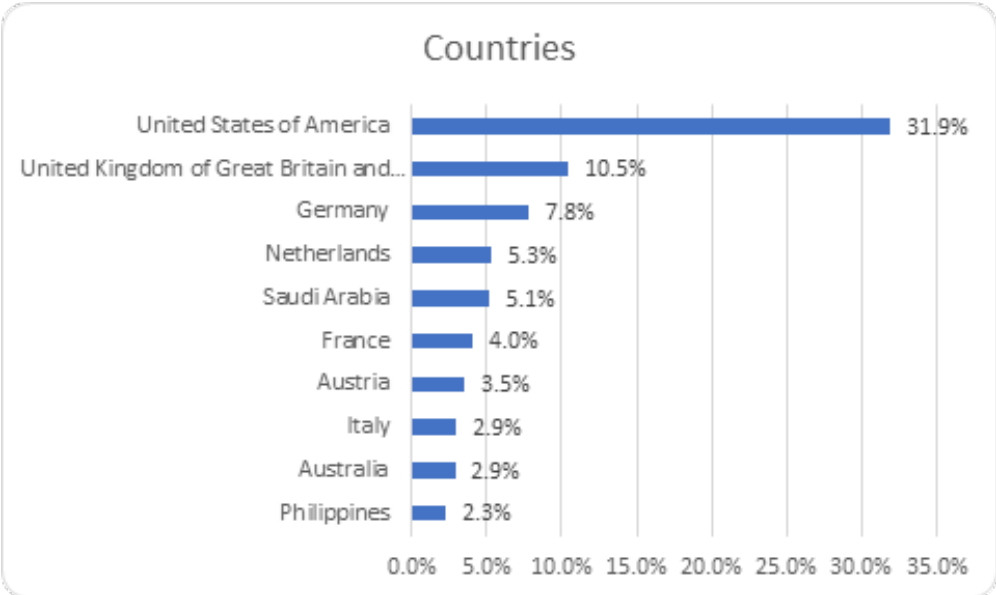


Fig 1. Top countries with the most reported AEFIs to COVID-19 vaccines.

Response in Public Health Emergency Due to COVID-19

As early as 2020, the FDA is one of the primary government agencies eagerly responding to the pandemic brought about by SARS-CoV-2 causing COVID-19. In 2022, the Pharmacovigilance Section of the CDRR continuously monitored the safety of COVID-19 vaccines used in the PinasLakas campaign, previously known as Resbakuna Kasangga ng Bida. The team started monitoring the vaccines since its rollout in 2021.

The FDA has been part of the National Task Force Against COVID-19 which spearheads the Special Task Group on Safety Surveillance and Response Team with the DOH-Epidemiology Bureau and other agencies. The FDA is also a member of the Task Group Vaccine Evaluation and Selection led by the Department of Science and Technology (DOST). The FDA regularly meets with other teams of the National COVID-19 Vaccination Operations Center (NVOC) housed in the Philippine International Convention Center (PICC), Pasay City, chaired by Undersecretary Myrna C. Cabotaje.

Ms. Carolyn P. Custodio, Dr. Iris Conela D. Tagaro, and Mark Ryann A. Lirasan, representing the FDA in collaboration with various government agencies.

In April 2022, the polishing of the revision of The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines was held in Baguio City in preparation for the transition of the new administration of President Ferdinand B. Marcos, Jr. from the previous Duterte administration.

Launching of the Electronic Post Marketing Surveillance (ePMS)

The Covid-19 pandemic has brought challenges to the operations of the Food and Drug Administration. The series of lengthy lockdowns had limited the functions of the FDA which had a crucial role in safeguarding public health. To augment the work capacity of the Center for Cosmetics and Household/ Urban Hazardous Substances (CCHUHSRR), the Product Research and Standards Division launched the Electronic Post Marketing Surveillance (ePMS). This digitalized the conduct of Post-Marketing Surveillance activities within relevant FDA Offices. The development of the ePMS started in January 2019. The first working version of the ePMS was approved by the Director General Rolando Enrique D. Domingo by virtue of FDA Order 2020-065 issued on 26 February 2020.

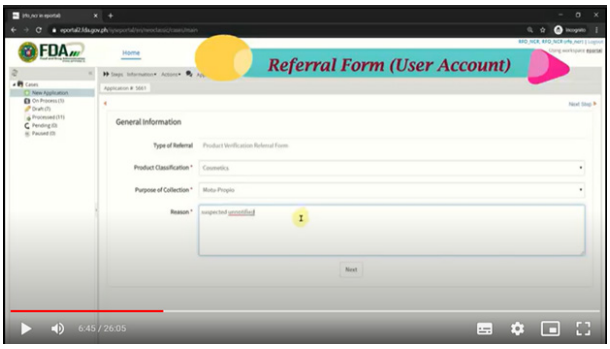


Fig 2. Video Tutorial on ePMS uploaded on the FDA Website

Since then, updates have been continuously introduced to further enhance the efficiency of the electronic platform. Currently, the system includes the verification process for products, licenses, advertisements and promos, referred by the Field Regulations Operations Offices and Regional Enforcement Units to CCHUHSRR and the Center for Food Regulation and Research.

The system allows the automation of certain steps, such as the sending and receiving of requests and feedback, and the drafting of Product Verification reports, FDA Advisories and Orders. Another feature of the system is its accessibility within or outside the FDA. The system also facilitated the removal of the submission of actual collected food/cosmetic samples by the requesting entity to the Center. Despite the limitations provided by the pandemic, ePMS has been useful as a system to enable PMS activities. With its digital features and accessibility, data gathering and monitoring for PMS has become easier for the FDA.

Regulation of COVID-19 Related Medical Devices

The fight against the COVID-19 virus is far from over. The CDRRHR continues to be one of the Offices providing services to the country in combating the spread of the virus through the regulation of Covid-19 related medical device products. The regulation aims to ensure continuous access to safe and quality Covid 19 medical devices such as, but not limited to COVID-19 test kits, ventilators, clinical and non-contact thermometers, personal protective equipment facemasks which includes protective clothing, gloves, head cover, and shoe cover.

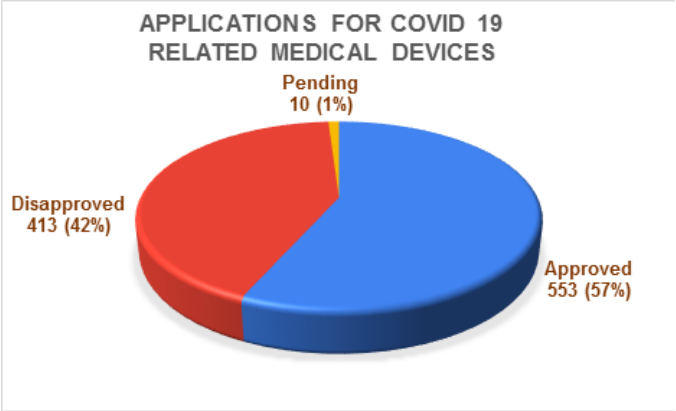


Fig 3. Applications for COVID-19 related Medical Devices

Out of the nine hundred and seventy-six (976) COVID -19 related applications for 2022, ninety-nine percent (99%) or nine hundred sixty-six (966) were processed accordingly and only one percent (1%) or ten (10) applications received during the last days of 2022 were for evaluation in January 2023.

Collaboration with the Department of Science and technology - Philippine Textile Research Institute

The use of personal protective equipment (PPE), specifically the facemasks, will continue for quite a period of time. Thus, testing of these PPEs are important to ensure that they will serve their purpose as intended by the manufacturers.

On 18 October 2022, the CDRRHR had a meeting with the DOST-Philippine Textile Research Institute (PTRI). The meeting aims for possible collaboration with DOST-PTRI regarding the testing of PPEs.

Monitoring and Inspection of Vaccines in Cold Chain Facilities

The FROO Regional Field Offices were able to inspect/monitor 88 cold chain facilities storing COVID-19 vaccines in the country for 2022 to ensure that the COVID-19 vaccines administered to the Filipino people are being stored, transported, and distributed all over the country in accordance with WHO Cold Chain Guidelines/Requirements.

RFO V also conducted price monitoring of COVID-19 related medicines and health products in Naga City, Camarines Sur on 16 February 2022

Policies

Senate Bill (SB) No. 230 or the proposed Medical Cannabis Compassionate Access Act of the Philippines

Ms. Lanette Lee A. Querubin, RPh, MSc, Chief, CDRR-PRSDD representing the FDA in the Senate Hearing for Medical Cannabis Compassionate Access Act of the Philippines.

On 13 December 2022, Lanette Lee A. Querubin, RPh, MSc, Chief of the Product Research and Standards Development Division (PRSDD) of the Center for Drug Regulation and Research (CDRR), attended the Senate Hearing for the Medical Cannabis Compassionate Access Act of the Philippines.

In the said committee's hearing on Senate Bill (SB) No. 230, president Dr. Donnabel Trias-Cunanan of Cannahopefuls Inc. said the bill — authored by Senator Robinhood Padilla — would allow the safe purchase of cannabis-based products for the treatment of epilepsy and cerebral palsy.

Sen. Padilla's SB No. 230 seeks to allow the use of cannabis-based treatment and supplements to aid debilitating medical conditions such as:

- Cancer
- Glaucoma
- Multiplesclerosis
- Damage to the nervous system of the spinal cord, with an objective neurological indication of intractable spasticity
- Epilepsy
- Positive status for human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS)
- Rheumatoid arthritis or similar chronic autoimmune inflammatory disorders
- Diseases requiring admission into hospice care
- Severe nausea of any cause
- Sleep disorders, including insomnia and sleep apnea
- Mood disorders including severe anxiety, panic attacks, bipolar disorder, depression, post-traumatic stress disorder, social anxiety disorder
- Recurring migraine headaches

Issuance of Updated Policies Regulating Pest Control Operators and their Services

Affirming the mandate of the FDA, the Center for Cosmetics and Household/ Urban Hazardous Substances Regulation and Research has been continuously seeking ways to promote the general public's safety by updating the regulation responding to the needs of the times. The industry of pest control operators (PCO) and their services is an industry that was previously under the regulation of the Fertilizer and Pesticide Authority (FPA), until the issuance of Republic Act No. 9711 or the "Food and Drug Administration Act of 2009" transferring such to the FDA.

Under the initiative of the Policy team of the Products Research and Standards Development Division, the CCHUHSRRR amended Administrative Order (AO) No. 2019-0010 entitled "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers" on 10 Aug 2022. The purpose of the amendment was to respond to the call of the regulated stakeholders to allow the supervision of pest control activities of multiple branch offices of a PCO by a single Supervising Pesticide Handler and to include application of disinfectants among activities performed by PCOs.

Pursuant to such changes and to provide the implementing guidelines of the DOH AO, the FDA, through CCHUHSRR developed and issued FDA Circular No.2022-010 and was recently published on 30 December 2022.

Approved and Published Policies for Medical Devices

1. FDA Circular No. 2021-002-B: Amendment to FDA Circular No 2021-002-A entitled "Addendum to FDA Circular No. 2021-002 Re: Full Implementation of AO No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a MD based on the ASEAN Harmonized Technical Requirements" (The Manila Times - 17 May 2022)

2. FDA Circular No. 2022-003: Banning of all Mercury-Added Thermometers, Sphygmomanometers, Dental Amalgam Capsules, and Liquid Mercury for Use in Dental Restorative Purposes (Published in The Philippines Star - 1 July 2022)

3. Publication of AO No. 2022-0022: Basic Radiation Protection and Safety Standards on the Use of Ionizing Radiation Devices in Planned Exposure Situation (Philippine Star - 23 August 2022)

4. FDA Circular No. 2022-008: Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country (The Manila Times – November 2022)

Updating of Radiation Regulatory Policies

CDRRHR has become adamant in the development and updating of radiation regulatory policies. FDA Circular No. 2017-013 or the "Guidelines on the Issuance of Clearance for Customs Release of Radiation Devices by the FDA-CDRRHR" has been amended with the issuance of FDA Circular 2017-013-A on 30 June 2022. This has successfully harmonized the policy on the importation of medical radiation devices in line with the provisions of DOH Administrative Order No. 2018-0002 entitled, "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" and its subsequent implementing FDA Circulars.

Adoption of the 2014 International Atomic Energy Agency's (IAEA) General Safety Requirements (GSR) Part Three (3)

CDRRHR has successfully adopted the 2014 International Atomic Energy Agency's (IAEA) General Safety Requirements (GSR) Part Three (3) entitled, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards" through the issuance of DOH Administrative Order No. 2022-0022 or the "Basic Radiation Protection and Safety Standards on the Use of Ionizing Radiation Devices in Planned Exposure Situation." This Order aims to update the national basic radiation protection and safety standards for radiation devices repealing DOH AO No. 149 s. 2004 or the "Basic Standards on Radiation Protection and Safety Governing the Authorization for the Introduction and Conduct of Practices involving X-ray Sources in the Philippines, as amended, and Department Circular No. 323 s. 2004.

Rationalized Guidelines for the Conduct of Regulatory Inspections for Radiation Facilities

The new rationalized guidelines in the conduct of regulatory inspections for radiation facilities were issued as FDA Circular entitled "Conduct of Regulatory Inspections for Radiation Facilities", on 28 December 2022. This guideline operationalized and supplemented the provisions of DOH AO No. 2020-0035 or the "Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations" and has repealed FDA Circular No. 2020-035 or the Interim Guidelines for the Inspection of Radiation Facilities During the COVID-19 pandemic.

In-depth Legal Assessment and Review of the Submitted Proposed Legislations

The Legal Services Support Center (LSSC) by virtue of its duties and function embodied in Republic Act (R.A.) No. 3720, as amended by R.A. No. 9711, has provided legal assistance through legal review of some of the major House and/or Senate Bills/Acts relating to the regulatory power of the Food and Drug Administration.

In consideration of the anticipated impact of the submitted draft Bills in the FDA's mandate and regulatory function, the LSSC had undertaken a thorough assessment of these Bills not only on the health aspect implementation thereof but also taking into account a holistic or whole-of-government approach in order to have a clear view of possible linkages or interaction with other government agencies or entities that the implementation might entail. Accordingly, the FDA has submitted its official position paper based on the comments from the FDA's LSSC's taking into consideration the available inputs from relevant FDA technical centers and offices.

The FDA's official position paper were submitted on the following relevant House and/or Senate Bills/Acts for CY 2022.

1. Traditional and Alternative Medicine Act 2022-0080;

2. Proposed Bill on the Biological and Toxin Weapon Act of 2021;

3. Consolidated Enrolled House Bill No. 90007/Senate Bill No. 2239, entitled, "An Act Regulation the Importation, Manufacture, Sale, Packaging, Distribution, Use, and Communication of Vaporized Nicotine and Non-Nicotine Products, and Novel Tobacco Products";

4. Proposed (a) House Bill No. 337, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing Programs for Micro, Small and Medium Enterprises"; (b) House Bill No. 641, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing And Other Support Programs for Micro, Small and Medium Enterprises"; (c) House Bill No. 713, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing Programs for Micro, Small and Medium Enterprises"; (d) House Bill No. 1178, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing and Other Support Programs for Micro, Small and Medium Enterprises (MSMEs)"; (e) House Bill No. 2463, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing and Other Support Programs for Micro, Small and Medium Enterprises"; and (f) House Bill No. 2622, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing Programs for Micro, Small and Medium Enterprises (MSMEs)";

5. Proposed Substitute Bill, entitled, "Philippine Center for Disease Control Act";

6. Proposed (a) House Bill No. 4501, entitled, "An Act Further Promoting Entrepreneurship by Strengthening, Empowering and Enhancing the Financing Programs for Micro, Small and Medium Enterprises"; and (b) House Bill No. 4821, entitled, "An Act Further Promoting Entrepreneurship by Strengthening the Financing And Other Support Programs for Micro, Small and Medium Enterprises";

7. Proposed Various House Bills on the Virology Institute of the Philippines, in relation to the Matrix of House Bills, namely: (a) HB No. 10, et al – "An Act Establishing the Philippine Virology Science and Technology Institute and Appropriating Funds Therefor"; (b) HB No. 308, et al – also entitled as "An Act Establishing the Philippine Virology Science and Technology Institute and Appropriating Funds Therefor" (a leaner version of HB No. 10, et. al); (c) HB No. 1710 - "An Act Providing for the Framework for the Establishment and Operation of Virology Laboratories in the Philippines, creating for the Purpose the Virology Science and Technology Institute of the Philippines, and Appropriating Funds Therefore and for Other Purposes;" and (d) HB No. 2979, et al - "An Act Creating the Virology and Vaccine Institute of the Philippines, Defining its Powers and Functions, Providing Appropriations

Therefor, and for Other Purposes.";

8. Proposed House Bill No. 1976, also known as the Philippine Salt Industry Development Act; and

9. Proposed House and Senate Bills Amending Republic Act No. 9165, otherwise known as the Comprehensive Dangerous Drug Act of 2022.

10. Regulation of Stem Cell Facilities

11. Position Paper on Senate Bill Nos. 247, 260, 286, 424, 946 and 1246 known as the One Town, One Product (OTOP) Philippines Act of 2022

12. Medical Cannabis Compassionate Access Act of the Philippines

Direct and Active Participation in the Deliberation of the following Proposed Bills/ Repeal of Existing Law:

1. Philippine Center for Disease Control (CDC) Act (08 November 2022)

2. Virology Institute of the Philippines (08 November 2022)

3. Repeal of Republic Act No. 8203 otherwise known as "Special Law on Counterfeit Drugs" (29 November 2022)

Capability Development on the Institutionalization of Regulatory Impact Assessment (RIA) in the FDA

The Policy and Planning Service invited Ms.Lea Peralta, Project Manager (MGR Program) of Development Academy of the Philippines (DAP) as resource speaker for the Workshop

In compliance with Section 5 of Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018", National Government Agencies are directed to perform Regulatory Impact Assessment (RIA) for all proposed regulations, to with: "to establish if the proposed regulation does not add undue regulatory burden and cost to these agencies and the applicants or requesting parties". Hence, to further support the institutionalization of RIA in the FDA, developing a comprehensive manual that aims to strengthen the FDA's policy making capacity in conducting RIA is deemed imperative.

Dr. Irene V. Florentino-Fariñas, OIC, Director III of the Policy and Planning Service delivering the opening remarks of the program

The Policy and Planning Service initiated the Capability Development project, which aimed to facilitate the development of a guidance document on RIA in the context of FDA and identify measures, including policy support, to institutionalize the practice of RIA in the agency.

Monitoring and evaluation of Radiofrequency Radiation (RFR)

Training for Health Physicists on using the new Wave Control RFR monitoring device RFR monitoring, radiation protection surveys and evaluation.

To further enhance the capabilities of CDRRHR in monitoring and evaluating Radiofrequency Radiation (RFR) facilities and devices, an additional RFR monitoring device was procured in June 2022, for the enforcement and verification of RFR safety standards by the Health Physics team.

Discussion on the Appeal Process, Statute of Limitations, Graduation of Penalties, Rules on Disposal

On 05 - 07 October 2022, the LSSC discussed the appeal process, statute of limitations, graduation of penalties, rules on disposal, and other matters with participants from ODDG-FROO, ODDG-IM, and PPS. The following are the objectives of the meeting:

- Enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;
- Ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdictions; and
- Provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

Monitoring and evaluation of Radiofrequency Radiation (RFR)

Cardiac Catheterization technical evaluation and DRL data collection training of FDA-CDRRHR Health Physicists at Asian Hospital and Medical Center

CDRRHR has also initiated the collection of data for the establishment of the Philippine National Diagnostic Reference Levels (NDRL) for facilities under the jurisdiction of the FDA from May – September 2022. A total of seventeen (17) cardiac catheterization facilities were visited and tested for quality assurance and machine performance in line with the specifications set for NDRLs establishment. Evaluation and processing of data collected from targeted facilities are geared towards the publication of the NDRL within 2023.

Cardiac Catheterization technical verification test

FDA Preparation to meet the Maturity Level 3 as a functional NRA for Pharmaceuticals and Vaccines using the WHO computerized Global Benchmarking Tool (cGBT)

In reference to agenda item no 15.6 as stated during the 67th World Health Assembly Resolution No 6720 dated 24 May 2014, entitled "Regulatory system strengthening for medical products", all Member States were urged to strengthen national regulatory systems by undergoing self-evaluation through the application of the WHO evaluation tools which will identify and address gaps to reach a level of regulatory oversight capacity commensurate with a stable, well-functioning, and integrated regulatory system.

Accordingly, the use of the WHO global benchmarking tool (GBT) as the primary means by which WHO assesses regulatory systems for regulating medical products was introduced. The GBT enables the WHO and regulatory authorities to: 1) identify areas of strength as well as areas for improvement; 2) facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps; 3) aid in the prioritization of investments in IDP implementation; 4) to help monitor progress. It is designed to evaluate the overarching regulatory framework and the component regulatory functions. Further, it also incorporates the concept of 'maturity level' or ML (adapted from ISO 9004), allowing the WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).

In this regard, FDA Order 2021-0332, dated 01 July 2021, was issued to formally initiate the agency's journey to become a functional Regulatory Authority and reach its target Maturity Level (ML) 3. Further, the FDA Order was later amended to designate a pool of secretariat, include additional offices/ members to support the team and address the movement of FDA personnel, including the resignation of some of its members. Weekly virtual meetings were held during the pandemic requiring all focal points assigned in each respective nine (9) functions to give updates on their progress collaborate with colleagues from within the agency and other external institutions to help address the requirements stated in the indicators of the GBT.

On 13 - 16 June 2022, A ten-member WHO Team conducted an initial assessment (Pre-Benchmarking) of the FDA. During the four-day activity, details of which are presented in section II of this document.

To ensure FDA's realization of its target to reach ML3, FDA Order No. 2022-0731 dated 21 September 2022, was issued reorganizing and including additional members to the previously created Order. At this point, a directive to act using a wholistic approach was issued to address the identified gaps as stated in the initial assessment of the WHO.

Further, various meetings and activities are being conducted and hosted by the focal teams to directly address the required documents and compliance. Draft FDA Orders and Administrative Orders (listed in the Section II and Section III of this document) are in the process of completion for its implementation will be used as pieces of evidence in compliance to the uncomplied GBT sub-indicators to achieve its goal of reaching ML3. These documents, such as but not limited to revised FDA issuances, IMS-related procedures and records, and latest revised GBT data (responses to the GBT) are regularly uploaded in the WHO sharepoint.

Finally, on 9 December 2022, the FDA has formally submitted to the WHO Country Office, through the office of the BIHC, its intent to be assessed formally on the first quarter of 2023.

Licensing and Registration

Processing of Applications for FDA Authorizations

The enactment of Republic Act (RA) No. 7160, otherwise known as the Local Government Code (LGC) of 1991 led to the establishment of dual governance in the health sector, with the Department of Health (DOH) governing at the national level and the Local Government Units (LGU) at the sub-national level. The DOH serves as the over-all steward and technical authority on health being the national health policy-maker and regulatory institution. It is mandated to develop national plans, technical standards, and guidelines on health. It is also in charge of licensing hospitals, laboratories and other health facilities through the Health Facilities and Service Regulatory Bureau (HFSRB), and health products through the FDA.

The FDA is responsible for safeguarding the safety, efficacy and quality of health products and devices. Pursuant to RA No. 9711, otherwise known as the "Food and Drug Administration Act of 2009," strengthened the administrative and technical capacity of the FDA to regulate health products, pharmaceutical products, drug manufacturers, wholesalers and retailers, and medical devices. Entities involved in the manufacture, importation, exportation, sale, distribution, transfer, non consumer use, promotion, advertising or sponsorship of any pharmaceutical or health product are required to secure LTOs and certifi cates of product registration (CPRs)

PERFORMANCE INDICATORS

HEALTH REGULATORY PROGRAM			
	Target	Accomplishment	Variance
Outcome Indicators			
Percent of health establishments and health products compliant to regulatory policies	75%	86.44% (79,539/92,018))	11.44%
Output Indicators			
Percent of applications for permits, licenses, or accreditation processed within the Citizen's Charter Timeline	85%	86.57% (233,385/269,596)	1.57%
Percent (& Number) of establishments and health products monitored and evaluated for continuous compliance to regulatory policies	65% (74,854)	69.07% (79,539)	4.07%

Fig. 4. 2022 Budget Accountability Report

In 2022, the FDA continued to improve its performance and commitment to reduce the processing timeline of applications wherein 86.57% or 233,385 out of 269,596 applications received for licensing, registration and other permits were processed within the committed timeline.

Post-Market Surveillance (PMS)

REU Enforcement

The Regulatory Enforcement Unit (REU) of the FROO has confiscated/seized more than Three Hundred Million (PHP 325,947,810.30) worth of unregistered and counterfeit health products for 2022.

The FDA REU was able to serve 724 legal orders; acted upon 335 referrals in the form of complaints from stakeholders and other Law Enforcement Agencies (LEAs) and 164 surveillance activities through online monitoring of E-Commerce Platforms, establishments and alleged illegal products in the market. The REU is continuously coordinating with the FDA Inspectorate and other law enforcement agencies by ensuring that only safe, quality, and effective health products are available to the Filipino people.

PMS Data

For 2022, the target number of health establishments and products for monitoring and evaluation is 74,854 or 65% of the 115,160 estimated registered health establishments and products. The agency was able to achieve 69.07% 79,539 exceeded its annual target by 4.07%.

As the year 2022 ends, the percentage and number of health establishments and health products compliant with FDA's regulatory policies has reached 86.44% (79,539/92,018)

Region II Monitoring and Seizure of Violative Health Prodcuts

Foreign GMP Applications

Due to the COVID-19 outbreak, the conduct of foreign inspections remained suspended in 2022. But to address the pending applications, the validity of FDA Circular No. 2020-020 was extended. It provided the interim guidelines for the thorough evaluation of submitted applications for GMP Clearance which was recommended for inspection, and the appropriate action was given to facilitate imported drug product registration and inspection of foreign manufacturers in the country.

In 2022, 166 Recommended Letters were issued by FROO for the issuance of Permit to Register.

Trainings and Seminar

Trainings/Workshop and Policy Review in line with the engagement of Dr. Anabelle Villalobos under the DOST Balik-Scientist Program

CDRR-PRSDD with Dr. Annabelle Villalobos

Dr. Annabelle Villalobos, US-Based Filipino Scientist with extensive experience in Biopharmaceuticals, who was engaged by the Department of Science and Technology (DOST) under the Balik-Scientist Program (BSP) conducted the following trainings/ workshops to FDA inspectors and registration evaluators:

- Manufacturing of Biologicals including vaccines
- Quality Control – Microbiology
- Validation of Biological Manufacturing Process

The training aimed to have an understanding of the following:

- Manufacture, control and testing of biological products for human use – from starting materials and preparations (including seed lots, cell banks and intermediates) to the finished product.
- Process of manufacturing of biological products using different biological sources and biotechnology (mRNA vaccines, virus-vectored vaccines, protein subunit vaccine) and Biotech products which is critical in the evaluation of drug product dossier.
- Development of Investigational Products (IP), with focus on vaccines (including COVID-19) and standardized herbal drugs
- Review of pharmaceutical data of IP
- Concept of Biosimilars
- Overview of product development of biosimilars
- Overview of quality data review
- Clinical data requirements to support the product registration of biosimilars

DOH All Health Experts Convening from COVID-19 to UHC

DOH All Experts Convening From COVID-19 to UHC

On April 29, 2022, the Department of Health (DOH) held a recognition program for DOH All Health Experts with the theme: "Looking Back, Marching Forward: DOH All Health Experts Convening from Covid-19 to UHC." This program was held to give appreciation to the many scientific experts who guided the DOH, the Inter-Agency Task Force (IATF) for the Management of Emerging Infectious Diseases, and the Philippine government in the successful pandemic response over the last two years.

The program featured a speech by the World Health Organization (WHO) regional director for Western Pacific Dr. Takeshi Kasai, who commended the Philippines for its rigorous science-based approach. He also highlighted how the Philippine government became one of their models in the region for its innovative response of rapidly adopting the latest scientific findings into policy. For instance, the early decision to deploy boosters at three months from the second dose was seen as an integral strategy in tempering the BA.2 wave in January 2022.

ASEAN Cosmetics Association Workshop – Winning in ASEAN

The CCHUHSRR attended a two-day webinar spearheaded by the ASEAN Cosmetics Association entitled "Winning in ASEAN" on September 28-29, 2022. The presentations on the first day of the workshop focused on the cosmetics trend in terms of innovative and sustainability practices from the industry, and the upcoming changes and challenges of claim communication and its corresponding evaluation brought by the digital transformation and ASEAN harmonization. On the second day, Mintel, a marketing intelligence agency, presented their market insights for the cosmetics industry. The International Fragrance Association (IFRA) also gave a presentation discussing key topics for collaboration with the ASEAN Cosmetics Scientific Body, an overview of the IFRA standards, and the quantitative risk assessment for skin sensitization (QRA2).

The event was fully attended by the cosmetics industry professionals for regulatory, business development, and branding/marketing and regulators from ASEAN member states.

Natural Ingredients and Regulatory Update: A Webinar by the Philippine Society for Cosmetic Science, Inc.

During the technical seminar hosted by the Philippine Society for Cosmetic Science, Inc. entitled, "An Overview on Natural Ingredients", the FDA through CCHUHSRR shared its expertise through a presentation of the regulatory updates from the ASEAN Cosmetics Scientific Body and FDA regulations of natural products.

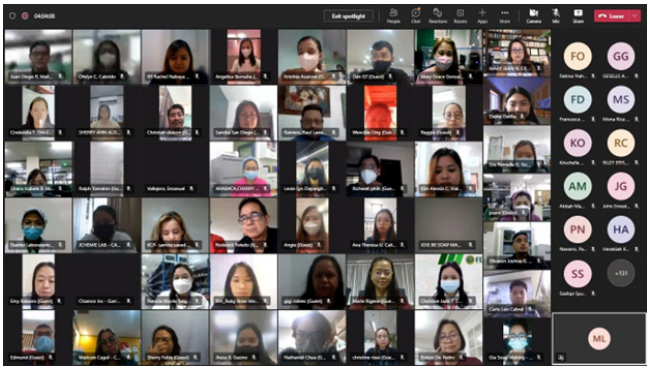
Technical Assistance to the FDA Regional Inspectors (Visayas and Mindanao Cluster)

The FDA through CCHUHSRR conducted workshops in September and October 2022, which aimed to enrich the knowledge and deepen the expertise of the FDA regional inspectors from the Visayas and Mindanao clusters on topics relevant to the regulation of cosmetics, household/urban hazardous substances, including household pesticides and toys and childcare articles. With the recent changes and developments in the regulatory policies and practice, industry landscape, and structure of the Center, capacitating the field regulatory officers is vital since they are the FDA link to the industry.

The primary agenda of the 3-day workshop was to cascade the functions and processes of the CCHUHSRR. Topics included updates on the registration/notification and post marketing surveillance activities of the health products and licensing of establishments that are under its jurisdiction. The event also highlighted a workshop on the review of product information files of cosmetic products which will be useful for the assessment of safety and routine field inspection. Likewise, the Visayas and Mindanao regional inspectors conveyed their issues and concerns especially those that are arising from their fieldwork experiences.

CCHUHSRR Stakeholder Technical Assistance on Post Marketing Surveillance (PMS)

On December 02, 2022, CCHUHSRR held a webinar entitled, "CCHUHSRR Stakeholder Technical Assistance on Post Marketing Surveillance", which aimed to improve the understanding of Market Authorization Holders on the post marketing surveillance activities conducted by the agency.



Post marketing surveillance, as one of the core processes of the FDA, aims to ensure the safety, efficacy, and quality of the notified health products. PMS activities include the following:

1. Product verification of collected market samples
2. Post-evaluation for notified cosmetics,
3. Handling of consumer complaints,
4. Monitoring of promotions and advertisements
5. Disposition of products tested as out-of-specifications
6. Product recall
7. Verification of product authenticity,
8. Product information file audit
9. Filing of reports of violation
10. Issuance of FDA Advisories.

Participation in the DOH's Philippine Acceleration Action Plan for Tuberculosis (PAAP-TB)

The CDRRHR participated in the DOH's Philippine Acceleration Action Plan for TB (PAAP-TB) and its sectoral consultation and consolidation workshop held on October 19, 2022 and November 11, 2022 respectively. A series of TWG meetings was conducted in 2022 for the Innovations and Technology Program for TB screening. Deployment of portable x-ray machines and TB screening kits at identified sites in the Philippines were initiated as part of the program to eliminate TB.

Participation in the Telco Summit 2022

Ms. Maria Gladys R. Cabrera of CDRRHR-RRD, representing the participation of FDA in the Telco Summit 2022.

The FDA, through CDRRHR, was one with the national government and its sectoral partners in establishing communication, learning mechanisms, and pushing initiatives in the telecommunications industry through the recently conducted Telco Summit 2022 held at the Philippine International Convention Center (PICC) on December 6, 2022.

President Ferdinand R. Marcos, Jr. addressing the delegates and participants of the Telco Summit 2022. (Photo courtesy of PTV/RTVM)

No less than the President, His Excellency Ferdinand R. Marcos Jr., who emphasized on the importance of a robust national telco infrastructure in the new normal as the driver of national and global economic progress.

Cascading of Updated Processes of Request for Analysis

Drug GMP Inspectors' on-the-job learning activity at the CSL-Cebu Testing and Quality Assurance Laboratory

The Receiving and Releasing Unit of the CSL Alabang Testing and Quality Assurance Laboratory conducted a series of virtual cascading activities with its internal and external customers regarding the updated process of receiving and processing requests for analysis (RFA) and introduction to the new RFA form. Participants include inspectors from the regional field offices in Luzon, Visayas, and Mindanao, as well as the laboratory's external customers such as the DOH-Regional Health Offices, Regional Health Units of LGUs, and other government agencies such as the Philippine Pharma Procurement Inc. (PPPI) and Philippine Charity Sweepstakes Office (PCSO).

On 07 to 18 November 2022, selected Food-Drug Regulation Officers assigned as Drug Good Manufacturing Practice (GMP) Taskforce from different Regional Field Offices have undergone on-the-job learning activities within the testing and quality assurance laboratories of CSL. The activity has provided the selected officers new knowledge, skills, and competencies in conducting GMP inspections and good laboratory practices.

Strengthening FDA's Testing Capability in Food Sensory and Food Contaminants Detection

CSL-ATQAL, CTQAL, and DTQAL attending the training in Food Sensory Analysis with Dr. Pierre Gavard

Selected laboratory personnel of the Food Section from the quality assurance laboratories of CSL in Alabang, Cebu, and Davao have undergone training in food sensory analysis at the Institute of Food Science and Technology-University of the Philippines, Los Baños from 27 to 30 June 2022. Sensory analysis is a critical tool that requires the precision, accuracy, and sensitivity of the analyst to provide a reliable sensory evaluation. As such, acquiring the competency to perform this analysis is beneficial to the laboratory personnel in performing the regulatory functions of the laboratory.

The ARISE Plus Philippines Project, which is funded by the European Union (EU) and implemented by the International Trade Centre (ITC) in partnership with the Philippine Department of Trade and Industry (DTI), has an overall objective of improving the country's international trade performance and competitiveness as well as economic integration into the global market. Through this project, selected laboratory personnel from CSL had undergone theoretical and practical training in protocol preparation and validation of methods for food contaminants such as pesticide residues, veterinary medicines residue, and food additives using highly-technical equipment such as the gas chromatography-mass spectrometry (GC-MS). Both the theoretical and practical training activities were conducted by an international technical consultant in quality and food safety, Dr. Pierre Gavard.

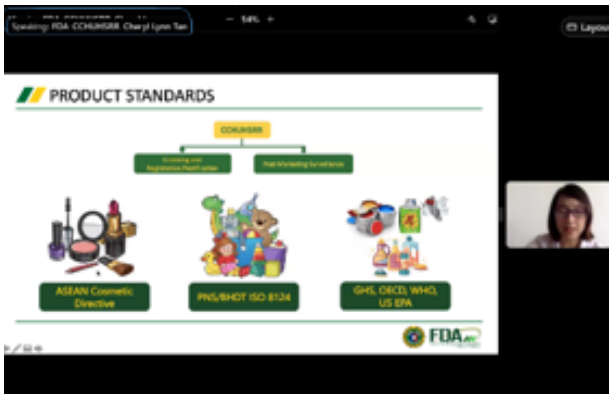
Harmonization of Regulatory Legal System & Processes

Atty. Emilio L. Polig, Director IV of LSSC, delivering the opening remarks of the program

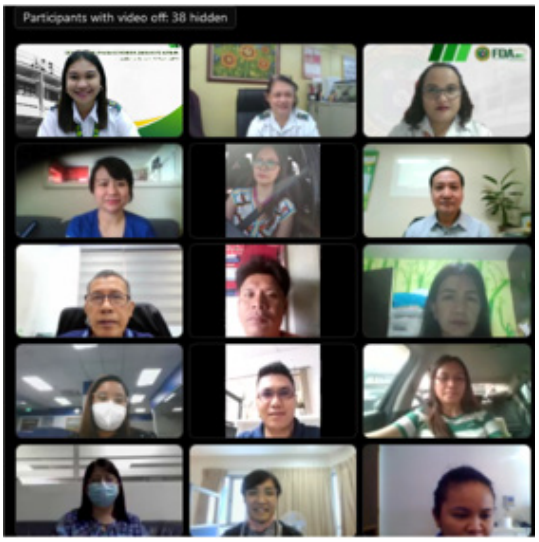
The LSSC has successfully conducted the "Continuing Legal Updates and Harmonization of Regulatory Legal System and Processes attended by the Food and Drug Regulation Officers (FDROs) and Special Investigators (SIs) of the Field Regulatory Operations Office namely: Visayas Cluster (March), South Luzon Cluster (June), North Luzon Cluster (July), Mindanao West Cluster (November), and Mindanao East Cluster (December).

The objectives of these activities were to provide updates on the recent policy developments, and an assessment and evaluation of existing inspection and enforcement processes in view of the objective of continuously enhancing the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction.

FDA Academy Seminars

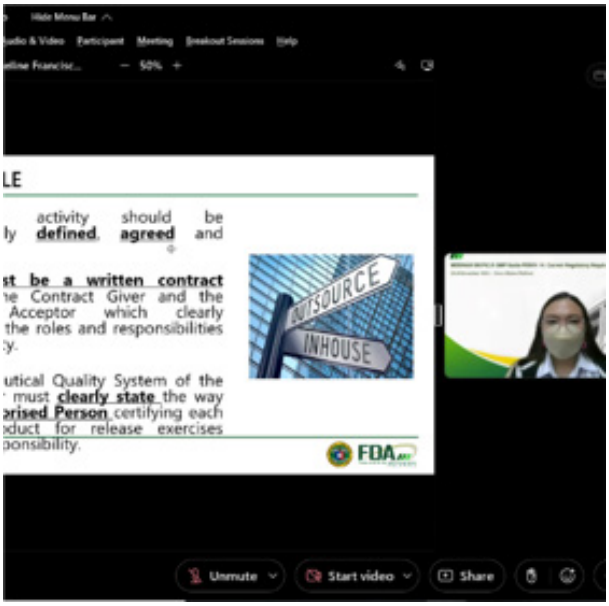


With the many challenges experienced for the past two (2) years brought about by the Covid-19 pandemic, the FDA Academy has continued to pursue its endeavor of providing relevant and effective trainings as part of its continuous service to FDA's external stakeholders and partner industries. The FDA Academy which was established as the learning provider of the FDA for its stakeholders, has provided seminar on health regulatory policies and technical training programs to inform, educate and capacitate the industries under FDA's jurisdiction as well as those establishments involved in the manufacture and distribution of pharmaceuticals, vaccines, processed food products, cosmetics, household and urban hazardous substances and medical devices. Other stakeholders such as the academe, private organizations/associations and private individuals who registered and enrolled in the FDA Academy trainings/seminars were likewise capacitated.



Although the government has started the easing of Covid-19 restrictions in most parts of the country and gradually transitioning to new normal in year 2022, the FDA Academy continued with the adoption of online learning to comply with the existing health protocols and ensure the safety of the participants as well as the FDA employees. As a guidance in the conduct of such activities, the FDA has been implementing FDA Circular No. 2021-007 dated 29 March 2021 entitled "Guidelines on the Attendance/Enrollment to FDA Academy Training/Seminar Programs Offered Thru Online Video Conferencing Platform", ever since it was approved in March 2021.

For CY 2022, the FDA Academy in collaboration with the four (4) FDA Centers and Field Regulatory Operations Office (FROO) has organized and conducted 50 webinars composed of (17) licensing seminars and (33) technical trainings. There was a total of 7,214 participants who attended the various online offerings of the FDA Academy. To assist the business entities particularly the MSMEs secure License to Operate and comply with other regulatory requirements of the FDA, all licensing seminar for food, drugs, cosmetics and medical device establishments were offered for free including the webinar on the procedure for registration of all prepackaged processed food products.



In addition to the offered trainings/seminars by the FDA Academy, there were also free online FDA Licensing Seminars for Food and Drug Establishments uploaded thru the E-Learning Platform of the DOH Academy. Since its launching in June 2021, it has been accessible to all interested individuals who wish to avail of these licensing seminars anywhere at their own convenient time.

Based on the data provided by the DOH Academy, a total of 6,064 registered for Licensing Seminar for Drug Establishments while there were 1,069 enrolled learners for Licensing Seminar for Food Establishments for CY 2022. Participants of various professions and affiliations who enrolled in the said online platform came from the different regions/parts of the country.

As an added value to the trainings/seminars provided by the FDA Academy, the FDA as an accredited CPD Provider offered nine (9) CPD programs with corresponding approved credits units from the concerned Council of Profession of the Professional Regulation Commission (PRC).

The FDA Academy is committed to continuously provide quality and relevant trainings to promote and increase industry compliance with FDA's regulations and to reach as many stakeholders as possible to ensure health regulatory policies are disseminated and implemented efficiently.

Center/Office	***No. of Offered Trainings Conducted***		*Total No. of Participants Attended*
	Free Seminar	*Technical Trainings with Registration Fee*	
CCHUHSRR	4	0	918
CDRR	4	13	2,166
CDRRHR	5	4	1,426
CFRR	7	4	1,712
FROO	0	9	992
Total	**20**	**30**	**1,7214**

Table 2. Summary of the training programs conducted for CY 2022

Advocacy Activities

2022 National Pharmacy Week Opening Ceremonies

The Philippine Pharmacists Association (PPhA) and the Filipino pharmacists celebrate the second week of December of every year as National Pharmacy Week pursuant to Proclamation No. 219 s. 1950.

The Food and Drug Administration representatives attended the 2022 National Pharmacy Week Opening Ceremonies. It was held at the Grand Ballroom of the Blessed Buenaventura Garcia Paredes, OP Building, University of Santo Tomas, from 9:00 AM to 12:00 noon, on 05 December 2022. The theme for the 2022 celebration is "Upholding the Culture of Excellence in Pharmacy Practice." The 2022 National Pharmacy Week was opened through a Eucharistic celebration and a keynote speech tackling the characteristics of an excellent pharmacist was delivered by Ms. Yolanda R. Robles, President of Federation of Asian Pharmaceutical Associations (FAPA). The FDA was recognized as one of the partners in celebrating and recognizing the pharmacy profession on its vital role and impact on public health.

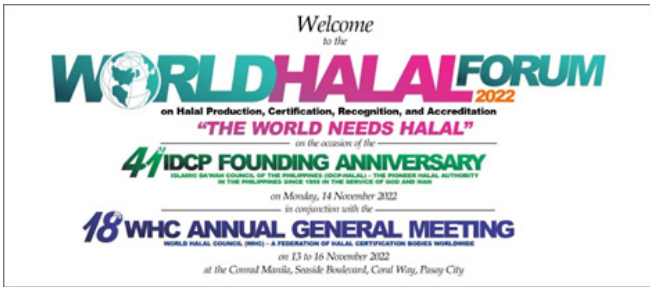
#MedSafetyWeek 2022

The #MedSafetyWeek is the annual social media campaign of the FDA together with other National Regulatory Authorities in partnership with Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for International Drug Monitoring. The campaign was held on 07-13 November 2022 with the message that "All medicines may cause side effects. That is why there are steps in place to monitor their safety. By reporting suspected side effects, you are actively participating in identifying emerging safety issues – so that we can take action when necessary and protect others from harm." The campaign espouses the reporting of side effects and increase awareness of national pharmacovigilance systems.

The platforms that were used were the FDA website and FDA Facebook page. This was also shared in the DOH Facebook page and DOH Philippines Viber group. The campaign had eight (8) posts on our Facebook page and a total reach of 850,389. Our teaser post had the most reach during the campaign period.

#MedSafety 2022 is the FDA's 5th time to participate in this global campaign and the 7th campaign of its kind.

World Halal Forum 2022



The FDA, through the CCHUHSRR, presented at the World Halal Forum 2022 the regulatory practices and policies relevant to the halal cosmetics industry. In addition, the Center has expressed its intention to cooperate and collaborate on future capacity building.

FDA receives awards during the National Exporter's Week 2022

Ms. Lanette Lee Querubin of CDRR and Maria Victoria Calub of CSL representing the FDA in the DTI Exporter's Night

The Food and Drug Administration (FDA) received Certificates of Recognition for the Office of the Director General, Center for Drug Regulation and Research, Center for Food Regulation and Research, and Center for Cosmetics and Household / Urban Hazardous Substances Regulation and Research for the invaluable support and contribution as a key partner in fostering an enabling business and collaborative environment for exporters towards development and growth of the export industry. The awards were given during the DTI's Exporter's Night on 06 December 2022 at the Marriott Hotel, Pasay City in celebration of the National Exporter's Week 2022.

Resource Speaker for BAN TOXICS Advocacy Group

Ms. Analyn Ignacio, team lead of the Product Information File Audit unit of CCHUHSRR, discussing the regulatory practices for cosmetics and HUHS under the jurisdiction of the FDA

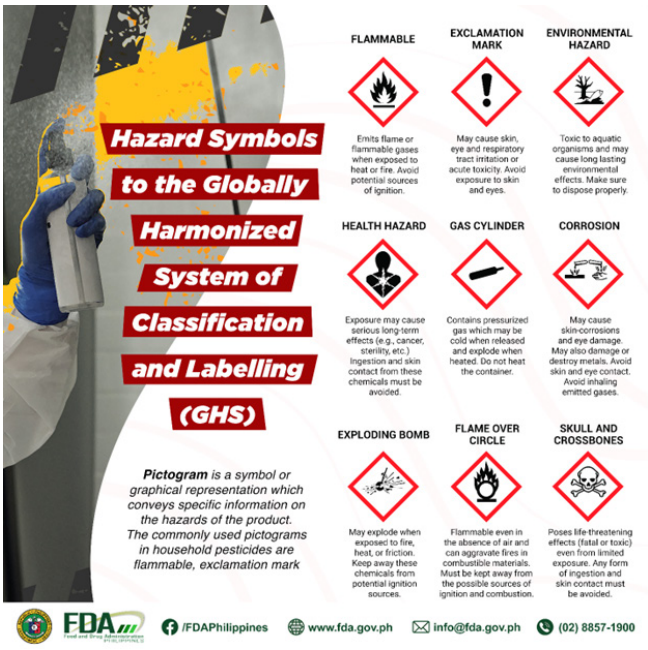
The CCHUHSRR recognizes that knowledge sharing is essential to raise awareness on the proper handling of household/urban hazardous substances and promoting the safety of the general public. Our Center welcomed the invitation of the BAN Toxics to be one of their resource speakers for their event, "Usapang Konsyumer" which was held on the 21st of October 2022. BAN Toxics Group is a non-government organization advocating for sound chemicals and waste management and environmental justice. Ms. Analyn Ignacio, team lead of the Product Information File Audit unit represented the CCHUHSRR-FDA. She discussed the regulatory practices for cosmetics and household/urban hazardous substances under the jurisdiction and functions of the Center and the FDA. The presentation was also an opportunity to advocate the best practices they can do to protect themselves from hazardous substances.

Information Dissemination Activities of CCHUHSRR

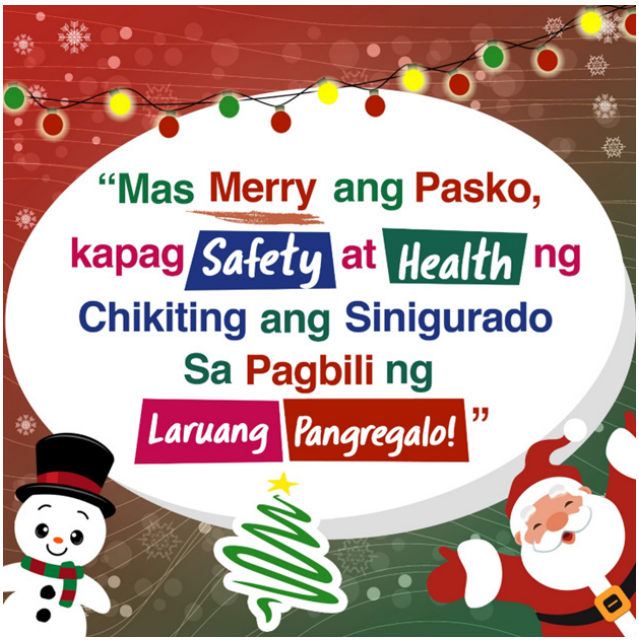
The Center for Cosmetics and Household/ Urban Hazardous Substances Regulation and Research launched several Information Education Communication (IEC) materials to promote reading and understanding of the labels of household/urban pesticides and toys.

The first IEC campaign, entitled, "Reading and Understanding Household Pesticide Labelling 101", featured five (5) materials with topics on household pesticides.

The IEC about household/urban pesticides focused on reading and understanding the product's labels. The infographics advised on the control measures to keep insects, e.g. mosquitoes away from people, the types of information that should be present on a registered pesticide product, the common hazard symbols and their meanings, and poison centers for emergency purposes. Lastly, the three easy steps to verify the certificate of product registration were also highlighted to remind the public that pesticides for household/urban uses should be registered and approved first by the FDA before their release to the market.



The second campaign was conducted during the Christmas season providing practical advice in selecting gifts for children. The IEC material emphasized three (3) practical reminders for selecting toys. The first reminder is to read the label, featuring the six pieces of information that need to be present on a toy's label (i.e., age grading, cautionary statements/warnings, instructional literature, manufacturer's markings, license to operate (LTO) number, and item model/ stock keeping unit (SKU) number). The second and third reminders, included reminders to buy from legitimate sources and for consumers to check for recalls and if the product has been notified by FDA.



Cosmetics and Oral Health: Maintaining Maximum Safe Limits for Use in Cosmetics

Ms. Ofelyn C. Cabrido and Ms. Ma. Florita H. Gabuna of CCHUHSRR with Dr. Ma. Susan Yanga-Mabunga

To further improve the understanding of cosmetic products for oral health, the CCHUHSRR organized a training activity, inviting Dr. Ma. Susan Yanga-Mabunga. She is one of the leading figures in the field of dental public health and her advocacy focuses on the promotion of Oral Health. The activity served as a venue to capacitate the CCHUHSRR staff on the science behind common oral health problems, and a venue to discuss the gaps in the public oral health that the Center can address through regulation.

Hosting of the IAEA Occupational Radiation Protection Appraisal Service (ORPAS)

Engr. Maria Cecilia C. Matienzo, Director IV of CDRRHR and the representatives of PNRI hosting the IAEA ORPAS

The FDA, through CDRRHR and the Philippine Nuclear Research Institute (PNRI), jointly hosted the IAEA Occupational Radiation Protection Appraisal Service (ORPAS) on October 2-11, 2022, for the independent assessment and evaluation of all the aspects of the country's occupational radiation protection program based on international safety standards. ORPAS findings highlighted and applauded the national system of protection established by the country for occupational workers while recommending further enhancements on the implementation of the established safety standards.

The CDRRHR continually supports the development and growth of the radiation device industry without compromising public health. Last year's accomplishments and good regulatory practices would serve as building blocks towards the future centered on a culture of safety. Continuous monitoring, evaluation, and review of existing policies and implementation strategies are important to achieve the FDA's mission of guaranteeing the safety, quality, and efficacy of radiation devices in the Philippines.

Hosting of the 2022 National Consciousness Week Against Counterfeit Medicines (NCWACM)

DG Samuel A. Zacate, MD, Atty. Ronald R. De Veyra, MBA, CESO II, and PBGEN Ronaldo O. Lee, CIDG Director

Pursuant to the provisions of Republic Act No. 8203 or the "Special Law on Counterfeit Drugs," and by virtue of Presidential Proclamation No. 2082 s. 2010 declaring every third (3rd) week of November as the National Consciousness Week Against Counterfeit Medicines (NCWACM), the FDA, with CSL as the host, spearheaded this year's NCWACM on 14-18 November 2022 with the theme "Technology and Regulation at the forefront of Fighting Counterfeit Medicines - Maging Mapanuri, MAGKAISA! Labanan Pekeng Medisina!" In line with this year's NCWACM theme, the week-long activities utilized interactive technologies to disseminate comprehensive awareness against counterfeit medicines and the role of the FDA in combating the proliferation of such. Harnessing social media platforms' wide reach and great impact of social media platforms, this year's NCWACM also featured digital video making (infomercial), TikTok video recording, and NCWACM mascot design contests that enabled positive engagements in fighting counterfeit medicines.

The week-long celebration started with a Zumba Awareness Drive led by with none other than the DOH's Dancing Undersecretary, Dr. Eric Tayag. This was followed by a nationwide simultaneous university forum at the University of Santo Tomas, Centro

Escolar University, Adamson University, and the University of Perpetual Help – Biñan Campus for Luzon, while a symposium was simultaneously conducted at the University of San Carlos, Cebu Doctors University, the University of Southern Philippines Foundation, University of the Visayas and Southwestern University for the Visayas regions. The gathering was also attended by representatives from Tagum Doctor's College, San Pedro College, University of Mindanao, Brokenshire College of Davao, Lyceum of the Philippines University-Davao, and the University of Immaculate Concepcion, which were held in Tagum City and Davao City. In addition, the Field Regulatory Operations Office (FROO) in North and South Luzon has also conducted a caravan campaign against counterfeit medicines, spanning the barangays of Muntinlupa City.

With the ease of COVID-19 restrictions, the culminating activity for the week-long celebration was once again held at the Philippine International Convention Center (PICC) in Pasay City and was attended by more than 400 people from partner local and international agencies, pharmaceutical industries and associations, colleges and universities, as well as various consumer groups throughout the country. The event covered topics on advanced technologies and current regulatory actions employed in the country against counterfeit medicines. The event also featured a manifesto signing with partner local government agencies, pharmaceutical industries and associations, and active consumer welfare groups to continuously strengthen its capacities in protecting the health and safety of Filipino people from counterfeit medicines.

Technical Assistance to LGU and Other Public or Private Organizations

As part of FROO's advocacy, the Regional Field Offices provided technical assistance (e.g. Guidelines on LTO application, inspection, counterfeit detection) to the Local Government Units, and other public or private organizations.

Also, as part of other government programs such as the "Kapatid Mentor Me Program", "Bantay Asin Task Force" and "Oxygen Task Unit", the RFOs participate in the activities of such programs in their regions.

Online Licensing Seminars for Drug Outlet

PPS-PDTD with FROO-SLC conducting the Online Licensing Seminar for Drug Outlets

To strengthen the implementation of the FDA's mandates and to harmonize compliance with the regulation of Drug Outlets, the agency collaborated with the Drug Store Association of the Philippines and conducted an online licensing seminar via the Cisco Webex Conference Platform.

The agency informed the stakeholders of current regulations, processes, and requirements in applying for License to Operate (LTO). In addition, the webinar provided a step-by-step procedure to promote the convenience of using the FDA's eService Portal System in submitting accurate and complete documents.

The FDA continuosly coordinate and collaborate with different stakeholders and agencies for the effective implementation and promotion of regulatory compliance to maintain safe and quality health products under its jurisdiction.

FDA 59th Anniversary Webinars

As the country faced the burden brought by the COVID-19 virus to conduct a face-to-face seminar, it did not hinder the agency from formulating, updating, and conducting advocacy campaigns for appropriate legislation on health products through webinars to promote and protect the right to health of the general public.

The celebration of the FDA 59th Founding Anniversary conducted a series of advocacy to further inform stakeholders about the agency's mandates, the health products and establishments under its jurisdiction, and the licenses and authorization it issues.

The conducted webinars raised the participants' awareness of the issues concerning health products, thus helping them understand their roles in protecting themselves and the people around them.

List of Webinars | Via Cisco Webex Conference Platform

- How to Read Labels in Processed Food Products (20 June 2022)
- How to Spot Counterfeit Drugs (21 June 2022)
- COVID-19 Self -Administered Antigen Test Kits (22 June 2022)
- What you need to Know: Buying Cosmetic Products Online (23 June 2022)
- Understanding Vapor and Heated Tobacco Products (24 June 2022)

Training for Micro, Small, and Medium Enterprises (MSMEs) Food Establishment on FDA Regulatory Process and Requirements

As part of the Food and Drug Administration (FDA)'s commitment to update and educate its stakeholders about Micro, Small, and Medium Enterprises (MSMEs) for Food Establishments, it conducted training/seminars in collaboration with the Department of Trade and Industry, Provincial Government of Ilocos Sur (PGIS) held at the Provincial Farmers Livelihood Development Center, Vigan City.

The training capacitated our local food processors/manufacturers in Ilocos Sur on FDA-implemented rules and regulations concerning licensing process and requirements of establishments and registration of health products, labeling guidelines for prepackaged processed food products, and understanding the post-marketing surveillance and monitoring activities and procedures in the inspection of establishments.

Thus, it showed support for the government's commitment to help and assist the MSMEs in coping and recovering from the challenges brought upon by the pandemic and helped them revitalize their business by creating a more sustainable environment under the new normal.

18th National Biotechnology Week (NBW)

By virtue of Presidential Proclamation No. 1414, National Biotechnology Week was declared to be celebrated every last week of November. This year's theme, "Responding to Challenges: Business Opportunities in Biotechnology," highlights biotechnology's valuable contributions to the health industry.

Dr. Oscar G. Gutierrez, Jr, MPA, DDG for FROO delivering the Opening Remarks of the 18th NBW

On 23 November 2022, the DOH FDA conducted a one-day forum with the Colleges and Universities' participation. It successfully delivered relevant information on Monkeypox and its Causative Agent, Signs and Symptoms, Mode of Transmission, Prevention and Control, Diagnostic Test for Monkeypox, and Regulations on In-Vitro Diagnostics (IVD). The activity successfully raised participants' awareness and knowledge about the Monkeypox virus and correlated the importance of Biotechnology in detecting and confirming of the reemerging infection.

This year's 18th NBW achieved its purpose of advocating timely topics that connect Biotechnology's seizing opportunities to fulfill and sustain the public health needs.

Licensing Seminar for Drug Outlet

Dr. Irene V. Florentino-Fariñas, delivering the opening remarks of the program

The Food and Drug Administration (FDA) conducted a Licensing Seminar held at the Bohol Tropics, Tagbilaran City, Bohol, pursuant to DOH Administrative Order No. 2020-0017, entitled "Revised Guidelines on the Unified Licensing Requirements and Procedures of the FDA, Repealing Administrative Order No. 2016-0003".

The Licensing Seminar was organized and facilitated by the FDA-Policy and Planning Service (PPS) in collaboration with the Bohol Pharmacist Association and Drugstore Association of the Philippines (DSAP/CPhAD) Bohol Chapter, and was participated by the latter's members.

The activity provided an understanding of the mandate, functions, and services offered by the FDA to promote the current regulations and process in the application of drug outlets' License to Operate (LTO) and the importance of Good Dispensing, Distribution, and Storage Practices Management to guarantee and provide access to safe and quality health products to the general public. The use of eServices Portal System in the initial, renewal or variation in the LTO application, Certificate of Product Registration for certain drug products, and Compassionate Special Permit providing convenient transactions by qualified or authorized personnel of the establishments, was also discussed.

The conducted activity is part of the agency's advocacy and commitment to deliver seminars in every part of the Philippines, ultimately resulting in tits regulated entities' full compliance. Thus, ensuring safe, quality, and efficacious health products in the market.

Hybrid National Food Fair (NFF) herald borderless opportunities for MSMEs

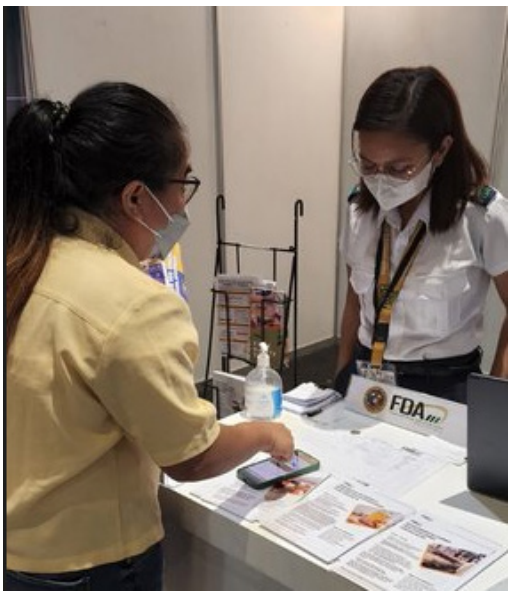
Ms. Estrellita B. Pastolero, Chief, PPS-PDTD and OIC of FDAC along with PDTD and FDAC team participating in the DTI NFF

Pursuant to RA 9711 and A.O. 2024-2029, the Food and Drug Administration (FDA) participated in the Hybrid National Food Fair (NFF) programs and initiatives undertaken by the Department of Trade and Industry (DTI), as part of its commitment in updating and educating food Industry stakeholders with the Agency's regulatory policy.

It is a venue for participants to improve their understanding of application processes and requirements to obtain a License to Operate (LTO) and a Complete Guide on how to apply for a Certificate of Product Registration (CPR), and an opportunity for the Agency to introduce the convenience of using the FDA's eService Portal System.

The success of the introduction of innovative solutions to keep the market open for MSMEs opens a substantial economic potential for the county and and realize a borderless marketplace for the food industry to serve and provide safe and high-quality product made available to the general public.

International Food Exhibition (IFEX) Philippines



PDTD and FDAC participating assisting consumers and stakeholders in the event

Organized by the Center for International Trade Expositions and Missions (CITEM), an attached agency of the Department of Trade and Industry (DTI), IFEX Philippines 2022 has multiple trade components, including exhibitions, business matching activities, seminars and talks, and product presentations to promote micro and small local entrepreneurs and potential exporters.

At the event, the FDA discussed the requirements and processes of securing pre-market authorizations, such as License to Operate (LTO) and Certificate of Product Registration (CPR). In addition, the FDA booth displayed IEC documents available for distribution. It served as a venue for the Agency to successfully advocate its programs and directly assist business owners and customers with their concerns or inquiries.

Philippine Generics Summit 2022

Dr. Irene V. Florentino-Fariñas, PPS Director, Ms. Lanette Lee Querubin, CDRR-PRSDD, and Ms. Joanne Arce, ODG, representing FDA in the event

With the theme "ACCESS sa Gamot at Serbisyo, Ipaabot sa mga Pilipino", in this year's Philippine Generics Summit, Filipinos will have access to affordable yet high-quality essential medicines and services by encouraging competition among pharmaceutical companies. This is in relation to the Philippine Competition Act (PCA) or R.A. 10667, wherein drug prices will be decreased, and there will be a reduction in the out-of-pocket spending of Filipino consumers while an increase in the country's supply chain will be observed.

In accordance with the government's campaign towards Universal Health Care (UHC) and in view of the significant changes in the pharmaceutical landscape, the Department of Health (DOH), through the Pharmaceutical Division, crafted the Philippine Medicines Policy, which would take effect in the years 2022 to 2030.

FDA Director General Samuel A. Zacate assured its commitment to the implementation of the Philippine Medicines Policy "With this, the FDA expresses its full support and commitment to the implementation of this national policy that will strengthen the pharmaceutical regulatory standards to be at par with international standards, promote mutual reliance with our counterpart national regulatory authorities, and ensure sustainable access to essential medicines while fortifying domestic capacity to meet the local demands for medicines."

International Commitments

FDA International Affairs

The FDA has been actively collaborating with International Organizations (IO) and other National Regulatory Authorities (NRAs) through information sharing and participation in capacity-building activities organized and sponsored by the aforementioned. The International Affairs Unit (IAU) was responsible for developing, maintaining, and enhancing relationships with IOs and foreign NRAs.

Organizer	Number of Capacity Building and Meetings
Asian Productivity Organization	1
Asia-Pacific Economic Cooperation (APEC)	7
Association of Southeast Asian Nations (ASEAN)	23
Clulabhorn Research Institute	1
Codex Alimentarius Commission (CAC)	4
Duke-NUS Medical School	4
Food and Agriculture Organization	2
Forum for Innovative Regenerative Medicine (FIRM)	1
Government of Australia	1
Health Insurance Review and Assessment Service (HIRA)	1
Indian Technical and Economic Cooperation (ITEC)	1
International Atomic Energy Agency (IAEA)	2
Kobe University	1
McCabe Centre for Law and Cancer	1
Medlab Asia and Asia Health	1
Michigan State University	1
Ministry of Food and Drug Korea	1
Ministry of Science and Technology of the P.R. of China	1
National Health Commission P.R. of Chine	1
National Institute for Korean Medicine Development (NIKOM)	1
Pharmaceutical Inspection Co-operation Scheme (PIC/S)	3
Pharmaceuticals and Medical Devices Agency (PMDA)	11
Taiwan Food and Drug Administration	2
United States Agency for International Development (USAID)	1
United States Department of Agriculture (USDA)	1
World Bank	1
World Health Organization(WHO)	13

Table 3. Number of Activities Attended, Assisted, and Facilitated by the IAU in 2022

NRA Function assessed	Sub-indicators implemented/ Expected to be implemented	Indicators implemented/ Expected to be implemented	Sub-indicators implementation %	Maturity level
01-National Regulatory System (RS)	53.25/60.0	10 out of 10	89.0%	3
02-Registration and Marketing Authorization (MA)	30.5/35.0	5 out of 6	87.0%	2
03-Vigilance (VL)	23.75/26.0	6 out of 6	91.0%	2
04-Market Surveillance and Control (MC)	24.75/27.0	6 out of 6	92.0%	1
05-Licensing Establishment (LI)	16.75/19.0	5 out of 6	88.0%	2
06-Regulatory Inspection (RI)	24.0/26.0	6 out of 6	92.0%	3
07-Laboratory Testing (LT)	27.0/28.0	10 out of 10	96.0%	2
08-Clinical Trial's Oversight (CT)	26.75/30.0	5 out of 6	89.0%	1
09-NRA Lot Release (LR)	16.75/17.0	6 out of 6	99.0%	3

Table 4. Status of Regulatory Functions after Writeshop and presented in the Virtual Follow-Up

34th Pharmaceutical Product Working Group (PPWG) Meeting and its Related Events (via video conference)

1. 5th Meeting of the Joint Sectoral Committee (JSC) on the ASEAN Mutual Recognition Arrangement (MRA) for BE Study Reports of Generic Medicinal Products – 3-4 November 2022.
2. 11th Meeting of the JSC on the ASEAN Sectoral MRA for GMP Inspection of Manufacturers of Medicinal Products – 7-8 November 2022.
3. 3rd Meeting of the ASEAN Pharmaceutical Testing Laboratory Committee (APTLC) – 10-11 November 2022.
4. 7th Meeting of the Joint Assessment Coordinating Group (JACG) – 14-15 November 2022.
5. WHO Briefing on Technical Report Series (TRS) 1033 – 16 November 2022
6. 34th PPWG Plenary Meeting – 17-18 November 2022.

Highlights of the 34th PPWG Meeting: MRA on GMP

Ongoing domestic process for individual AMS to obtain the Instrument of Full Power (IFP) for the signing of the Protocol to Amend the MRA on GMP to expand its scope to:

- APIs
- Biologicals

Remaining AMS expressed no intention to apply as a Listed Inspection Service in the near term, in addition to:

- HSA Singapore
- NPRA Malaysia
- Indonesian FDA (formerly NADFC / Badan POM)

Handover of Chairmanship from Malaysia to the Philippines, and Vice-Chairmanship from the Philippines to Singapore

Highlights of the 34th PPWG Meeting: MRA on BE Study

Full implementation of the MRA beginning November 2022

- Training of potential Panel of Experts from the 10 AMS covering 3 modules completed in 2022
- Initiation of the process of listing of ASEAN BE Centers in 2023
- Completion of the Registry of Panel of Experts by 30 June 2023

11th Meeting of the Member State Mechanism on Substandard and Falsified Medical Products

Ms. Sheralyn O. Opeña of CDRR, representing the FDA in the meeting

The 11th meeting of the Member State Mechanism on substandard and falsified (SF) medical products was held in Geneva, Switzerland in a hybrid format from 19-20 October 2022 and attended by the Philippine Food and Drug Administration (PFDA) delegates from the Center for Drug Regulation and Research (CDRR). The WHO Director-General, Dr. Tedros opened the meeting and underscored the importance of access to safe and quality medical products as a cornerstone of Universal Health Coverage. Substandard and falsified medical products undermine health systems and put everyone in every country at risk. During the meeting, the Secretariat provided an update on the activities and budget to implement the mechanism's work plan. Further, the WHO Global Surveillance and Monitoring System (GSMS) reporting trends were shared wherein annual increase in reported incidents over the past four years were noted. There is also reporting disparity among WHO regions and the classification of reported products along with the ongoing challenges concerning information sharing and transparency were identified as barriers to reporting. Member State focal points were encouraged to continue to enter their reports into the GSMS system for the benefit of all Members States. Updates on the following prioritized activities for 2022-2023 were reported by the lead Member States:

- Activity A: Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products
- Activity B: Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration
- Activity C: Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products, and the implementation of national traceability systems
- Activity D: Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products
- Activity E: Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products
- Activity F: Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products
- Activity G: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet
- Activity H: Develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products through the informal market

The FDA expressed its interest in joining the working group for these prioritized activities, specifically for Activities A, C and G. Experiences regarding the gaps/challenges on SF products and how they handle the situation were also shared by other regulatory agencies.

WHO Pre-benchmarking activity

WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in particular element three, which calls for establishing and strengthening regulatory capacity in developing countries as one effective policy for building and improving innovative capacity, as specified in element six. It also promotes establishing and strengthening mechanisms to improve ethical review and regulate health products' quality, safety and efficacy of as stipulated in element six. The Center for Drug Regulation and Research (CDRR), together with other Offices of the Food and Drug Administration (FDA), started the Global Benchmarking Activity with the World Health Organization in 2019 geared towards becoming a WHO-Listed Authority.

The CDRR and other Offices of the FDA have prepared all the necessary documents to be presented for the WHO team to Evaluate primarily the regulatory systems of the Philippines with the WHO global benchmarking tool (GBT), following the NRA self-benchmarking.

The Pre-benchmarking activity was conducted so the Philippine FDA can update the status of its vaccines and medicines regulatory system, to address any existing gaps and build upon strengths of the vaccines regulatory system, and have an agreement on dates and preparatory activities for the upcoming formal benchmarking activity.

After the preassessment, the FDA was given a Corrective and Preventive Action (CAPA) Plan and agreed to have a virtual follow-up and review of progress on 07 October 2022. A Writeshop in Tagaytay ensured to complete and polish all the identified responses and issuances and/ or procedures that will serve as pieces of evidence to the WHO cGBT tool as a response to the CAPA given by the WHO Team to the FDA last Pre-Benchmarking assessment.

After clarifying with the WHO team and following their recommendation, the FDA Philippines is preparing for the formal benchmarking activity to be conducted in February 2023.

NRA Function assessed	Sub-indicators implemented/ Expected to be implemented	Indicators implemented/ Expected to be implemented	Sub-indicators implementation %	Maturity level
01-National Regulatory system (RS)	49.75/60.0	10 out of 10	83.0%	1
02-Registration and Marketing Authorization (MA)	28.75/35.0	5 out of 6	82.0%	1
03-Vigilance (VL)	23.0/26.0	6 out of 6	88.0%	2
04-Market Surveillance and Control (MC)	22.75/27.0	6 out of 6	84.0%	1
05-Licensing Establishment (LI)	15.75/19.0	5 out of 6	83.0%	2
06-Regulatory Inspection (RI)	22.75/26.0	6 out of 6	88.0%	2
07-Laboratory Testing (LT)	26.75/28.0	10 out of 10	96.0%	2
08-Clinical Trial's Oversight (CT)	24.75/30.0	5 out of 6	84.0%	1
09-NRA Lot Release (LR)	16.75/17.0	6 out of 6	99.0%	3

Table 5 . Status of Regulatory Functions after Pre-assessment

PICS Committee Meeting, 50th PICS Anniversary Seminar and PICS Workshop, Dublin, Ireland

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) celebrated its 50th anniversary at a special symposium in Dublin (Ireland) on 4 October 2022. Since the first meeting of the PIC Committee in 1972, PIC/S has come a long way. The symposium titled "Thriving at 50 and Striving Forward" aimed at promoting and highlighting PIC/S' contributions to international collaboration and co-operation while being resolutely turned towards the future.

Close to 200 participants from all continents participated in the event, including most of PIC/S 54 Participating Authorities and 7 (Pre-)Applicant Authorities, PIC/S Associated Partner Organisations (European Commission, EDQM, EMA, UNICEF, WHO and WOAH) as well as a number of non-PIC/S Competent Authorities. The anniversary also provided a unique opportunity to meet and engage with various invited stakeholders present for the occasion and reconnect with the more comprehensive PIC/S network. A more detailed press release will follow covering also PIC/S meetings and the 2022 Annual Training Seminar, which took place in Dublin with a back-to-back anniversary symposium.

National Codex Organization Technical Committee (NCO-TC) and Codex Committee on Food Hygiene meetings

The CSL participated in the National Codex Organization Technical Committee (NCO-TC) Quarterly Meetings and the Codex Committee on Food Hygiene Meetings to keep abreast of the latest international food standards, guidelines, and codes of practice for the safety, quality, and fairness of international food trade.

58th ASEAN Consultative Committee on Standards and Quality (ACCSQ) Meeting in Boracay

The Department of Trade and Industry's Bureau of Philippine Standards (DTI-BPS), under the Consumer Protection Group (CPG), successfully hosted the 58th ASEAN Consultative Committee on Standards and Quality (ACCSQ) Meeting and its Related Meetings in Boracay, Malay, Aklan on 6 - 9 December 2022.

The Meeting was attended by ACCSQ Leaders from the following ASEAN Member States: Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam with the ASEAN Secretariat. The Meeting was chaired by Mr. Nou Thara, Deputy Director General, Institute of Standards Cambodia and vice-chaired by Mrs. Konny Sagala, Director, Directorate of Standard Implementation System and Conformity Assessment, National Standardization Agency of Indonesia.

The Philippine Delegation was led by BPS Director Neil P. Catajay as Head of Delegation, Director Jesusa Joyce Cirunay from the Department of Health - Food and Drug Administration (DOH-FDA), Director Romulo Aggangan from the Department of Science and Technology - Forest Products Research and Development Institute (DOST-FPRDI) together with representatives from the DTI-Philippine Accreditation Bureau (PAB), DTI-Fair Trade Enforcement Bureau (FTEB), DTI-Aklan, DOST-Industrial Technology Development Institute (ITDI), and other BPS partners.

Participation on the ASEAN Medical Device Technical Committee

Though face to face meeting is not allowed during the pandemic, the international collaboration is still being continued.

The CDRRHR attended the 9th ASEAN Medical Device Technical Committee on 26-27 April 2022 and the 11th ASEAN Medical Device Committee Meeting on 5-8 September 2022 through virtual conference. The objective of this series of meetings is to harmonize the classification of medical devices among the ASEAN member Economies together with the identification of borderline products. The harmonization of the classification and the borderline products is essential to fully implement the harmonization of the technical regulation of medical devices in the ASEAN and compliance to non-barrier to trade agreements.

The CDRRHR also have continuous collaboration with the Medical Device Authority, Ministry of Health of Malaysia. The Philippines has an agreement with the Government of Malaysia. Medical Device Regulation is one of the areas of this agreement. The two countries have exchanged regulation requirements and processes. Further collaboration will include capacity building.

Sectoral Round Table Discussion (RTD) for the Co-Development of the Philippine Acceleration Action Plan for TB (PAAP-TB)

On 19 October 2022, the CDRRHR attended a meeting with USAID and the DOH - Disease Prevention and Control Bureau, and USAID's TB Innovations and Health Systems Strengthening (TBIHSS) Project. The meeting aims for possible collaboration with USAID and Government agencies regarding the fight against tuberculosis.

The workshop has brought together different sectors from both private and public organizations to discuss how each agency or organization's contribution can help eradicate tuberculosis. This brings the CDRRHR to create policies and strategies to implement programs that will help strengthen health programs targeting tuberculosis through the regulation of radiation-emitting equipment used to diagnose tuberculosis.

Philippine Self-Assessment Annual Reporting (SPAR) Tool

Dr. Maria Victoria D. Pinion of CFRR representing the FDA

The Philippines, in accordance with the Republic Act 10611 or the Food Safety Act of 2013, participated in the 45th Session of the Codex Alimentarius Commission with Dr. Maria Victoria D. Pinion as the official head of the Philippine delegation. There were more than 700 delegates, of these numbers more than 350 have attended online while almost 400 have attended in the physical session. The FAO and WHO highlighted the importance of science and data in the work of the Codex standard-setting body and the Commission's role in guiding country regulations that promote health, while facilitating fair trade. Significantly, the Commission approved more than 500 new food safety standards. Moreover, among the highlights, the Commission adopted a set of guidelines on Ready-to-Use Therapeutic Foods (RUTF) used for children with severe acute malnutrition, Guidelines for the Management of Biological Foodborne Outbreaks, standards for fresh dates and onions and shallots, and a Code of Practice for Prevention and Reduction of Cadmium Contamination in Cocoa Beans. Also, it established 476 new maximum residue limits for pesticides and 13 maximum levels for contaminants among others. The Philippines articulated its position/comments on the proposed codex standards, which were adopted by the Commission.

Philippine Self-Assessment Annual Reporting (SPAR) Tool

The CDRRHR continues to coordinate with the DOH's International Health Regulation (IHR) Team in updating the Philippine Self-Assessment Annual Reporting (SPAR) Tool for its commitments in radiation emergencies. Technical Working Group (TWG) discussions were held last year, towards the finalization of the DOH Administrative Order on the Medical Response to Nuclear and Radiological Emergencies and its subsequent Manual of Operations. Along with this, the CDRRHR, as a technical support provider for DOH in radiation protection and regulation, actively participates in the Chemical / Biological / Radiological / Nuclear (CBRN) - Health Sector's initiatives and programs.

18th ASEAN Cosmetics Testing Laboratory Committee

Selected personnel from the Cosmetics-Toxicology and Microbiology Section of ATQAL, CTQAL, and DTQAL attended the 18th ASEAN Cosmetics Testing Laboratory Committee (ACTLC) Meeting via online conferencing. The meeting served as the venue for testing laboratories of the national regulatory authorities of the ten (10) ASEAN Member States to coordinate, review, and update methods being developed to analyze different cosmetic ingredients in accordance with the ASEAN Cosmetic Directive (ACD). Other issues discussed were the applicability of harmonized methods, participation in interlaboratory studies, and capability building. The Philippines, thru the FDA-CSL, initiated the coordination of a Comparative Study for Methanol. This included the preparation of interlaboratory comparison protocol, preparation and distribution of the collaborative sample, and reporting of the comparative study results, which were presented in May 2022 at the 18th ACTLC Meeting.

CSL joins the pre-benchmarking activity for the World Health Organization's (WHO) Global Benchmarking Tool (GBT)

The WHO assesses regulatory systems for the regulation of medical products through its Global Benchmarking Tool (GBT). The GBT is designed to evaluate the overarching regulatory framework and the component regulatory functions such as vigilance, regulatory inspection, and clinical trial oversight among others. Incorporating the concept of Maturity Level (ML) from the ISO 9004, the WHO and regulatory authorities can now assess the overall maturity of the regulatory system from a scale of 1, being the existence of some elements of a regulatory system, to 4, being the most advanced level of performance for a regulatory system.

In pursuit of excellence and in compliance with international standards, the FDA Philippines, as a national regulatory agency, participated in the pre-benchmarking activity conducted by the WHO assessors to reach the ML 3 level. A total of nine (9) regulatory functions of the FDA were assessed, two (2) of which were assigned to the CSL, namely 07-Laboratory Testing (LT) and 09-NRA Lot Release (LR). The two functions were pre-benchmarked and have been found to have implemented 96.0% and 99.0% of their sub-indicators, reaching ML 2 and 3, respectively.

EU Arise and Republic of Korea Visits the FDA

On 08 April 2022, EU technical expert Mr. Khemraj Ramful and ASEAN Regional Integration Support from the EU (ARISE) representative Ms. Hema Menon visited the FDA Philippines to discuss the technical needs of the FDA and to visit its laboratory facilities. Recommendations were conveyed on the need for technical capability training on microbiological and chemical testing with the goal of aligning the quality and standards of export priorities and the CSL's testing capabilities with the EU standard. The requested training activities also aimed to strengthen the testing capacity of the CSL on food contaminants such as pesticide residues, veterinary medicine residues, and food additives on exported food products, as well as enhance the skills of laboratory personnel in preparing protocol and validation of methods to be used in the detection of such food contaminants. This meeting resulted in two (2) successful mission visits from an International Consultant, Mr. Pierre Gavard, who conducted theoretical and practical training for laboratory analysts of the CSL in Alabang, Cebu, and Davao.

On 8 to 9 June 2022, delegates from the Traditional Korean Medicine Bureau and the Ministry of Health and Welfare of the Republic of Korea, together with a representative from the World Health Organization Western Pacific, visited the FDA Philippines to discuss key issues in strengthening the regulatory system for traditional medicine products and practitioners. The CSL prepared a presentation on its laboratory activities with traditional and complementary medicines, the challenges it faces related to the testing of such products, potential collaboration with the Republic of Korea, as well as the result of the concluded remote training on laboratory capacity building for improving quality control of traditional medicine in the Philippines.

FDA Philippines through the CSL joins the World Health Organization (WHO) – National Control Laboratory Network for Biologicals (NNB)

World Health Organization  Organisation Mondiale de la Santé

PARTICIPATION and CONFIDENTIALITY AGREEMENT

as a Full or Associate Member, in the
WHO National Control Laboratory (NCL) Network for Biologicals (WHO-NNB)

(hereinafter referred to as the "Network")

The Food and Drug Administration – Philippines, thru the Common Services Laboratory – Experimental Animal House/Vaccine Biological Unit, has recently joined the World Health Organization's National Control Laboratory Network for Biologicals (WHO-NNB) as an Associate Member. The Network was made possible through the collaboration of national regulatory authorities (NRAs) and national control laboratories (NCLs) responsible for testing and releasing WHO-prequalified vaccines. The Network serves as a platform for other country members to exchange quality and technical information on prequalified vaccines, as well as ease of access to vaccines through the recognition of the responsible NRA's lot release by recipient countries.

Through this Network, the FDA Philippines, as a national regulatory authority, and the Common Services Laboratory, as the national control laboratory, can ensure cost-effective testing of vaccines and/or apply reliance to testing and lot release of vaccines, therefore providing accelerated access of Filipinos to socially and economically-important vaccines such as the WHO prequalified vaccines.

Other Accomplishments

CSL continuously commits to ISO/IEC 17025:2017

The Common Services Laboratories in Alabang, Cebu, and Davao have all successfully transitioned to the 2017 version of ISO/IEC 17025 and received accreditation for chemical and biological testing from the Department of Trade and Industry - Philippine Accreditation Bureau (DTI-PAB) in 2021. To ensure the laboratory's compliance with the standards, the CSL Laboratories have participated in the remote surveillance audit and special assessment conducted by the PAB Assessment Team. The continued accreditation of FDA-CSL laboratories to the ISO/IEC 17025 version 2017 solidified its commitment to maintaining the competency and consistency of laboratory operations, as well as ensuring the quality, impartiality, and accuracy of its test results.

Establishment of Independent FDA Regional Field Offices

- The construction of the FDA Regional Field Office XII Office Building in Koronadal City was completed on 31 August 2022.
- The Phase 1 of the FDA Regional Field Office V Office Building in Legazpi City was completed on 16 June 2022 while the Phase 2 is set to start in 2023.
- Through the efforts of FROO, the Local Government of Pagadian City and the National Economic and Development Authority in Region II have donated 2,000 sqm of lot for FDA Regional Field Office IX and II, respectively.
- FROO had coordinated and collaborated with the DOH Health Facilities Enhancement Program (HFEP) – Management Office for the development of Standard Design for FDA Regional Field Offices and Warehouses.

Conduct of National FROO Conference

DG Samuel A. Zacate, MD and DDG Oscar G. Gutierrez, Jr. in the National FROO Conference

On 5 - 7 December 5-7, 2022, the FDA regional inspectors gathered for the National FDA-FROO Conference 2022 with the theme "Empowered Regulators Gearing up for Global Recognition". During this 3-day event, the role of the inspectors in the Universal Health Care and in the FDA's vision to be a recognized center of excellence for health product regulation by 2026 was reiterated. Distinguished guests from all over the globe and the country, shared their knowledge and expertise on WHO-GBT, PIC/S Accession, and ISO 17020:2012 Accreditation.

Disposal of Unserviceable Properties and Personal Protective Equipments (PPE)

Mr. Manuel G. Guevarra of GSD, leading Inventory and Disposal Committee

In compliance with COA Audit Observation Memorandum (AOM) No. 22-10 dated 30 March 2022, AFS-GSD and the Inventory and Disposal Committee (IDC) submitted the updated Inventory Inspection Report for Unserviceable Property (IIRUP) showing the history of disposal. AFS-GSD and IDC also facilitated the immediate disposal of the remaining unserviceable PPE to prevent its further deterioration.

IDC has also prepared and submitted to the Head of the Agency the following Inventory and Inspection Reports(s) of Unserviceable PPE (IIRUPs) for approval.

- CY 2022 IIRUP - Disposal Thru Destruction - Furniture & Fixture (termites infested): 38 pieces

- CY 2022 IIRUP - Disposal Thru Public Action/Bid/Sale/Negotiated Sale
  Consists of the following unserviceable and obsolete PPE for disposal:
  1. ICT, TSE, Communication and Office Equipment (15k above) - 192 items
  2. ICT, TSE, Communication and Office Equipment (15k below) - 80 items
  3. ICT, TSE, Communication and Office Equipment (above & below) 45 items

- CY 2022 IIRUP - Disposal Thru Destruction - Furniture & Fixture (termites infested): 172 pieces

Upon approval of the IIRUP by the Top Management, IDC was instructed for the immediate Disposal of the PPEs.

Annex B Tables and Figures

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Center for Food Regulation and Research	cfrr@fda.gov.ph
Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research	cchuhsrr@fda.gov.ph
Center for Drug Regulation and Research	cdrr@fda.gov.ph
Center for Device Regulation Radiation Health and Research	cdrrhr@fda.gov.ph
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