Two-Year Accomplishment Report
September 2012 to September 2014
Highlights of Gains and Success

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Finding Balance between Innovation and Sound Regulation

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THE FDA TEAM
I. BACKGROUND

This two-year accomplishment report was prepared to highlight the accomplishments, gains and success of the Food and Drug Administration (FDA) covering the period from September 2012 to September 2014. This report was prepared two years after the Bureau of Food and Drugs (BFAD) underwent transformation into FDA as mandated by RA 9711, otherwise known as the FDA Act of 2009. The two-year transition period was led by Dr. Kenneth Y. Hartigan-Go, the FDA Acting Director General.

Effective September 12, 2012, His Excellency Benigno S. Aquino III, President of the Republic of the Philippines, appointed Dr. Kenneth Y. Hartigan-Go, MD, MD (UK), FACP, FACP, FRCP (Edin), FICD, FPSECP, FPSCOT, as the Acting Director General of the Food and Drug Administration (FDA) upon the recommendation of the Secretary of Health, Dr. Enrique T. Ona. With more than 20 years of experience as a clinician, professor and manager of health programs with unsullied track records of accomplishments and experience as facilitator of public-private partnerships from arranging drug donations for indigent clinics to bringing together the pharmaceutical industry, business leaders and government for round-table discussions on rational health policy, he served the FDA for two years from September 12, 2014 to October 1, 2014. His two years stint with the FDA was not his first, having served as the Deputy Director of the BFAD from 1999 to 2001. His extensive links with the Philippine health governance communities and business sector as well as various experiences as advisor and consultant to USAID, WHO and the European Community in the field of health and drug policy, health leadership and management, community health partnerships, and health governance, were evident in the reforms and innovations he instituted in the FDA.

Established in 1963, the FDA is an attached agency of the DOH, and its role is to promote public health through regulation of food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, radiation-emitting devices or equipment, and household/urban hazardous substances, including pesticides and toys, among other consumer products that may have adverse effect on health. The extent of the consumer market regulated by the FDA in the country and how much is spent by households on health products is staggering, given the budget allotted by the national government to the agency. In 2011, the Philippines spent around Php 1.4 trillion in pharmaceutical and healthcare products, and Php 5.8 trillion in food and drinks. At 2000 constant prices, 49.7% or 2.2 trillion pesos of the total household expenditure for 2012 was spent on products directly within FDA’s jurisdiction. The market impact extends to 3.27 trillion pesos or 73.5% of total household expenditure if we include the industries affected by the instruments and devices that FDA regulates.

From an organization of functional Divisions, the FDA became an organization of Centers of major products, namely the Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Cosmetic Regulation and Research (CCRR), and Center for Device Regulation, Radiation Health and Research (CDRRHR).
The FDA is accountable to each and every Filipino consumer. The seeds for the complete transformation of the FDA have been planted, but they need to be nurtured. The FDA is an organic organization, and reforms and innovations to improve the quality of the delivery of services will always be an on-going process. With more than 50 years of existence, the FDA as an organization with dedicated officials and employees stands firm in its commitment to ensure public health and consumer protection.

II. CHALLENGES, OPPORTUNITIES AND PROSPECTS (2012 to 2014)


By 2014, the Congress of the Philippines passed another 5 legislative landmarks to be implemented, in part or in full, by the FDA:

- o RA 10354, or The Responsible Parenthood and Reproductive Health Bill of 2012,
- o RA 10623 (2013), or The Price Act,
- o RA 10620, or The Toy and Game Safety Labeling Act of 2013,
- o RA 10611, or The Food Safety Act of 2013, and
- o RA 10643, or The Tobacco Products Graphic Health Warnings Law (2014).

Moreover, the Senate of the Philippines ratified several international protocols or agreement, namely WHO Framework Convention on Tobacco Control (FCTC), Montreal Protocol on substances that deplete the ozone layer, Rotterdam Convention for hazardous chemicals and pesticides, Stockholm Convention on persistent organic pollutants, and Minamata Convention on phase down of mercury, which are also implemented or enforced in part by the FDA.
The legal mandates of the DOH Bureau of Health Devices and Technology (BHDT) to regulate medical devices and radiation-emitting equipment and health products were absorbed by the FDA, by virtue of RA No. 9711. The BHDT is now the FDA CDRRHR. The legal mandates includes PD 480, Creating a Radiation Health Office in the DOH, PD 1372, Amendment to Presidential Decree No. 480 which created the Radiation Health Office of the DOH, EO 119, Re-organizing the MOH, its Attached Agencies and for Other Purposes, and EO 102, Redirecting the Functions and Operations of the DOH.

On top of regulating and testing cosmetic products, the Center for Cosmetic Regulation and Research (CCRR) has been tasked to regulate children’s toys (for up to the age of 13 years old), soaps and detergents, among other household hazardous substances, as well as urban pesticides, the pest control operators, applicators and workers (http://lawphil.net/judjuris/juri2007/feb2007/gr_161594_2007.html).

The 14th Congress of the Philippines passed two legislative landmarks, namely Republic Act No. 9502 (Cheaper Medicine Act of 2008) and Republic Act No. 9711 (FDA Act of 2009), which were signed into law by the President of the Philippines, in recognition of the important role of the FDA in ensuring public health and protecting the safety, welfare and interest of the consumers. The provisions of the two Republic Acts were consistent with the 1987 Philippine Constitution which declares that the State shall “establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country’s health needs and problems” (Section 12, Article XIII, Health).

Both laws empowered the FDA to retain its income and, thereby, to attain financial independence or stability, such that its projects, activities and programs are not hampered by budgetary constraints. Budget preparation, hearings, review and approval all year round are cumbersome for the FDA, given the number of national laws and presidential decrees it implements or enforce, among other international protocols, commitment and agreements acceded by the country through the Senate of the Philippines.

Two important matters, however, must be satisfied before the FDA can use the retained income for expansion and development of its manpower and for other purposes. First, the FDA has to prepare the 5-Year Business Plan, as provided by RA 9711 and RA 9502, and submit it to the Department of Budget and Management (DBM) for approval. Second, the FDA has to restructure the current FDA fees and charges, and rationalize the FDA regulatory services in order to attain financial stability to fund its expansion and development within 5 years. Based on the 5-Year Business Plan, the FDA will need funds to cover for personnel services as the number of employees increase from the current 400+ to 1,600 all over the country as well as funds for MOOE, capital outlay and operational funds for programs, projects and activities.

As provided by RA 9711, the (new) FDA will be a blend of the officials and employees of the BFAD and Bureau of Health Devices and Technology (BHDT). The transition from the BFAD composed of divisions to the FDA composed of four (4) Centers and several Offices presented a major challenge to the FDA Acting Director General. The changes made through the years were meant to increase efficiency and quality of the delivery of FDA’s products and services, as well as increase transparency and accountability among its officers and staff. It was also an opportunity to create several Units within the FDA to ensure the relevance of the FDA to consumers it protects and the industries it regulates. The FDA need inform the general public on what the FDA represents ensuring public health and
consumer protection.

The perennial issues and concerns of the industries to improve turnaround time in issuing the FDA licenses and market authorizations, such as the Certificate of Product Registration (CPR) and Product Notification Number, which were placed under four Centers, namely CDRR, CFRR, CCRR, and CDRRHR, posed as the biggest challenge for the FDA Acting Director General in the midst of reorganization, reforms and full utilization of ICT-based application in the FDA systems and work processes. The FDA must ensure that licensed establishments consistently produced safe, effective and quality health products according to the standards set by the FDA, following a risk-based regulatory approach.

The year 2015 is the year when the ASEAN Member States collectively fulfill and implement the commitments made towards one ASEAN Community (AC). The AC is based on the 3 Pillars, Political-Security, Economic and Socio-Cultural Pillars. The ASEAN Economic Community (AEC) envisions a competitive region with a single market and production base, with micro, small and medium enterprises (MSMEs) as the backbone.

As of 2012, the Department of Trade and Industry (DTI) reported that there are 944,897 business enterprises operating in the Philippines. Of these, 99.58% (940,886) are micro, small, and medium enterprises (MSMEs) and the remaining 0.42% (4,011) are large enterprises. Of the total number of MSMEs, 89.78% (844,764) are micro enterprises, 9.78% (92,027) are small enterprises, and 0.44% (4,095) are medium enterprises.

The MSMEs generated a total of 4,930,851 jobs in 2012 versus 2,658,740 for the large enterprises. This indicates that MSMEs contributed almost 64.97% of the total jobs generated by all types of business establishments that year. Of these, 47.0% or 2,316,664 jobs were generated by micro enterprises; 41.8% or 2,061,090 by small enterprises; and 11.2% or 553,097 by medium enterprises.

The FDA needs to actively participate and makes sure that excessive national product standards or a very strict application of these standards do not impede the flow of trade in goods. The FDA should contribute to initiatives to dismantle national borders represented by standards, technical regulations and conformity assessment procedures that are unnecessary for facilitating trade or for achieving connectivity among similar regulatory institutions in the region. The FDA has attend to several interagency meetings or workshops and participate in collaborative programs with other government agencies that are concerned with trade, finance, tourism, agriculture, national security, public health, disaster management, nutrition, and price control, among others.

As a member economy of APEC, with 21 member economies that account for approximately 40% of the world’s population, 55% of world’s GDP and about 44% of world trade, the FDA participates in APEC meetings and workshops that support free and open trade and investment which redound to growth of the economy, creation of jobs and lower costs of production, and thus reduces the prices of goods and services, a direct benefit to all member economies. The key to achieve the APEC's vision is embodied or referred to as the 'Bogor Goals' of free and open trade and investment in the
Asia-Pacific by 2010 for industrialized economies and 2020 for developing economies. Member economies, through the industries, academe and regulatory agencies, work toward safe and efficient movement, not only of goods, health products and services, but also people across borders through policy alignment and economic and technical cooperation.

There was a need to institute real reforms at the FDA that will address inefficiency, wastage of resources and time, and unorganized and unnecessary processes, as well as increase transparency and accountability, consistent with the Tuwid na Daan program. The eventual transformation of the FDA into a more organized, highly motivated and efficient bureaucracy, should also be devoid of graft and corruption.

As a regulatory agency with several mandates, the FDA participated in government programs and discussions concerning legislative matters and national policies. The FDA supported discussion on the following bills: responsible parenthood and reproductive health, food safety, labelling of toys and tobacco graphics materials. It participated in the discussions on medical marijuana, orphan drugs, regulation of office supplies as household hazardous substances. It collaborated with the Ad Standard Council (ASC), the Self-Regulatory Organization (SRO) of the Philippines, in reviewing guidelines as basis for issuing the ASC Advertisement Clearance. It invited the Department of Trade and Industry-Fair Trade and Enforcement Bureau (DTI-FTEB) to a workshop to learn the basis for issuing the Promotional Permits. The FDA responded to the call of the IPOPhils to review the provisions of the Cheaper Medicine Act and its Implementing Rules and Regulations (IRR) on intellectual property rights and data protection. For more effective and efficient delivery of services, the FDA signed several memoranda of agreement or understanding with other government agencies and non-governmental organizations.

The FDA attends and participates in international meetings, workshops, conferences and assemblies or summit upon the invitation of international organizers, such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), Codex Alimentarius Committee (CODEX), and Pharmaceutical Inspection Convention (PIC/s), among others. As Member State of the United Nations, the FDA represents the Philippines in international conferences and assemblies or summits. The FDA also participates in discussions that facilitate trade to ensure availability, accessibility and affordability of health products in the market.
III. HIGHLIGHTS OF ACCOMPLISHMENTS, GAINS AND SUCCESS

The FDA is mandated to ensure the safety, efficacy and quality of health products and the truthfulness of information and product claims to protect the interests of the consumer, promote his general welfare and to establish standards of conduct for business and industry. The following are some of the accomplishments, gains and success of the FDA from September 2012 to September 2014.

A. Full Implementation of the provisions of RA 9711. The FDA initiated the full implementation of RA 9711 and RA 9502, which authorizes the FDA to retain its income for human resource expansion and development, capital outlay, laboratory and office space, purchase of laboratory equipment, and to conduct and sustain regulatory operations to protect the consumers and legitimate establishments. The FDA submitted the 5-Year Business Plan to DBM on June 23, 2013. In addition, Administrative Order on restructuring of fees and rationalization of regulatory services was drafted and subjected to a series of public consultation and hearings. The plan and the AO have remained unapproved and signed by the DBM and the Secretary of Health. The FDA needs to invest on human capital - from the current workforce of around 464 plus to 1,600. It needs additional budget to pay the salaries of new recruits who will conduct technical evaluation, laboratory analysis, inspections, and enforce rules and regulations all over the country. It will need a budget on capital outlay for additional laboratory and office space and for new and better laboratory equipment.

Some resistance from some sectors on the approval of the Administrative Order (AO) on the restructuring of fees and rationalization of regulatory services throughout the discussion period, which started in the December 2010 BFAD public hearing, were met by the FDA. Failure, however, to support the signing of the AO was a loss of opportunity to implement the vision of the Filipino people that is enshrined in the 1987 Philippine Constitution to establish an integrated and comprehensive approach to health development, which endeavors to make essential goods, health and other social services available to all the people at affordable cost, and to establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems.

Substandard, spurious, falsely labelled, falsified, and counterfeit health products as well as toxic, adulterated or contaminated food products should be prevented from entering the Philippine market. Only a strengthened FDA, as provided by RA 9711 and RA 9502, can stand a chance against unscrupulous businessmen or traders. The FDA has to work in collaboration with other government agencies, health regulatory agencies in other countries, and all the industries it regulates.
B. Reorganization of the FDA. The FDA Acting Director General, with the approval of the Secretary of Health, completed the reorganization of the FDA as provided by law. The Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CDFRR), Center for Cosmetic Regulation and Research (CCRR) under the direct supervision of the FDA Director General (DG). The FDA Office of the Deputy Director General for Administration and Finance and the ODDG Field Regulation Operations were created with Units and/or Regional Offices under them. The Legal Services Support Center (LSSC) which used to be the Legal, Information and Compliance Division, and the Policy and Planning Office (PPO) which used to be the Policy, Planning and Advocacy Division were strengthened. The Central Laboratory (CL), which used to be the Laboratory Services Division, was retained. Some laboratory sections were placed under the CDRR, CCRR and CFRR.

All employees of the BHDT were transferred to the CDRRHR. The employees of the BFAD were transferred to any one of the centers, offices or laboratories.

Recently, the FDA Acting Director-General issued the FDA Personnel Order No. 2014-360, dated 16 September 2014, and FDA Officers were assigned as Officers-in-Charge of 5 FDA Regional Clusters, namely North Luzon (CAR, I, II, III), NCR South Luzon (IV-A, IV-B, V), Visayas (VI, VII, VIII), Mindanao West (IX, X, XI), and Mindanao East (X, XI, CARAGA). The following Units were created to enhance protection of consumers as well as protection of the legitimate establishments:

- The Regulatory Enforcement Unit (REU), as mandated by RA No. 9711, was established. Its presence throughout the country will be felt eventually since it is under the supervision of the Deputy Director-General for Field Regulatory Operations. The REU personnel will bear arms, wear official uniforms and insignias and will be classified as law enforcement agents. The REU has completed the appropriate training and has completed several missions.

- The Health Scam Unit was created to coordinate with the different FDA offices and centers to gather data information on pending or unacted cases involving deceptive advertisement, including the internet, and other marketing practices. It often meets with other government agencies, such as Cybercrimes
Division of the National Bureau of Investigation (NBI) and the National Law Enforcement Coordinating Committee (NALECC) of CIDG. It is also tasked to monitor compliance of advertisement materials to FDA standards to ensure that all information and claims given to consumers are truthful and not misleading so that consumer can make informed choice. Misleading information, often times, lead to premature death and disabilities.

- The Pharmacovigilance (PV) Unit was created to protect consumers from adverse drug reactions or events. The safety of health products cannot be dissociated from the context of quality and benefit (efficacy) of such products; this is in essence a risk/harm/cost and benefit ratio and balance. The creation of the PV Unit is a response to the increasing complexity of regulatory work with new technology, globalization of commercial activities and internationalization of product development. There is increasing autonomy of management and decision-making in governmental regulatory systems, while there is also greater interaction between regulators and the private sector in the development of standards and regulations. This fast-paced climate presses regulators to draw fair balance between potential risks of new drug and public’s expectation of safety. One of the main functions of the Unit is to create database, including background disease incidence, accumulated adverse drug reaction and adverse event reports, and other drug product problems.

- The Product Vigilance Unit was also created to complement the Pharmacovigilance Unit. It will focus on other health products that are under the jurisdiction of the FDA.

- The Clinical Trial Unit was formally created to attend to applications for clinical trials as well as to review clinical trial protocol. The Unit is tasked, among other tasks, to closely monitor the conduct of the clinical trials in the country as required by the FDA and the Code of Good Clinical Trial.

- The Ethical Marketing Communications Unit was created primarily to implement the APEC Mexico Principles and declaration for ethical marketing of biopharmaceutical products. Unethical marketing of medicines leads to irrational drug use and poses additional burden on the health systems. Patients are made to pay higher for their medicines. Through this Unit, marketing and promotions for prescription medicines can only be made to clinicians and pharmacists, but not to students of health sciences. Only over the counter medicines can be marketed to public at large. The Unit is coordinating with other relevant stakeholders with the end objective of achieving better ethical behavior and help make medicines affordable and accessible.

- The Customs Liaison Unit was created to extend the regulatory coverage of the FDA on health product up to the ports of entry all over the country. It serves as the linkage between the FDA and the Bureau of Customs (BOC) on matters of mutual concerns, and where importation and exportation of health products, passing thru all
ports of entries, are guaranteed quality, safety, and legitimacy of source. The engagement between FDA and BOC is material in helping curb graft and corruption and illegal entry of health products, while giving boost to the aims and challenges of the National Single Window (NSW) integration of the ASEAN Economic Community (AEC).

- The FDA launched its intern program for college students from different fields of disciplines on February 28, 2013. The FDA hopes to elicit interests among its interns to take on a career at the FDA someday. The FDA believes that health product regulation is such a specialized science that requires proper preparation. More than knowledge and skills, regulators must possess proper attitude, ethics and integrity, among other values. There were around 80 college students from different schools who participated in the first internship program. As of today, more 300 students, including two interns from France, have completed the program.

C. Timely Delivery or Issuance of LTO, and Market Authorization and Compassionate Special Permit, among other Services. The perennial complaint of poor turnaround time on the issuance of LTO, market authorization (CPR and Notification) and the Compassionate Special Permit, stem, in part, from misunderstanding and misinformed clients, as reported perhaps by the liaison officers, who expect that authorizations are automatically issued after filing the application and payment of corresponding fees. Upon determination of the respective FDA Center, only those applications that have been assessed to have the complete and correct sets of requirement are evaluated for approval or disapproval. Filing of applications and payment of fees do not guarantee automatic issuance of authorization by the FDA. Failure to submit a correct document or requirement within the prescribed period will require a new application and payment. Payments made before the prescribed period of compliance are non-refundable.

The FDA instituted the training and accreditation system for company liaison and regulatory affairs officers who are directly in-charge of submitting technical dossier for market authorization to the FDA. This training and accreditation scheme contribute to faster turnaround time by lessening regulatory burden of reviewing technical documents that are from the start incomplete or incorrect. The QPIRA training and accreditation will hopefully bridge the gap in communication, competence and variation in the interpretation of technical data and information. The success of the QPIRA as an innovation to fast track release of market authorization (CPR) applications is dependent on the information, communication and technology (ICT) infrastructure of the FDA. The FDA has not yet gone fully automated, except for the CCRR.

- The FDA introduced full use of Information and Communication Technology (ICT) in its system and process of application, evaluation, approval and release of licenses and market authorizations. Automating the receiving, review, approval and release of market
authorization is one way of improving turnaround time, cutting down on red tape as well as graft and corruption.


- The FDA issued FDA Circular 2013-004, dated 22 February 2013, after it concluded that it was pointless to overregulate new drug products entering the Philippine. The FDA no longer required drug companies to undertake or conduct Monitored Release for new drugs or newly introduced drugs in around 3,000 patients for a period of three (3) years. Prior to their application in the Philippines, these products are already available in the global market and used extensively by doctors abroad. Monitored Release studies that BFAD required in the past did not offer any new scientific knowledge. However, in lieu of the monitored Release reports, a Periodic Safety Update Report and a Benefit Risk Evaluation Report, as appropriate, shall be periodically submitted to FDA during the entire life of the product in the market, consistent with the global regulatory standard. On a case by case basis, a non-interventional safety or efficacy study may be required in order to confirm reports, studies or information regarding the safety profile of the product or to measure the effectiveness of risk management, among other reasons. (http://www.fda.gov.ph/attachments/article/15838/FC%202013-004.pdf)

- In line with the commitment of the FDA to provide customer and client-oriented public service, that capture the dimensions of quality, efficiency, professionalism, and timeliness, the FDA opened the Public Assistance, Information and Receiving (PAIR) Unit on August 27, 2013. All filing of applications and submissions of requirements are now centralized. Automating the receiving, review, approval and release of market authorization is one way of improving turnaround time, cutting down on red tape as well as eliminating graft and corruption.

An on-line application process was established using the FDA website (http://www.fda.gov.ph/industry-corner/downloads/237-fda-public-assistance-information-and-receiving-pair). A video can be viewed at the FDA website which shows the step by step filing an application for FDA authorization.
All inquiries are attended to personally through phone or email with the document tracking log. Clients can email the FDA for any inquiry via info@fda.gov.ph. The FDA created a library with internet connection, which can be used by clients who would like to be guided with their on-line applications. An IT expert from the FDA Academy orPAIR Unit may be requested for help.

- The FDA Acting Director General established the FDA Academy in 2012. One of the functions of the FDA Academy is to train and produce Qualified Persons in Regulatory Affairs (QPIRA) to ensure correct and complete submission of documents, which would prevent applications from being returned to the applicant. The FDA Academy was introduced as an innovation during the FDA Strategic Planning in Subic on October 2012 to address the inefficiency of the BFAD, wherein all the BFAD Technical Divisions, namely the Product Services Division (PSD), Laboratory Services Division (LSD), Regulation Division 1 (RD1), Regulation Division 2 (RD2), and the Legal, Information and Compliance Division (LICD), separately plan, prepare the program, announce seminars/training courses/workshops, book the venue for the event, select food to be served, document proceedings, prepare the report, and follow-up on commitments made or translate output into policies, rules and regulations. The FDA Academy was created to address the inefficiency in terms of utilization of time, money and human resources. With the FDA Academy, administrative and technical services are coordinated with the 4 Centers whenever training courses, seminars, round table discussions, public consultations and public hearing, workshops, and Kapihan at Talakayan between the FDA and the industries are conducted. Last year, more than 3,000 employees and clients were served by the FDA Academy with more than 70 training courses, seminars, round table discussions, public consultations and public hearing, workshops, and Kapihan at Talakayan sa FDA conducted. This innovation has proven to be cost-effective, efficient, and outputs were translated into policies, rules and regulations, which have direct benefits to consumers and the industries. The fees collected by the FDA PPO/FDA Academy go into a Special Regulatory Fund (SRF). Unused SRFs at the end of the year are returned to the Bureau of Treasury The cost of training allows flexibility to the FDA to provide and administer the best service to its clients, subject to the usual accounting and audit rules and regulations.

- The FDA introduced the electronic notification system for product registration of market authorization. This is actually a system developed by the IT Expert of the FDA in compliance with the ASEAN Cosmetic Notification scheme. The FDA Center for Cosmetic Regulation and Research (CCRR) has fully implemented the Electronic Cosmetic Product Notification (e-Notification) System last 15 April 2013. The development of the FDA e-Notification System is in accordance with the revised ASEAN Cosmetic Notification Template (http://www.fda.gov.ph/industry-corner/downloadables/197-asean-cosmetic-armonization.pdf; http://www.fda.gov.ph/attachments/article/110339/FMC2013-022.pdf). Market authorization is issued by the CCRR within 10 days, compared to a turnaround time of 40 days or more in the past. The other three Centers are expected to adopt the ICT-based evaluation and approval process.

- The Post Marketing Surveillance (PMS) was strengthened by the FDA Acting Director General. The FDA Circular on Post Market Surveillance (PMS) of Authorized Drug Products was issued by the FDA Acting Director General on 22 February 2013. It sets the standards and requirements on PMS system. Among others, the Circular defines
The duties, responsibilities and obligations of Market Authorization Holders (MAH) or CPR holders. (http://www.fda.gov.ph/attachments/article/15838/FC%202013-004.pdf) Consumers can report any complaint via report@fda.gov.ph.

- The FDA is also monitoring advertisement and promotional materials. Some of the food supplements, that are all approved by the FDA as processed food, carry false and misleading therapeutic claims. The FDA is collaborating with the Ad Standards Council and the industries to protect the health and welfare of the consumers. Several FDA advisories have been issued to warn the consumers and the public against deceptive and unsubstantiated health and therapeutic claims.

- The FDA aligned its activities and functions with the National Center for Pharmaceutical Access to Medicine (NCPAM). In a meeting conducted during the first week of February 2012, the FDA and the National Center for Pharmaceutical Access and Management (NCPAM) aligned their activities with the objectives of the FDA. The DOH is pursuing the goal of Kalusugan Pangkalahatan (KP) to overcome inequities in our health system and to deliver better health outcomes. It is built on three strategic thrusts, namely financial risk protection through expansion of the National Health Insurance Program enrolment and benefit delivery, improved hospitals, health facilities and services and scaling up public health interventions to attain our health-related Millennium Development Goals, and to control the rise of non-communicable diseases. Under the DOH guidance, the NCPAM leads in ensuring universal access to quality essential medicines. The NCPAM improves the supply side access to quality essential medicines and institutionalizes transparency and good governance in the pricing and procurement of medicines, among others.

- The FDA has initiated moves to train clinicians from government and private hospitals all over the country on bioavailability/bioequivalence (BA/BE). It will ensure availability of clinical trial services all over the country that complies with FDA standards and requirements. The conduct of BA/BE studies in government hospitals present an opportunity for hospitals to increase their revenues as well as to generate employment for allied health care providers. The Philippine government would be spending around 1.93, 2.01, and 2.10 billion pesos in 2013, 2014 and 2015, respectively, on essential medicines. The BA/BE studies on generic drugs help ensure consistent production of drug products according to FDA-approved specifications and compliance with cGMP requirements on a batch to batch basis. Establishing the BA/BE profile of generic drug products is a requirement for drug registration or to be listed in the national formulary or cross reference index, which may be used by Philippine National Health Insurance Corporation (PhilHealth) for reimbursement purposes.

- The FDA developed a software or program for digital cartography of drug outlets all over the country. Using a Google map, the FDA will be able to upload all the drug outlets all over the country and the consumers will be able to access the map. It will help the consumer decide where to buy drugs, taking into consideration the distance from his location and the price of essential drug products that would appear on the map if he or she clicks on the bubble specific for the drug outlet of interest. In this way, the consumer is able to save money and exercise his or her freedom to choose. This is a form of a market-driven and demand-driven scheme for lowering drug prices since the chains of drugstore will have incentives to lower their retail prices to compete for market shares. The FDA
field inspectors, armed with computer tablets, can locate and coordinate the GPS position of every drug outlet nationwide.

- To increase efficiency in inspection or reporting by field regulatory officers, which will have impact on efficiency of issuance of the License to Operate, the FDA has partnered with PLDT-SMART Enterprise to enhance on-field operations with the use of SMART’s machine-to-machine (M2M) solutions. With the partnership, the FDA Inspectorate will be deployed in the field armed with tablet PCs connected to SMART’s largest network. Each tablet will come with a customized SMART M2M application pre-installed. Moreover, with the customized SMART M2M app, the FDA’s field personnel will be able to carry out audits and inspections with more efficiency. Preparation of inspection reports will be virtually paperless and submission to the supervisors will be done in near real time. Information is directly encoded into the application via the tablet PC. In addition, the program allows field personnel to attach photos using the tablet PCs. All these are sent directly to the FDA office via SMART’s wireless data connection for the bureau’s perusal. This shortens the time involved for inspection and report creation, reducing the turnaround time for license applications. The use of internet may be used to verify if the pharmacist on duty is indeed a PRC-licensed pharmacist. FDA data and information can be accessed through the internet (www.fda.gov.ph). The FDA in Alabang may be useful in monitoring the location of its field inspectors in case of saturation drives.

- From March 6 to 8, 2013, the FDA Acting Director General went on a series of multi-sectoral discussions clarifying the role of the agency, while pushing forward the agenda of the DOH. Upon the invitation of the Center for Health Development of Cagayan Valley, a roundtable discussion of current challenges and exciting prospects was conducted. There is a government building in Tuguegaro City which was left unfinished, and that the FDA is willing to convert into a Satellite or Regional Laboratory. With the plan to construct a Satellite Laboratory in Subic as mandated by RA No. 9711, constructing regional laboratories in strategic locations would improve the accessibility of FDA laboratory services to consumers as well as to the local government units (LGUs). These plans will be executed when the retained income is authorized for use. More and better equipped laboratories all over the country will translate into more efficient LGU drug procurement and drug distribution systems. With a more efficient
utilization of funds for drug procurement, wastage due to expiring drug products will be prevented.

- On 01 July 2014, the FDA and the Ali Mall management inaugurated the FDA Satellite Office located in the Government Center of Ali Mall, Cubao, Quezon City. The Satellite Office will bring the FDA closer to its client and the customers, especially the MSMEs. When fully operational, applicants may transact LTO and CPR applications to FDA at the heart of Cubao, Quezon City. The 30.4 square meter office will maintain a Public Assistance, Information and Receiving (PAIR) Unit, which is connected with the main PAIR System in Alabang. The Satellite Office will serve as office to the FDA Inspectorate for better and more efficient delivery of service.

- The FDA signed a MOA with the LandBank in 2013. FDA fees and charges may be accepted through different branches of LandBank. On September 26, 2014, the FDA inked an agreement with BancNet which made it possible for FDA clients to pay fees and charges online. There is no need to actually go to the bank to make payments. Transactions can be made right in the offices or homes of the applicants. On the other hand, this payment scheme will only be effective and efficient if the Centers adopt an online application and issuance of market authorization.

- During the 51st FDA Anniversary Celebration on June 24, 2014, the FDA Director General, Dr. Kenneth Y. Hartigan-Go, and CHD-XI Director, Dr. Abdullah B. Dumama signed a Memorandum of Agreement which grants the FDA to use a portion of the land at the CHD-XI Office in Davao City to build the P30M FDA Regulatory Field Office in Mindanao. On September 25, 2014, the Deed of Usufruct
between FDA and DOH Regional Offices II, V and IX were also signed.

D. ASEAN Economic and Socio-Cultural Community. Trade facilitation is a key component of the economic integration agenda of the ASEAN. The FDA instituted reforms to support trade facilitation and to slowly dismantle national borders, represented by unnecessary regulations, towards an ASEAN Economic Community (AEC) with a single market and production base, with micro, small and medium enterprises (MSMEs) as the backbone of the AEC.

- In 2013, the FDA reviewed all the technical and administrative requirements in order to apply for FDA authorizations (License to Operate and Certificate of Product Registration, including product notification and permits). The FDA implemented the 3 R’s – Remove Redundant Regulations. The FDA Director General issued a Personnel Order to form the Technical Working Group (TWG), headed by the FDA Deputy Director General for Administration and Finance, with members from both the FDA and the industries. The TWG identified the obsolete BFAD issuances and reviewed the current ones. Workshops were conducted specifically to rationalize the requirements for food and drug product registration requirements. Retooling of evaluators from the different Centers were conducted to standardize evaluation processes. Inspectors underwent training to implement the new requirements of the Centers on compliance to FDA standards for establishments.

- The FDA helped the BOC shorten the lead time in clearing health products at the ports of entry. Finished products, as well as raw materials or ingredients, have faster customs clearance processing. The FDA requires all FDA-licensed manufacturers and distributor-importers to secure market authorization issued by the FDA prior to arrival of health products. (http://www.fda.gov.ph/attachments/article/93217/FDA%20MEMORANDUM%202013-058.pdf). Importers will have to simply show their valid LTO and market authorization (like the CPR) to the Bureau of Customs (BOC). The BOC can simply validate/verify the LTOs and CPRs through the FDA website using the Industry Corner and Consumer Corner tab or the SEARCH platform (http://www.fda.gov.ph/attachments/article/100783/FDA%20Memo%20Circular%202013-032.pdf and http://www.fda.gov.ph/attachments/article/109784/FMC2013-035.pdf).

To ensure authenticity of LTOs and CPRs presented to BOC, the FDA began using the FDA security papers. (http://www.fda.gov.ph/attachments/article/118207/FDA%20Security%20Paper.pdf).

The FDA issued FDA Circular No. 2013-006-A RE: Amendment to FDA Circular No. 2013-006 Dated 28 February 2013, "Bureau of Customs Cargo Import or Export Permits and Clearance in Electronic Form Requirement through the Philippines National Single Window". This initiative, however, did not pushed through since the
BOC has not yet installed the proper infrastructure. (http://www.fda.gov.ph/attachments/article/19818/FC2013-006-A.pdf)

- The FDA improved its transparency of operations and accountability to the Filipino people by upgrading its FDA Website (www.fda.gov.ph). These measures helped enhance impartiality and non-discrimination policy of the government. Clients are now able to access valuable information to help them make decisions about health products. Consumers can now check if establishments and products have authorizations issued by the FDA.

- The FDA posted in its website (www.fda.gov.ph) all the recognized laboratories that are capable of testing specific health products under its jurisdiction. The FDA also sends samples to other government agencies with laboratories that are capable of testing specific analytes.

- The FDA conducted public consultation by posting at the FDA website (www.fda.gov.ph) the draft for comments and public hearing (with online registration to participate through www.fda.gov.ph/fda-academy before the final drafting of issuances.

- The FDA posted all the existing laws, rules and regulations in its website (http://www.fda.gov.ph/). Clients can use the Menu under Issuance to download copies of laws, orders, circulars and memos issued by the FDA/BFAD. Under the Industry Corner, all information relevant to the industry like downloadable forms, checklist, and flowcharts, and fees may be viewed. The website contains complete and updated information of licensed companies: Manufacturers, Distributors (Importers/Exporters), and Traders, including Drug Manufacturers with Valid cGMP. The Certificate of Product Registration (CPR), License to Operate (LTO) and Notice of Deficiency (NOD) for release or pick-up are also posted. The Central Laboratory has information on the list of laboratories recognized by FDA, and Batch Notification, Export-Commodity Clearance, and Lot Release Certification, for release.

- The FDA published or posted its fees and charges. The schedule of fees and charges (FDA AO 163-B, series 2000) is posted in the FDA website (http://www.fda.gov.ph/attachments/article/45415/ao%2020163b%2020200.pdf).

- The FDA Philippines actively participated in the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and other ASEAN Meetings on health products to ensure that FDA imposes national standards and technical regulations on domestically produced and imported products equally and at the same time ensure the public’s interest for safety and quality.
The FDA Philippines participated in the following ASEAN Working Groups or Committee:

1. Under the Healthcare Sector of the ASEAN Economic Community (AEC) Pillar:
   a. ASEAN Committee. The ASEAN Cosmetic Committee (ACC). The working group has already achieved a committee status when it completed all 4 main activities enumerated above. It has already achieved the ACCSQ objective to establish an ASEAN Free Trade Area for cosmetics by implementing Mutual Recognition Agreement (MRA) and adoption of ASEAN technical regulations by the National Competent Authority (NCA), the FDA Center for Cosmetic Regulation and Research.

   b. ASEAN Consultative Committee for Standards and Quality (ACCSQ)
      i. ACCSQ-Medical Device Products Working Group (MDPWG)
      ii. ACCSQ-Pharmaceutical Product Working Group (PPWG)
      iii. ACCSQ-Traditional Medicine and Health Supplement Products Working Group (TMHSPWG)

      The different product Working Groups are still in the process of developing a harmonization scheme of regulations, guidelines, requirements or glossary of terms, or discussing the MRA, among other activities.

   c. Under the Agro-based Product Sector of ACCSQ

      The ACCSQ-Prepared Foodstuff Products Working Group (PFPWG) is still in the process of developing a harmonization scheme of regulations, guidelines, requirements or glossary of terms, or discussing the MRA, among other activities.

2. Under the Pillar of ASEAN Socio-Cultural Community (ASCC), the FDA Philippines with the DOH National Center for Disease Prevention and Control participates in the ASEAN Expert Group on Food Safety (AEGFS).

The FDA attended all ASEAN 2012, 2013, 2014 meetings on standards and conformance initiatives or activities that are focused on four main activities: 1) Harmonization of national standards with international standards, practices and guides, thereby eliminating conflict among national standards that are a restriction to trade; 2) Harmonization of mandatory technical requirements that include registration and premarket approval requirements to ensure free movement of goods; 3) Harmonization of conformity assessment procedures which include accreditation, certification, testing and inspection, and mutual recognition of test reports and certification to save transaction time and to avoid high cost through multiple testing requirements; and 4) Harmonization of technical regulations for national adoption. Some of these meetings or workshops are as follows:

- 17th ASEAN Meeting of the Prepared Foodstuff Product Working Group (PFPWG) and its Related Meetings, Singapore
- 15th ASEAN TMHS Good Manufacturing Practice Task Force Meeting - Kuala Lumpur, Malaysia
- 20th ASEAN Cosmetic Scientific Body (ACSB) - Bangkok, Thailand,
o 29th Meeting of the ASEAN Working Group on Pharmaceutical Development (AWGPD)
o Workshop in the Review and Development of ASEAN Guidelines ASEAN Common Food Control Requirements and 2.Inter-sessional Meeting of the Task Force on M RA for Prepared Foodstuff
o 10th ASEAN Expert Group in Food Safety (AEGFS), Brunei Darussalam
o 18th Meeting of the ASEAN Prepared Food Stuff Product Working Group (PFPWG) and Related Meetings, Hanoi, Vietnam,
o 19th ASEAN Cosmetic Committee (ACC) Meeting and Related Meetings, Vientaine, Lao PDR
o 19th ASEAN Meeting of the Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) and its Related Meetings, Bagan, Myanmar
o 20th ACCSQ TMHS and Related Meetings, Yogjakarta, Indonesia
o 20th ASEAN Cosmetic Committee (ACC) and Related Meetings, Kuala Lumpur, Malaysia
o 20th Meeting of the ASEAN TMHS Scientific Committee (ATSC) and 13th Meeting of the Task Force on ASEAN Regulatory Framework for TMHS
  Bangkok Thailand
o 21st ASEAN Consultative Committee for Standards and Quality Pharmaceutical Product Working Group (ACCSQ-PPWG) Meeting 17-20 June 2014 Jaya Malaysia Seminar - Updates on Anti Malaria Medicines (for regulars only) 16 June 2014
o 21st ASEAN Meeting of the ASEAN Consultative Committee for Standards and Quality of Traditional Medicine and Health Supplement product Working Group and its related meetings
o 22nd Meeting of the ASEAN TMHS Scientific Committee (ATSC) and the Related Meetings of the ASEAN Consultative Committee on Standards and Quality Traditional Medicines - Health Supplements Products Working Group (ACCSQ TMHS PWG) Task Forces
o 2nd ASEAN Food Consumption Data & Exposure Assessment Workshop for the Strengthening ASEAN Risk Assessment Capacities: Food Consumption Data Project, Kuala Lumpur, Malaysia
o 2nd China-ASEAN Drug Safety Forum, China
o 2nd Workshop on the Preparation of the Book of Herbal Medicines Used in Primary Health Care in ASEAN, ASIA Hotel, Bangkok, Thailand
o 4th ASEAN-USP Scientific Symposium: Strengthening Collaborations Towards Harmonization of Pharmaceutical Standards in Asean Regions for Standards and Quality (ACCSQ) Traditional Medicines and Health
o 5th Meeting of the ASEAN Food Laboratory Committee (AFTLC)
o ASEAN Life Sciences Conference, Bangkok Thailand
o ASEAN Plus Three Partnership Laboratories for Communicable Disease (APL): Meeting of National Laboratory Contact Person Meeting (NCLP)
o ASEAN Plus Three Partnership Laboratories for Communicable Diseases (APL) National Laboratory Contact Persons Meeting
o ASEAN Variation Guideline Workshop, NPCB, Malaysia
o Regional Workshop for ASEAN Countries on Hygiene and Safety at the retail end, Singapore
o Food Additives Workshop: Southeast Asia Regional Scientific Exchange, Bangkok, Thailand
o ASEAN (ACCSQ) Traditional Medicines and Health Health Sciences Authority Inspection Coaching Singapore
- Recognizing that the MSMEs are the backbone of the ASEAN Economic Community and that investments help fuel economic growth, the FDA Director General created the Micro, Small and Medium Enterprise Affairs under the Policy and Planning Office. The MSMEs provide jobs for the country’s growing labor force and progress across the country. They serve as valuable partners to large enterprises as suppliers and providers of support services. They serve as the breeding ground for new entrepreneurs and large corporations. The functions of the FDA MSMEs Affairs are as follows:

  - Ensure a “watchdog function” to monitor FDA policies and actions affecting MSMEs and ensuring potential impacts on MSMEs are properly assessed
  - Develop methodologies how to reduce administrative and regulatory burdens;
  - Create and organize a “MSME network” in order to increase awareness about MSME issues; promote linkages between large and small enterprises to encourage the establishment of common services facilities;
  - Communicate and support the dissemination and application of identified good regulatory practices through the DTI SMED Roving Academy;
  - Conduct direct dialogue through meetings and visits with MSME organizations at the national and regional level;
  - Inform the MSMEs and MSME representatives regularly about new regulations currently being developed;
  - Collect feedback from the MSME Business community on issues of interest to them; and
  - Facilitate access of MSMEs to information on programs and initiatives.

As required by RA No. 9711 (The FDA Act of 2009) and RA No. 10611 (The Food Safety Act of 2013), the FDA is mandated to issue license to operate (LTO) to all food business operators. A 10-day training course, which was funded by the DOH-Center for Health Development IV-B through the Palawan State University and the UP Institute for Small Scale Industries, entitled, “Training of Trainors on Food Safety and Sanitation Management”, was piloted in Palawan City, at the Palawan State University, in collaboration with the Bureau of Micro, Small and Medium Enterprises Development and the EU-TRTA III Project under the Department of Trade and Industry. The main goal of the pilot project is to contribute to the capacity development of food MSMEs in the country and ensure their adherence to regulatory standards on food safety and hygiene standards. At the outset, the Local Government Unit Sanitary Inspectors will be trained on food safety, earn food safety certificate of completion or even degree under a laderized program, undergo risk-based inspection training of food establishment, and then later accredited certified and deputized to inspect food establishments and implement food safety regulations in the localities, down to the barangay level. The FDA will monitor their performance as part of quality management system of the FDA. An on line food safety training course for Sanitary Inspector is now in progress at the Palawan State University. The pilot training course will be improved and replicated in other regions of the country.

As support to the micro enterprises, the FDA issued FDA Circular No. 2014-024 RE: Rules and Regulations on Securing FDA Authorization for Food and Cosmetic Micro Enterprises and their Products in Collaboration with Department of Trade and Industry (DTI) Negosyo Centers and Local Government Units (LGU’s)

- On pharmaceutical products,
  - As part of the Risk Management Plan, pharmaceutical companies will be required to conduct PASS (post-authorization safety studies) or PAES (post-authorization efficacy studies), which is akin to a clinical trial but using a global population, or Filipino population as the case maybe.
• On cosmetic products,
  o In line with the FDA’s mission to share its best practices with other ASEAN Member States and other
countries and the vision to be an internationally recognized regulatory authority, the Center for
Cosmetics Regulation and Research (FDA-CCRR), in coordination with the ASEAN Regional
Integration Support from the EU (ARISE), hosted a study tour on the Electronic Cosmetic
Product Notification (e-Notification) system for regulatory agencies for some of our fellow ASEAN member states. The study tour was conducted on 08 to 09 May 2014 at the FDA Central Office, Alabang, Muntinlupa City. Dr. Kenneth Y.Hartigan-Go, the Acting Director General welcomed the officers from different regulatory agencies of Cambodia, Lao PDR, Myanmar and Vietnam (CLMV). The study tour served as an immersion for CLMV in their journey to develop their cosmetic e-notification system with the support of ARISE.

• On August 15, 2013, the FDA also reached out to special sectors of groups like the Federation of Filipino-Chinese Chamber of Commerce and Industry, Inc. (FFCCCI) to guide them in complying with the FDA requirements for securing the LTO and the Certificate of Product Registration. Several health products from China that are in the market have no FDA market authorization and a lot of unregistered products fail the laboratory test for safety. The activity ensured compliance to the FDA health product requirements and standards as well as compliance to other government requirements, like payment of taxes (BIR) and duties (BOC).

E. Initiatives in line with the APEC’s vision of free and open trade and investment in the Asia-Pacific by 2020 for developing economies. The FDA participates in APEC meetings and workshops that support free and open trade and investment, which support inclusive economic growth, poverty reduction, creation of jobs, and lower costs of production, and thus reduction of prices of goods and services, a direct benefit to all member economies. The FDA, together with representatives from government, industry and academe, attended the following:
2014 APEC Harmonization Center Biotherapeutics Workshop Progress towards Convergence - Seoul, Republic of Korea
2013 APEC Harmonization Center Biotherapeutics Workshop
2013 APEC Harmonization Center Pharmacovigilance Workshop Seoul, South Korea
2014 APEC Harmonization Center-Health Sciences Authority Cell and Tissue-based Therapeutic Products (AHC-HAS-CTT) Workshop
"APEC BUSINESS ETHICS FORUM – “ Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors.”
APEC Food Safety Cooperation Forum Partnership Training Institute Network (APEC FSCF PTIN) Workshop on Improved Food Inspection Capacity Building on Risk Analysis
APEC Healthcare Stakeholders Awareness High-Level Workshop
APEC Multi-Regional Clinical (MRCTs) Regulatory Science Center of Excellence - Pilot Training Workshop Singapore
APEC Wine Regulatory Forum (WRF) 2013 Technical Workshop, Washington, DC, USA
APEC Workshop on Enhancing Standards, Conformity Assessment, Technical Regulations and Promoting Regulatory Cooperation in Food Allergen Management
The First Stocktaking Meeting of Regulators and Experts to Review Implementation of the APEC RHSC Roadmap for Medical Product Quality and Supply Chain Integrity
Workshop and First Stocking Meeting of Regulators and Experts to Review Implementation of APEC RHSC Roadmap for Medical Product Quality and Safety

In line with the APEC’s vision, such as streamlining bureaucratic procedures, fostering transparency, promoting e-commerce and ICT-enabled automation and partnerships with the private sector to reduce the burden on the side of investors and business sectors, the FDA accomplished the following:

The FDA issued FDA Circular No. 2014-011 RE: Adoption of Unique Global Product Identification Number. The FDA issuance is aligned with the 25th APEC Ministers Meeting on October 5, 2013 where a joint ministerial statement was issued adopting global data standards in addressing chokepoints requirement in the Supply Chain Framework Action Plan. Specific chokepoints include the documentation for border clearance, security and data reporting for export, documentation for regulatory clearance as part of importation, and inspections. The Philippine border will be empowered to control the entry of substandard, spurious, falsified, falsely labelled, and counterfeit health products, as well as detection of unregistered and possibly toxic, adulterated or contaminated food products. (http://www.fda.gov.ph/issuances-2/others-laws-and-regulations-not-applicable-to-the-above-categories/others-fda-circular/153598-fda-circular-no-2014-011)

Adoption of the Mexico Principles. In 2013, the Food and Drug Administration (FDA) officially announced the adoption of the Mexico Principles to guide the FDA in its regulatory work (http://www.fda.gov.ph/issuances/273-others/103511-fda-circular-no-2013-024 and http://www.fda.gov.ph/issuances/273-others/147416-fda-circular-no-2014-007). Specifically, the FDA will be implementing the provisions of the Principles through the Medical Directors of drug establishments. The FDA, likewise, issued FDA Circular No. 2014-007 RE: Adoption of the Kuala Lumpur Principles Device Sector Codes of Ethics (http://www.fda.gov.ph/issuances-2/others-
laws-and-regulations-not-applicable-to-the-above-categories/others-fda-circular/147416-fda-circular-no-2014-007). This was in line with 2011 signing, by His Excellency President Benigno S. Aquino III, of the declaration on the Mexico Principles, a voluntary compliance to ethical marketing practices for biopharmaceuticals and ethical interactions with health professional organizations, with 21 other economies.

The adoption of the Mexico and Kuala Lumpur Principles will have impact on the proper use of the resources of the pharmaceutical industry, which should be channeled to real scientific endeavors that would benefit the patients and consumers, and to set high ethical rules for health professional organizations. All forms of junkets, and similar marketing ploys, have no place in a healthy economy.

- The Philippines hosted the first event of the APEC Blood Safety Project on 30 September to 1 October 2014. It will be a two-day training workshop course which will kick-off the project as part of APEC 2014 deliverables.

- The FDA created the Cellular Therapy Unit and will cover blood, blood components, and blood devices. The APEC Life Science Innovation Forum secured funding to launch the Project. The proponents come from US State Department. Philippines co-sponsored the Project and hence a member of the task force.

- The FDA helped the DOH HIV/AIDS Program to access HIV/AIDS medicines through the MPP-UNITAID. A meeting between the FDA and the staff of the Medicine Patent Pool (MPP) during the World Health Assembly 2014 facilitated the discussion. The FDA conducted online meeting with the National Center on Pharmaceutical Access to Medicine (NCPAM) and HIV/AIDS Program to access affordable HIV/AIDS medicines. The MPP is a United Nations backed organization that offers a public-health driven business model that aims to lower the prices of HIV medicines and facilitate the development of better-adapted HIV medicines in developing countries through the voluntary licensing of patented HIV medicines.


- The FDA issued FDA Circular No. 2014-009 RE: Filing and Submission of Applications for the Approval of Clinical Trial Protocol, Compassionate Special Permit (CSP), Import Permit for Investigational Drug Products, Pharmacovigilance,
Adverse Events/Adverse Reaction Reports. Filing and Submission of Applications for the Approval of Clinical Trial Protocol, Compassion Special Permit (CSP), Import Permit for Investigational Drug Products, Pharmacovigilance, Adverse Events/Adverse Reaction Reports, and Other Related Documents (http://www.fda.gov.ph/attachments/article/150837/FC2014-009-%20Filling%20and%20Subscription%20of%20Application%20for%20the%20Approval%20of%20Clinical%20Trial,%20Protocol,%20Compassionate%20Special%20Permit%20(CSP)%20Import%20permit%20for%20Investigational%20Drug%20Products.pdf)

- The FDA issued FDA Circular No. 2014-015 RE: Manufacture, Sale and Distribution of Traditional and Alternative Medicines. Consistent with the mandates provided to FDA by Republic Act 9711 also known as "Food and Drug Administration (FDA) Act of 2009", and Republic Act 3720 also known as the "Food, Drug and Cosmetic Act" as amended, as well as the provisions of Republic Act 9502 also known as "Universally Accessible Cheaper and Quality Medicines Act of 2008", the FDA reiterated that establishments involved in the manufacture, importation, exportation, sale, offer for sale, and distribution of all drug products, including the following are required to be licensed with FDA: (1) allopathic, (2) traditional/alternative (e.g. traditional Chinese medicines, Ayurvedic medicines, homeopathic medicines), and (3) herbal medicines. Furthermore, all drug products are required to be registered before they can be marketed, distributed or sold.

- The FDA, in collaboration with the DOH-NCPAM, conducted training for FDA employees and economist on Health Technology Assessment (HTA). Cost effectiveness is now a major consideration in assessing effectiveness of health products. Market claims vs price to be sold will gradually be subjected to HTA by the FDA in collaboration with the DOH-NCPAM. Training on statistics and epidemiological tools by staff under the Center for Drug Regulation and Research (CDRR) and the Pharmacovigilance Unit and Clinical Trial Unit (CTU) will be needed to do more sophisticated work.

- The FDA is strongly considering the reduction of needless technical barriers to wine trade by requiring registration of a specific wine product, but any reference to vintage will no longer require a new CPR. It shall be treated as a variant that will require online notification.

F. Tuwid na Daan Program. The FDA instituted reforms and innovation to address inefficiency, wastage of resources and time, and unorganized and unnecessary processes, as well as to increase transparency.

- In September 2013, FDA passed the Anti-Red Tape Act (ARTA) survey with a Civil Service Commission (CSC) ARTA Report Card rating of 84.83%, up from 70.57% on April 24-26, 2013. Passing the CSC ARTA audit and ISO-9001 accreditation was the First for FDA.

In March 2013, three months before
FDA’s 50th anniversary, the FDA earned the ISO 9001:2008 Certificate of Accreditation for Quality Management System which was awarded by the TÜV Rheinland. The scope of the ISO accreditation includes licensing of food, drugs and devices, and cosmetic establishments, and registration of all health products manufactured or distributed by FDA-licensed establishments.

In December 2013, the President of the Philippines recognized the FDA’s accomplishments in a simple ceremony in Malacanang Palace. In the final analysis, however, both accomplishments will redound to better delivery of quality health products and health care services to consumers, patients and the general public.

The FDA improved its transparency and accountability to the Filipino people, by upgrading its FDA Website. Consumers and client industries are now able to access valuable information to help them make decisions about their health and products. Consumer reporting system and pharmacovigilance were heightened by the FDA, such that consumers are now able to report any adverse reactions and events after using health products. Consumers can now check if products have been issued with FDA market authorization or if an establishment is licensed by the FDA.

- The FDA harnessed the full use of ICT in order to work smarter and more efficiently.
  - **FDA Email System.** On 3 December 2012, the FDA Director-General instituted a highly secured and reliable email system for the FDA employees. The FDA email system has improved work efficiency among the personnel. It has bridged the communication gap that exists between and among FDA officers and staff. Face to face meetings are less and more time is being devoted to doing actual tasks. Exchange of documents and sharing of information have been facilitated, which resulted to faster and collective decision-making process. Informing all FDA employees by the Administrative and Finance Office is now faster. The FDA email system has also lent credibility to the FDA officers when communicating with the industries and other agencies in government, as well as with international organizations. The FDA email system is a critical tool for the FDA Director General to manage and monitor the Food and Drug Regulation Officers (FDROs) in Centers for Health Development (CHDs) all over the country.

  - **Upgrading of FDA Website** ([www.fda.gov.ph](http://www.fda.gov.ph)). The FDA has a new website which replaced the old FDA website. Noticeable in the new website are updated and critical information that consumers and the industry sector need. The FDA created an e-facility for consumers to file their complaints at report@fda.gov.ph or to make inquiries at info@fda.gov.ph. Moreover, the FDA created a Facebook, Twitter and Instagram accounts.

  - **Payment of Fees in the Bank or Online.** The FDA has completed bank and
online payment through the branches of the Land Bank of the Philippines (LBP) and through BancNet. This mode of payment significantly reduced the long queue at the FDA Cashier’s Office and decongested the foot traffic at the FDA. It has tremendously contributed in lessening face to face transactions, thus, more time for FDA employees to do their tasks on time. It has contributed to the transparency and accountability on financial transactions of the FDA.

d. **DocumentTrackStatus.** It is now possible to follow-up on all license and product registration applications through online. The FDA has developed a Doc Track Status platform (http://www.fda.gov.ph/doctrack-status-know-the-status-of-your-application) which will require the applicant to enter the application 14-digit number and his/her email address or telephone number. There is no need to come to the FDA to make follow-ups. The owners themselves need not rely on liaison officers to do the follow-ups, saving them money and time. The same DocTrack System is being utilized by the FDA to make sure that all documents are accounted for and appropriate actions have been taken by the office or person who has the document. In this way, improvement of the systems and procedures of the FDA are now based on facts and data generated by the system. It is now easier to improve the system if one can pinpoint exactly were the bottlenecks are.

**G. Inter-Agency Collaboration.** The FDA is concerned with the national affairs that have impact on public health and consumer protection.

- The FDA attended workshops and provided inputs on the following bills: Responsible parenthood and reproductive health act, Food safety act, Labelling of toys, Tobacco graphics materials, and E-cigarettes. It also received invitations to attend hearings on medical marijuana, orphan drugs, and office supplies as household hazardous substances, among others.

- The FDA led the drafting of the IRR of RA No. 10611, otherwise known as the Food Safety Act of 2013. It was instrumental in the inclusion of the specific provisions for FDA to make sure that the DOH “bear the specific responsibility of ensuring the safety of all food processing and product packaging activities” under Section 18. Specifically, the a) The DOH shall ensure the safety of all food processing and product packaging activities; (b) The FDA Center for Food Regulation and Research (CFRR) shall be responsible for implementing a performance-based food safety control management system which shall include, but not limited to, the following: (1) Development of food standards and regulations; (2) Post-market monitoring; (3) Enforcement, of HACCP and other risk-based control measures; (4) Strong participation in Codex and other international standard setting bodies, (5)
Communication of risks and development of interactive exchange among stakeholders; (6) Establishment of laboratories for food safety and strengthening the capabilities of existing laboratories; (7) Development of a database of food safety hazards and food-borne illness from epidemiological data; (8) Strengthening R&D capabilities on product, safety and quality standards; and (9) Certification of food safety inspectors.

Furthermore, Section 28 on Licensing, Registration of Establishments of the Food Safety Act of 2013, mandates all Departments and agencies that appropriate authorizations shall be developed and issued in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in production, post-harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations.

“Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products”.

The DOH Secretary will Chair the National Food Safety Coordinating Board with the FDA Director General as the alternate Chair.

- The FDA created a Technical Working Group (TWG) on Labelling of Toys, as per RA 10620, otherwise known as the Toy and Game Safety Labeling Act of 2013, in order to ensure effective coordination of the FDA with the Department of Trade and Industry in responding to the regulatory challenges posed by labelling of toy products.

- The FDA conducted 2 workshops, one on September 2013 and June 2014, to discuss clearance of advertisement and post-clearance mechanism of removing advertisements with the Self-Regulatory Organization of the Philippines, the Ad Standard Council (ASC),
consistent with the Best Practice embraced by the APEC member economies. A draft FDA issuance was reviewed by three groups and a report with recommendations is now being prepared. During the last workshop, the FDA invited a representative from the DTI Fair Trade and Enforcement Bureau (DTI-FTEB). The draft containing both guidelines on advertisement and issuance of promotional permit was reviewed. It was clarified during the workshop that issuance of promotional permit is a function of both the DTI-FTEB and the FDA. The FDA needs to develop clear rules and regulation on how each Center issues FDA Promotional Permit. The market authorization issued by the FDA is a requirement before the ASC accepts applications for Advertisement Clearance.

- The IPOPHiL invited the FDA-DOH in several meetings together with DOH- NCPAM and DOH-Bureau of International Health Cooperation (BIHC) to review the IRR on Cheaper Medicine Bill, specifically on data exclusivity and patent linkage. The discussion is part of the commitment of the Philippines to address the issues on USTR301 and as part of our initiatives to strengthen the enforcement of IP Rights in the country. In May 2014, the Philippines was removed from the USTR301 list. Consistent with one government policy, the IPOPphil and the FDA would like to enter into a MOA on how to lessen infringement of patents, which affect the availability and accessibility of health products in the market as well as generic drugs procured by the NCPAM.

- On June 30, 2014, FDA and PEZA finalized the Memorandum of Agreement on their partnership. While securing public health as the FDA’s top priority, the agency provides the regulatory milieu for investors and entrepreneurs to embark on beneficial and productive economic activities in the country, and seeks to be more trade and investment-friendly to support growth of the industries and national competitiveness as well as to ensure the country’s access to affordable and quality health products. The MOA will provide a venue to discuss different approaches or options to streamline administrative and technical regulatory process for PEZA-registered enterprises, consistent with Good Regulatory Practice. The agreement between the FDA and PEZA is a commitment that appropriate regulations are in place to promote ethical, fair, and legal business practices, making business enterprises, especially the SMEs that form the backbone of the Philippine economy and that generate the largest employment across the country, more credible.

- The EU Trade-Related Technical Assistance to Philippines, Phase III (TRTA-3). The DTI and the European Union (EU) launched the 3rd Phase of the Trade Related Technical Assistance (TRTA 3) Project at the Hotel InterContinental Manila in Makati City, on June 28, 2013. The overall objective of the TRTA 3 Project is to contribute to the Philippines’ integration into the international and regional trading and investment system thereby strengthening economic development,
inclusive growth and poverty reduction. To achieve this overall objective, one of the components of the project – Component 4: Sanitary and Phytosanitary (SPS) Conformity – supports efforts of selected government agencies and private sector organizations to improve capacities to implement and apply SPS procedures in conformity with international standards. The FDA is a beneficiary and one of the implementing agencies of Component 4.

On April 2014, the proposed undertaking to implement a capacity building program was envisaged for the FDA, the Bureau of Micro, Small and Medium Enterprise Development (BMSMED-DTI) and DTI-TRTA-3 Project. This joint program will address the lack of technical knowledge of government employees serving the food sector and will also equip the (MSMEs) with better appreciation for the FDA- issued License to Operate (LTO) as a vital means to improve their products and access bigger markets, as well as heighten understanding on food safety. (http://www.fda.gov.ph/news-and-events/85336-trta-3-bits-fda-to-further-enhance-global-competitiveness-of-food-products-with-new-european-union-support).

The FDA has allocated resources for the conduct of capacity building activities for stakeholders. In turn, TRTA-3 will provide research and training materials as well as other works of the project Key Experts and Short-Term Experts in the course of the project implementation. This partnership serves to make good use of these valuable documents and ensures that the contribution of the project to the country’s inclusive growth and poverty reduction will be actualized even past the conclusion of the project in the year 2016. A pilot Training of Trainers (TOT) was conducted from June 30 to July 9 of 2014 to jump-start the proposed capacity development program. With the support of the Center for Health Development (CHD) of the Department of Health (DOH), this pilot training was organized by the Palawan State University (PSU). The University of the Philippines Institute for Small-Scale Industries (UP ISSI) has been tapped as the designer and provider of this first training, which aims to equip identified trainers from the Province of Palawan with the necessary technical inputs for subsequently conducting “Food Safety and Sanitation Management for Food Inspectors” trainings to be assisted by relevant entities including DTI. The pilot training of trainers will be replicated in all regions of the country, focusing on the MSME food business operators. (eutrta3phil.org/infmomaterials/images/TRTA%203%20Communications%20&%20Visibility%20Progress%20Report%20(as%20of%2030%20June%202014.pdf)

- The FDA and the Philippine Metrology, Standards, Testing, and Quality (PhilMSTQ, Inc.), a non-stock, non-profit, professional association duly established under the laws of the Philippines, has agreed to enter into a Memorandum of Agreement to promote a responsive and sustainable National Quality Infrastructure, particularly in the food, pharmaceutical and
cosmetics industries. The MOA will be instrumental in the mutual objective of both parties to improve the quality of life of Filipinos through the promotion of safe and high quality products and services.

- On July 29, 2013, the International Rice Research Institute (IRRI) briefed the FDA on the on-going research on healthier rice varieties, namely biofortified rice with provitamin A and those enhanced with higher levels of iron and zinc. Dr. V. Bruce Tolentino, Deputy Director General for Communication and Partnership briefed the FDA on the research agenda of IRRI. Dr. Gerard Barry, Senior Scientist and Biotechnology Specialist, together with his team, discussed the research projects on healthier rice varieties that will help address the public health problem of “hidden hunger” or micronutrient deficiency.

- In the aftermath of the Yolanda super typhoon, FDA was visible in the ports of entry to make sure that donated medicines coming from international organizations and other countries are safe, effective and of good quality. The FDA instituted mechanisms to facilitate the release of medicines to patients in relief centers. The FDA worked closely with international organizations, the Dangerous Drug Board (DDB) and the Philippine Drug Enforcement Agencies (PDEA). The FDA also helped the lead government agencies in ensuring the safety and quality of vaccines and other infant food products that were administered or offered to infant and children. The FDA issued Circulars. One exempted the drug establishments from paying fees for their LTOs. The second one was a moratorium on the payment of penalty fees for later renewal of LTO for establishments engaged in the manufacture and distribution of health products.

- FDA is collaborating with the Bureau of Internal Revenues, Department of Finance to check for “questionable” feeds and feed raw materials entering the local market tax-free. Unless the importer or shipper can show certification from the Food and Drug Administration that the goods are unfit for human consumption and cannot be used to produce food for humans, the importers will be charged 12-percent Value Added Tax. Without the required FDA certification, taxmen are instructed to bar the cargo from leaving the port until shippers and importers settle first VAT. BIR will refund the collected tax at a later date only if the goods have not been used to produce human food. The order is contained in Revenue Memorandum Circular 55-2014 issued by BIR Commissioner Kim Henares on June 17, 2014. Implemented without proper consultation with stakeholders, the measure caught commodities traders, feed
millers and livestock and poultry farmers by surprise.

- The Board of Investments (BOI) and the Food and Drug Administration (FDA) entered into a Memorandum of Agreement (MOA) on September 9, 2014. The MOA will help facilitate the issuance of FDA permits and licenses for BOI applicants or investors in accordance with the FDA’s Citizen Charter. The MOA is the result of four (4) months of consultation between the two agencies. In drafting the MOA, both teams took paramount consideration of the two agencies’ existing requirements, business processes and procedures, as well as the level and ease of compliance with the said requirements. The overall objective is to make investing in the Philippines easier, and thus more attractive to investors. This initiative is part of the BOI’s “Going the Extra Mile” project to provide high impact services to investors that will result to favorable decision to retain investments, expand and/or diversify its operations in the Philippines. FDA welcomes this program as the agency has several on-going initiatives towards improving its services to client investors.

- The FDA and CHD-XI sealed a Memorandum of Agreement for the FDA Field Office in Mindanao. During the 51st FDA Anniversary Celebration on June 24, 2014, the FDA Director General, Dr. Kenneth Y. Hartigan-Go, and CHD-XI Director, Dr. Abdullah B. Dumama signed a Memorandum of Agreement which grants the FDA to use a portion of the land at the CHD-XI Office in Davao City to build the P30M FDA Regulatory Field Office in Mindanao.

- List of Conducted Public Hearings/Public Consultations and Round Table Discussions 2013-2014

  - 2012
    - Restructuring of Fees and Rationalization of Regulatory Services
  - 2013
    - Public Consultation for the Draft Administrative Order on the Registration of Biosimilar Products
    - Public Consultation on Electronic Nicotine Delivery System (E-cigarette)
2014

- Public Consultation on the Draft Administrative Order on the Licensing of Drug Establishments and Outlets (Mindanao)
- Doctors as Non-consumer Users of Vaccines and other Biologic Product
- Public Hearing for Cancer Patients, Cancer Survivors and their Family Members
- Public Hearing for Drug Manufacturers and Distributors of Anti-Cancer Drugs
- Public Hearing for Health Care Professionals, Oncologists and Members of Medical Specialty Societies
- FDA Basis for Classifying Medicines as Prescription (Rx) or Over-the-counter (OTC) Products
- Regulation of Homeopathic Products in the Philippines
- Public Hearing on Regulation of Stem Cell
- Public Consultation on the Revised Rules and Regulations Governing the Generic Labeling Requirements of Pharmaceutical Product for Human Use
- 3rd Public Hearing on 2014-2015 Restructuring of Fees and Rationalization of Services (AM-CCRR / PM-CFRR)
- Public Hearing on the Draft Administrative Order on the Implementing Guidelines in the Adoption of the Mexico City and Kuala Lumpur Principles and other Marketing Practices

Several Kapihan at Talakayan sa FDA were conducted per Center to talk about current issues and concerns raised by the industries.

H. International Meetings, Workshops and Developmental Interventions

The FDA accepted invitations from international organizations, like the WHO, FAO and USAID, among other organizations, to attend meetings, workshops and developmental interventions. The Philippines as a Member State was able to participate in discussions geared towards attainment of the Millennium Development Goals as well as in harmonizing regulatory requirements and facilitation of trade to ensure availability, accessibility and affordability of health products.
Meeting on Quality- Assured Drugs for Better Public Health: Strengthening and Harmonizing the Regulation of TB Medicines in the Western Pacific Region
1st Meeting of Access to Quality Medicines and other Technologies Task force (AQMFT) - Sydney Australia
6th PIC/S Expert Circle Meeting on Active Pharmaceutical Ingredients (API) - Advanced Training on API Inspections Rome Italy
Codex Coordinating Committee for Asia (CCASIA) Colloquium, 25-27 June 2014 Tokyo Japan
Fifth Meeting of the Regional Comprehensive Economic Partnership Trade Negotiating Committee and Related Meetings
Informal Technical Consultation on the Regulation of Electronic Nicotine Delivery Systems - Manila, Philippines
6th PIC/S Expert Circle Meeting on Active Pharmaceutical Ingredients (API) - Advanced Training on API Inspections Rome Italy
2013 PIC/S Annual Seminar in Ottawa, Ontario, Canada, "Global Supply Chains and GMP Compliance".
16th International Conference of Drug Regulatory Authorities (ICDRA)
11th INTERPOL Train-the-Trainer Workshop on IT Crime Investigation for Asia and South Pacific, Seoul, South Korea
2nd China-ASEAN Drug Safety Forum, China
2nd Meeting on Substandard/Suprious/Falsey Labelled/ Falsified/ Counterfeit Medical Products (SSFFC), Geneva, Switzerland
2nd Vaccine Hands-on Training, Ministry of Food and Drug Safety Korea
2nd Workshop on the Preparation of the Book of Herbal Medicines Used in Primary Health Care in ASEAN, ASIA Hotel, Bangkok, Thailand
35th Session of the Codex Committee on Methods of Analysis and Sampling
35th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Ramada Hotel Sodenam, Taunus, Germany
36th Meeting of Who Programme for International Drug Monitoring - Rome, Italy
36th Session of the CAC, Rome Italy
37th Session Codex Alimentarius Commission (CAC)
3rd Global Summit of the Pharmacopeias, Baltimore, Maryland USA
46th Session of the Codex Committee on food additives.
4th Meeting of the Regional Comprehensive Economic Partnership Trade Negotiating Committee and Related Meetings
4th Session of Codex Committee on Food Hygiene (45th CCFH) and FAO Regional Training Course: Establishment and Application of Microbiological Criteria, Hanoi, Vietnam
5th Meeting of the Regional Comprehensive Economic Partnership Trade Negotiating Committee and Related Meetings
66th World Health Assembly
67th World Health Assembly
6th Joint Commission for Bilateral Cooperation between the Philippines and Indonesia
8th Asian Conference on Pharmaco-Epidemiology, Hongkong, China
8th Meeting of the Codex Committee on Contaminants in Food
AFRL for VDRL Workshop 2014: Analysis of Antibiotics Residues in Animal Products
Asia Pacific Leaders Malaria Alliance Face to Face Meeting
Asia Pacific Regional Capacity Building for HTA (ARCH) Initiative Workshop
Coached Inspection Program on Traditional Medicine, Malaysian National Pharmaceutical Control Bureau, Petaling Jaya, Malaysia
Consultation for Priority Actions on Antimicrobial Resistance in the Western Pacific Region
Consumer Friendly GDA Nutrition Labeling Workshop, Chonburi Thailand
Council for International Organizations of Medical Sciences (CIOMS) on Vaccine Safety - 3rd Meeting
CPhl - Generics Southeast Asia Summit 2013 - Bangkok, Thailand
CPhl - Quality by Design 2013, Kuala Lumpur, Malaysia
FAO Regional Training Course: Strengthening Capacity in Data Collection and Generation for Food Safety Risk Analysis", Tokyo, Japan
Food Additives Workshop: Southeast Asia Regional Scientific Exchange,
IBC Asia's Regulatory Summit on Updates and Guidelines on GMC and Stability Study Requirements in the Philippines Singapore
Invitation to participate in the Michigan State University International Food Safety Program
ISoP Asia 2013 Symposium - Pharmacovigilance Across Borders in Asia Singapore
ISPE Conference 2013, Singapore
Joint Multi - Regional Clinical Trials (MRCT) and Good Clinical Practice (GCP) Inspection Workshop -
Joint Multi - Regional Clinical Trials (MRCT) and Good Clinical Practice (GCP) Inspection Workshop - Qing Dao, China,
- Korean Market Access Seminar on Agricultural Products
- Law and Cancer Intensive Legal Training Workshop - Melbourne, Australia
- Leaders in Economic Development Programme for Senior Public Officials from Asia - Singapore
- McCabe Centre for Law and Cancer Intensive Legal Training Program
- Meeting among Early-Adopter Countries (EAC) for Dengue Vaccine - Bangkok, Thailand
- Meeting among National Regulatory Authorities interested in adopting Dengue vaccine
- Meeting of the AHO Advisory Committee on Safety Medicinal Products (ACSoMP)
- Meeting on Harmonizing Quality Audit in Radiotherapy and Promoting the Concept of Audit in Member States, Vienna, Austria
- Operations Pangea Single Point of Contact (SPOC) Working Meeting, Lyon France
- Opson III Debriefing and Opson IV Planning Meeting, - Madrid Spain
- Pharmaceutical Inspection Cooperation Scheme (PIC/S) Expert Circle meeting on Human Blood, Tissues and Cells, Taipei, Taiwan
- Pharmaceutical Regulatory Affairs Management (Korea HT Excellence)
- Planning Meeting for INTERPOL Operation OPSON III, Bangkok Thailand
- Professional Capacity Building for Pharmaceutical Safety Management: The Korea HT Excellence Program (Intensive Course), Osong, Korea
- Regional Consultation Workshop on Implementation of GMP/HACC in Asia-a status review
- Regional Workshop for ASEAN Countries on Hygiene and Safety at the retail end, Singapore
- SEARO and WPRO First WHO NRA Planning Workshop for SEAR and WPR Countries, Bali, Indonesia
- Second Pharmaceutical Inspection Co-operation Scheme (PIC/S) Expert Circle Meeting on Good Distribution Practices
- Special Pharmaceutical Product Working Group Heads of Delegation Meeting
- Storm Enforcement Network Final Meeting, Kuala Lumpur, Malaysia
- Strategic Management of Regulatory and Enforcement Agencies, Massachusetts, USA
- Subject: Invitation to Asian Productivity Organization (APO) Workshop on Risk Management of Foodborne Pathogens, Pakistan
- The Third Senior Officials Meeting (SOM3) and Related Meetings
- Training Course on Applications of Biotechnology and its Regulations, India
- Validation of National Regulatory Authority Self-Assessment in Mongolia, Ulaanbaatar, Mongolia
- WHO Implementation Workshop: Evaluation of Biotherapeutic Products and Evaluation of Similar Biotherapeutic Products with Emphasis Monoclonal Antibody Products
- WHO Regional Alliance Steering Committee Meeting, Seoul, South Korea
- WHO Regional Workshop on Vaccine Evaluation - Dubai, UAE
- WHO Workshop on Implementation of Guidelines for Lot Release of Vaccines, New Delhi, India
- WHO Workshop on Laboratory Testing DTP Combined Vaccines - Indonesia
- Workshop and First Stocking Meeting of Regulators and Experts to Review Implementation of APEC RHSC Roadmap for Medical Product Quality and Supply Chain Integrity, Qingdao, China
Workshop on Ensuring Safe and Quality Traditional Medicine Products, Soul, South Korea
Workshop on Food Contact Materials Testing
Workshop on Nutrition Labeling, Claims and Effective Communication Strategies the Consumer
Workshop on Surveillance and Monitoring for Regulatory Authorities - Qingdao, China
Workshop on the Mutual Recognition Arrangement for Prepared Foodstuff, Jakarta, Indonesia
Workshop on Surveillance and Monitoring for Regulatory Authorities
Workshop on Surveillance and Monitoring for Regulatory Authorities

FDA Philippines hosted the study tour of delegates from Mongolia, consisting of five Members of Parliament and four senior officials of the Ministry of Health (MOH) on 01 to 04 April 2014. The visit was intended to learn from the Philippine FDA which could help the Mongolian legislators in their plan to revise the Mongolian Medicines Law.

I. Signed and Approved Administrative Orders, FDA Circulars and Memorandum Circulars by the DOH Secretary of Health and the FDA Acting Director General

The DOH-FDA issued Administrative Orders, FDA Circulars and Memorandum Circulars, which were approved and signed by the Secretary of Health or the FDA Acting Director General, to protect the health, welfare and interest of the consumers and provide guidelines and standards for the conduct of business. These issuances may be viewed at the FDA website under the tab Issuance (http://www.fda.gov.ph/) along with all the Republic Acts and Presidential Decrees and Executive Orders implemented by the FDA.

The following are the FDA Advisories which were issued from October 2012 to September 29, 2014 to warn the consumers and inform or educate the public:

- **2012**
  - 2012-008, 31-Oct-12, Warning the Public That Food or Dietary Supplement Has No Approved Therapeutic or Curative Effects
  - 2012-009, 31-Oct-12, Updates on Korean Noodles Contaminated with Benzopyrene
  - 2012-010, 30-Oct-12, Warning on the Possible Choking Hazard Associated with the use of Toy Whistles and Bubble Making Toys Containing Whistles
  - 2012-011, 12-Nov-12, Korean Noodle Issue
  - 2012-012, 12-Nov-12, Reported Recall of NESQUIK Chocolate Powder
  - 2012-013, 15-Nov-12, Voluntary Recall Order of Chalchews
  - 2012-014, 13-Nov-12, Warning on the Harms and Hazards of Plastic Toys
• 2012-015, 12-Nov-12, Holiday Food Safety Tips
• 2012-016, 22-Nov-12, Update on Cosmetic Products Found to Contain Highly Toxic Level of Mercury
• 2012-017, 29-Nov-12, Antimicrobial Resistance
• 2012-018, 28-Nov-12, Update on Banned Cosmetic Products Found to Contain Highly Toxic Level of Mercury
• 2012-018-A, 14-Mar-12, Ammendment DOH-FDA Advisory No. 2012-018 Re: Update on Banned Cosmetic Products Found to Contain Highly Toxic Level of Mercury

  o 2013
  • 2013-002, 12-Dec-12, Result of the Post-Market Surveillance / Monitoring Conducted by the Food and Drug Administration on the Safety of Toys in the Market
  • 2013-005, 1-Apr-13, Public Health Warning on Temporary Skin-Staining Cosmetic Products
  • 2013-006, 3-Apr-13, The Risks of Indiscriminate Use of Antimicrobials in Animals
  • 2013-007, 8-Apr-13, Ang mga Produktong Kosmetiko at ang Kapakanan ng mga Mamili
  • 2013-008, 10-Apr-13, Electronic Cigarettes and R.A. No. 9211, Otherwise Known as the Tobacco Act of 2003
  • 2013-009, 15-Apr-13, FDA Allows the Use of "Magic Sugar" But Requires All Importers, Traders and Distributors to Secure FDA Authorization
  • 2013-010, 19-Apr-13, Consumer eReport Facility on Cosmetic Products
  • 2013-011, 21-Apr-13, Ensuring Access of Filipino People to Safe, Effective and Affordable Essential Medicines and the Pharmacy Law of the Philippines
  • 2013-012, 15-May-13, Public Health Warning Against Receiving Unapproved Stem Cell Preparations in Non-Health Facilities
  • 2013-013, 6-Jun-13, Ban on Food Products Contaminated with Maleic Acid
  • 2013-014, 24-Jun-13, The Safety of Genetically-Modified Foods Produced Through Modern Biotechnology
  • 2013-015, 26-Jun-13, Secondary Exposure to E-Cigarette Emission Might Be Harmful to Health
  • 2013-017, 5-Jul-13, FDA Recalls Kanebo Skin Whitening Products Containing 4HPB (4-(4-hydroxyphenyl)-2-butanol) OR Rhododenol
  • 2013-018, 11-Jul-13, Concern on the Safety of Washable Hair Chalk Sold Through Internet
  • 2013-019, 17-Jul-13, FDA Orders Ban and Seizure of Sixteen Unauthorized Cosmetic Products From the Market
  • 2013-020, 17-Jul-13, Consumers Advised to Read Food/Dietary Supplement Product Labels and to Use the FDA Website (http://www.fda.gov.ph) to Validate Information and Health Claims
  • 2013-021, 2-Aug-13, Consumers Advised to Buy Only FDA- Authorized Cosmetic Products Verified Through FDA Website (www.fda.gov.ph) and To Buy Only From Legitimate Outlets
  • 2013-022, 6-Aug-13, Three Batches of Whey Protein Concentrate (WPC80) Produced by Fonterra in New Zealand that are Contaminated with Clostridium Botulinum Do Not Include Brands of Dairy Product and Infant Formula in the Philippines

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• 2013-023, 12-Aug-13, Online Consumer Reporting on Possible Adverse Events from Human Cells, Tissues, and Cellular and Tissue-Based Products (Stem Cells)
• 2013-025, 14-Aug-13, Deceptive On-Line Sale and Marketing of Stem Enhance Product
• 2013-026, 15-Aug-13, Arthrite Plus as Food Supplement and Arthrite SGC as Traditional Herbal Product
• 2013-027, 15-Aug-13, Consumer Tips on Buying Canned Goods in Groceries and Supermarket
• 2013-028, 23-Aug-13, Advisory on Disinfection of Non-Potable Water Using FDA-Registered Household Bleaching Products as Emergency Measure.
• 2013-029, 27-Aug-13, Consumer Tips on the Use of Mosquito Coils
• 2013-030, 21-Aug-13, Public Warning on Buying Citrange Vitamin Syrup Being Peddled in School Premises
• 2013-031, 28-Aug-13, Public Health Warning on Buying Unregistered Toxic Household Insecticides in the Market
• 2013-033, 6-Sep-13, Health Warning on Buying Unnotified Lipstick in the Market
• 2013-034, 11-Sep-13, FDA Sports Fest on 13 September, Friday
• 2013-035, 12-Sep-13, Consumer Protection Tips When Availing Treatment Modalities Outside of the Standard Medical Care
• 2013-036, 12-Sep-13, Public Warning on Unregistered Bio Stem Plus of Stem Cell Nutrition
• 2013-037, 20-Sep-13, Public Warning on Unregistered "Green Barley - A Total Food"
• 2013-038, 24-Sep-13, Consumer Tips on the Use of Front-of-Pack (FOP) Labels for Making Healthy Dietary Choices
• 2013-039, 2-Oct-13, Public Warning Against False, Misleading and Deceptive Health Claims in Advertisement and Promotional Materials of IgCo Skim Milk Powder
• 2013-040, 11-Oct-13, Result of Random Monitoring of Toiletries in Tourist Establishment
• 2013-041, 16-Oct-13, Consumer Tips on the Safe Use of Candles
• 2013-042, 16-Oct-13, Consumer Information on How Lead (Pb) from Toys Can Gain Entrance in the Body, and Some Tips for Parents
• 2013-043, 18-Oct-13, Public Warning on Counterfeit Multivitamin + Mineral Tablets (Centrum and Centrum Silver of Pfizer Consumer Healthcare) Sold Online by Groupon Philippines
• 2013-044, 21-Oct-13, Public Warning on the Use of Industrial Grade Coloring Dyes By Food Processors
• 2013-045, 23-Oct-13, Health Warning On Diwa Granted Coconut Which May Be Contaminated With Salmonella
• 2013-046, 22-Oct-13, Public Warning on Television Advertisements, Promotions and Marketing of Food Supplements Based on Anecdotal Evidence and Testimonials
• 2013-047, 30-Oct-13, Safety of Children First When Buying Christmas Toys
• 2013-048, 4-Nov-13, Quality Hold on Soluset 100 Burette IV (Intravenous) Set Imported By Hospira Philippines, INC.
• 2013-049, 4-Nov-13, Public Warning - More Processed Food Products In NCR and Cebu Markets Found Positive for Presence of Toxic Non-Permissible Colorants
• 2013-050, 8-Nov-13, Recall of Tadalafil (Cialis) 20 mg Tablet From The Philippine Market
• 2013-051, 12-Nov-13, Consumer Warning Against Unregistered Allercon Dust Mites Spray
• 2013-052, 14-Nov-13, Consumer Health Warning On OxyElite Pro Capsule and Powder Food/Dietary Supplements Linked To Liver Diseases
• 2013-053, 20-Nov-13, Consumer Warning Against Toxic Mercury-Laden Skin Whitening Cosmetic Products Without Notification That Were Tested By The FDA
• 2013-054, 22-Nov-13, Guidelines For Donors Of Medicines and Public Tips On Using Donated Medicines
• 2013-055, 20-Nov-13, Recall Of Unregistered Products Marketed By Eli Lilly (Philippines) INC.
• 2013-056, 25-Nov-13, Consumer Information on Electronics Cigarettes
• 2013-057, 28-Nov-13, Consumer Warning On Self-Medication
• 2013-058, 28-Nov-13, Safety of Monosodium Glutamate (MSG) And Aspartame As Food Additives
• 2013-059, 2-Dec-13, Practical Tips To Remember To Prevent Food Borne Disease And Outbreaks In Communities In Times Of Calamities And Disasters
• 2013-060, 28-Nov-13, Product Recall of Clarithromycin (Clarie DS 250) 250mg/5mL Powder For Oral Suspension
• 2013-060-A, 16-Dec-13, Clarification On Recalled Clarithromycin (Clarie DS) mg/5mL Powder For Oral Suspension
• 2013-061, 28-Nov-13, Public Warning on Counterfeit Purified Chick Embryo Cell (Rabipur) Rabies Vaccine
• 2013-062, 9-Dec-13, Mandatory Boiling Of Coliform Bacteria-Contaminated Drinking Water In Tacloban City And Nearby Areas, And Other Tips
• 2013-063, 12-Dec-13, Public Warning Against Health Scams In The Internet
• 2013-064, 13-Dec-13, Food Safety Tips On Christmas Holidays
• 2013-065, 16-Dec-13, FDA-Registered Human Papillomavirus Vaccine For Adolescent And Adult Women Is Safe And Effective For Prevention And Control Against Cervical Cancer
• 2013-066, 9-Dec-13, Product Recall Of Cefazolin (As Sodium) 1g Powder For Injection IM/IV (Cefazin)
• 2013-067, 18-Dec-13, Consumer Information On Immunization Of Children Against Vaccine-Preventable Diseases
• 2013-068, 12-Dec-13, Product Recall Of Batch Specific Amoxicillin (As Trihydrate) 500mg Capsule (Ambimox)
• 2013-069, 23-Dec-13, Consumer Tips On Buying Medicines from Drug Outlets

- 2014
  • 2013-053-A, 8-Sep-14, Update on FDA Advisory No. 2013-053 Re: Toxic Mercury-Laden Skin Whitening Cosmetic Products Notification That Were Tested By The FDA
  • 2014-001, 7-Jan-14, Consumer Tips On Healthy Eating
2014-002, 8-Jan-14, Public Health Warning Against The Use Of Banned Or Unregistered Slimming Or Anti-Obesity Products Sold In Outlets Or Offered Online
2014-003, 13-Jan-14, Recalled Processed Food Products Manufactured In Japan Are Not Registered with the Philippine Food and Drug Administration (FDA)
2014-004, 18-Dec-13, Consumer Warning Against Buying Counterfeit Vaccines From the Internet Buy and Sell Website Sulit.com.ph
2014-005, 14-Dec-14, Consumers Warning Against Buying Unregistered ONAMI Slimming Underwear Products that have Unsubstantiated and Baseless Claims that it Can Detoxify the Body and Burn Fats, among other Therapeutic Claims
2014-006, 15-Jan-14, Public Health Warning Against the Use of Unregistered Food Supplement SEHAT BADAN
2014-007, 17-Jan-14, Public Caution Against Laboratory Reports on Levels of Lead (Pb) in Toys Using Handheld XRF Instrument
2014-008, 22-Jan-14, Consumer Information on Food Products Contaminated with Carcinogenic Aflatoxins
2014-009, 17-Jan-14, Unnotified and Unlabeled Soap Bars Being Offered for Use in a Golf Club in Cavite
2014-010, 27-Jan-14, Consumer Warning Against False, Deceptive and Misleading Claims and Promotional Ploys on “Alkaline Water” and Oxygenated Water”
2014-011,  6-Feb-14, Public Health Warning Against Unregistered Fat Burner HCA 500mg Capsule Containing Both Amphetamine and Sibutramine
2014-012, 18-Feb-14, Lifting of Registration Amnesty Granted for Do-It- Yourself and Hobby Products, Classified as Household/Urban Hazardous Substances (HUHS)
2014-013, 3-Mar-14, Consumer Information on the Use of Fluoride Toothpaste to Prevent Dental Caries
2014-014, 3-Mar-14, Voluntary Product Recall of Specific Batches of B. Braun's 8.4% Sodium Bicarbonate Solution For IV Infusion
2014-015, 26-Feb-14, Recall of All Products Manufactured (From January 2012 Up to the Present) By Compact Pharmaceuticals Crop.
2014-016, 6-Mar-14, Review of Guidelines for Over-The-Counter-Drugs
2014-017, 6-Mar-14, Voluntary Recall of Nagaraya Cracker Nut Original Butter Flavor Under Lot No. 14019
2014-018 13-Mar-14 Additional Brands of Fluoride Toothpaste with FDA Notification for Consumer Use
2014-019, 25-Mar-14, FDA Cautions Medical Practitioners to Attend to Vaccine Cold Chain Management
2014-020, 12-Mar-14, Product Recall of Batch Specific Cefuroxime 750mg Powder for Injection
2014-021, 27-Mar-14, Consumer Information on Proper Use of Household Pesticides
2014-022, 28-Mar-14, Consumer Information - Findings on Health Products Used By Spas and Beauty, Skin, or Wellness Clinics
2014-023, 2-Apr-14, Releasing of All Authorizations Issued by the Center for Cosmetic Regulation and Research (CCRR) for Toys Establishments
• 2014-025, 25-Mar-14, Voluntary Product Recall of Specific Batch of Paclitaxel 30mg/1.5mL Solution for Nanoparticle Injection (Nanoxel) and Accompanying Concentrate of Excipients

• 2014-026, 20-Mar-14, Voluntary Product Recall of Batch Specific Triflusal 300mg Capsule (Grendis)

• 2014-027, 7-Apr-14, Public Health Warning Against Unregistered Cooking Oil and Sugar Products Repacked and Distributed By Authority Trading Corp.

• 2014-028, 11-Apr-14, Babala sa Publiko Tungkol sa Paggamit ng Hindi Rehistradong "CMD Eye Drop"

• 2014-029, 11-Apr-14, Public Health Warning Against the Use of Unregistered CMD Eye Drop

• 2014-030, 16-Apr-14, Consumer Information on Over Exposure Under the Sun and the Use of Sunscreen Products

• 2014-031, 24-Apr-14, Initial Findings Show that Lipsticks Tested for Lead (Pb), Arsenic (As) and Mercury (Hg) by Field X-ray Fluorescence (XRF) Instrument and the ASEAN Harmonized Laboratory Method Done by FDA Differ Significantly

• 2014-032, 30-Apr-14, False, Deceptive and Misleading Claims and Strategies to Promote "IZUMI 5P Antioxidant Alkaline Water Ionizer"

• 2014-033, 2-May-14, Updates on FDA Registration of Stem Cells or Human Cells, Tissues, and Cellular and Tissue-based Products

• 2014-034, 6-May-14, Recall of Unregistered and/or Falsified Product Registration of Pharmaceutical Products Imported and Distributed by ELI LILLY PHILIPPINES

• 2014-034-A, 9-May-14, Addendum to the Recall of Unregistered and/or Falsified Product Registration of Pharmaceutical Products Imported and Distributed by ELI LILLY PHILIPPINES

• 2014-035, 28-Apr-14, Sanofi-Aventis Philippines Inc. Voluntary Recalls Batch Nos. C1272H08, C12821120, and C1282H31 of Rabbit Anti-Human Thymocyte Immunoglobulin (Thymoglobulin)

• 2014-036, 13-May-14, Supreme Court Upholds FDA Authority Over Drug Manufacturers, Traders and Distributors to Require Bioavailability/Bioequivalence (BA/BE) Studies on Multisource Drug Products or Generic Drug Products

• 2014-037, 22-May-14, Public Health Warning Against Bortezomib (Velcade) 3.5 mg Lyophilized Powder for Injection (IV/SC) Under Batches of 102424, 102430, 102501, 102502, & 102648

• 2014-038, 12-May-14, Glaxosmithkline Philippines, INC. Voluntary Recalls Batch Nos. 601, 602M, and 603 of Paroxetine 20 mg Tablet (Seroxat)

• 2014-039, 22-May-14, Recall of Sterile Drug Products (Ophthalmic, Otic, and Parental) Manufactured by Ashford Pharmaceutical Laboratories, Inc. from September 2012 Up to the Present


• 2014-041, 29-May-14, Deceptive Online Sasle and Marketing of Inner Power Stem Cell Booster

• 2014-042, 29-May-14, Public Warning Against Advertisement, Promotion, Offer for Sale and Use of "Bangkok Pills"

• 2014-043, 30-May-14, Product Registration of Pharmaceutical Products Imported and Distributed by ELI LILLY PHILIPPINES
• 2014-044, 29-May-14, Warning Against the Use of Unregistered Watercolor Paints Containing High Levels of Lead (Ph)
• 2014-045, 27-May-14, Public Warning Against Advertisement, Promotion, Offer for Sale and Use of "Luxxe Whitening, Enhanced Glutathione."
• 2014-046, 9-Jun-14, Lifting of the Quality Hold on Soluset 100 Burette Intravenous (IV) Set Imported by Hospira Philippines, INC.
• 2014-047, 20-Jun-14, Voluntary Recall of Batch Specific Herapin Sodium (Meparin 5) 1000 IU/ML Solution for Injection (IV/SC) Batch Number N-3176 (DRP-3912)
• 2014-048, 20-Jun-14, Quality Hold on Heparin Sodium 1000 IU/mL Solution for Injection with Brand Names Diasea 5 and Meparin 5 Imported by Pharma-Surrey International., INC.
• 2014-049, 25-Jun-14 Public Warning on All Batches of Heparin Sodium 1000 IU/mL and 5000 IU/mL Solution for Injection (IV/SC) With Brand Names Meparin 5 and Meparin 25 Respectively
• 2014-050, 26-Jun-14, Food and Drug Administration (FDA) Advisory on Pharmacovigilance
• 2014-051, 2-Jul-14, Public Warning Against False Advertisement, Promotion, Offer for Sale and Use of "Optrimax Plum"
• 2014-052, 3-Jul-14, Caution Against Fraudulent Solicitations from the Food and Drug Administration
• 2014-053-A, 8-Jul-14, Public Health Warning Against the Use of Unregistered Product "Power Drops"
• 2014-053, 8-Jul-14, Babala sa Publiko Tungkol sa Paggamit ng Hindi Rehistradong "Power Drops"
• 2014-054, 7-Jul-14, Public Information on DOH-FDA Requirement for Senior Citizens to Avail 20% Discount on Medicines
• 2014-055, 9-Jul-14, Voluntary Recall of the Specific batches of Dobutamine (As Hydrochloride) 12.5 mg/mL (250 mg/20mL) Solution for Injection (Dobulon) with Batch Numbers DBI1301BC,DBI1302BC, and DBI1303BC (DRP-3997)
• 2014-056, 21-Jul-14, Reiteration of Public Health Warning Against the Use of Unregistered Food Supplement SEHAT BADAN POWDER
• 2014-057, 25-Jul-14, Patient Counselling by Physicians and Pharmacists
• 2014-058, 23-Jul-14, Warning on Fraudulent Sales Strategies Employed by Websites Involved in Buy and Sell of Health Products
• 2014-059, 30-Jul-14, Public Health Warning Against the Use of Unregistered Product "Prednisolone 5 mg per 5 mL Syrup (PRED)"
• 2014-059-A, 30-Jul-14, Babala sa Publiko Tungkol Sa Paggamit ng Hindi Rehistradong "Prednisolone 5 mg per 5 mL Syrup (PRED)"
• 2014-060, 30-Jul-14, Public Health Warning Against the Use of Unregistered Product "Cefuroxime 125 mg per 5 mL Granules for Oral Suspension (CEFX)"
• 2014-060-A, 30-Jul-14, Babala sa Publiko Tungkol sa Paggamit ng Hindi Rehistradong "Cefuroxime 125 mg per 5 mL Granules for Oral Suspension (CEFX)"
• 2014-061, 4-Aug-14, Certificates of General Acceptability or Safety
• 2014-062, 13-Aug-14, Voluntary Withdrawal of One Batch of Nan Pro Two Infant Formula with Lot Identification No. 414901898A
• 2014-063, 12-Aug-14, Public Health Warning Against the Use of Unregistered Product Vita Slim Appetite Suppressant Guava Flavored Juice
• 2014-064, 12-Aug-14, Public Health Warning Against the Use of Unregistered Product Leisure Burn Body Fat Orange Juice
• 2014-065, 12-Aug-14, Voluntary Recall of Specific Batches of Nicorandil (APRIOR) 5 mg and 10 mg Tablets with Registration Nos. DR-XY35217 and DR- XY31195
• 2014-066, 12-Aug-14, Voluntary Recall of Specific Batches of Tetrahydrozoline HCL 0.05% Ophthalmic Solution (Eye-mo Red Eyes Formula) With Registration Number DRHR-431
• 2014-067, 9-Sep-14, Food and Drug Administration (FDA) and Philippine Pharmacists Association (PPhA) Mull Plan to Authorize Community Pharmacists to Administer Vaccines
• 2014-068, 16-Sep-14, Public Health Advisory on Taiwan Food and Drug Administration's Announced lard Oil Products Believed to be Tainted with Recycled Waste Oil
• 2014-069, 18-Sep-14, Addendum to the Public Health Warning Against the Use of Unregistered Product "Prednisolone 5 mg per 5 mL Syrup (PRED)"
• 2014-070, 17-Sep-14, Public Health Warning Against False, Deceptive, and Misleading Advertisements of Tian Xian Liquid (TXL) and Capsules by Green and Gold International Exports
• 2014-071, 9-Sep-14, Voluntary Recall of Batch Specific Antazoline Hydrochloride / Tetryzoline Hydrochloride (Spersallerg) 500mg/400mg Per mL Ophthalmic Solution (Drops)
• 2014-72-A, 26-Sep-14, Amendment To FDA Advisory No. 2014-072 "The List of Drug Manufacturers (DM) with Issues on GMP Compliance
• 2014-72, 23-Sep-14, List of Drug Manufacturers (DM) with Issues on GMP Compliance
• 2014-073, 26-Sep-14, Public Warning Against False, Deceptive and Misleading Claims of Flor.Essence as Advertised in the Philippine Daily Inquirer and Through the Internet
• 2014-074, 9-Sep-14, Recall of Specific Batches of Tetrahydrozoline Hydrochloride (Visine) 0.5 mg/mL (0.05%) Ophthalmic Solution (Eye Drops)
• 2014-075, 1-Oct-14, Public Warning Against False, Deceptive and Misleading Claims of Turcumin Herbal Food Supplement Advertised in the Philippine Star and Bulgar
• 2014-076, 29-Sep-14, Voluntary Recall of Lot Specific Doxorubicin Hydrochloride 2 mg/mL Pegylated Liposomal Concentrate for I.V. Infusion (Caspria)

III. DISCUSSIONS, RECOMMENDATIONS AND CONCLUSION

The FDA has essentially four major functions: a) licensing of regulated establishments (LTO), b) issuance of market authorization for health products (CPR and notification), c) standards development and regulatory policy formulation, and d) effective post-marketing surveillance (PMS). During the last 2 years, the FDA management instituted reforms and innovations in the FDA’s business core processes. It laid down ICT-based regulatory frameworks and infrastructure, which must be sustained as the 21st FDA continues to march forward to the future.

The FDA needs bigger budget to continue and sustain the following: a) investment on human capital; b) streamlining of bureaucratic procedures, processes and system; c) full
utilization of ICT to foster a business friendly environment; d) development of a more predictable and transparent regulatory framework; e) upgrading of laboratory equipment and quality system; f) strengthening the inspectorate; g) comprehensive licensing of all regulated establishments; h) timely product evaluation and release of registration or market authorization for all regulated products; i) vigilant post-marketing surveillance; j) firm control of ads and promo of regulated products; k) strict enforcement of orders to ensure compliance to FDA standards; l) provision and dissemination of useful, timely, and m) posting of relevant information and publication of advisories. Priorities should be made on recruitment of technical workforce per Center and Office. New recruits should be technically trained, equipped with tools, skills and knowledge to deliver the FDA products and services, and molded with strong performance culture that is grounded on core values and virtue of continuous learning and improvement.

Full implementation of the provisions of the Republic Act No. 9502 (Universally Accessible Cheaper and Quality Medicine Act of 2008) and RA 9711 (The FDA Act of 2009) are two important landmark legislations that will pave the way for the complete transformation of the FDA into a more effective and efficient food and drug regulatory agency that is responsive to the country’s health needs and problems (Section 12, Article XIII on Health of the 1987 Philippine Constitution). The approval of the 5-year Business Plan by the DBM and the draft Administrative Order on restructuring of fees and rationalization of regulatory services should be pursued.

The FDA should continue to undertake ICT-based reforms and innovation to streamline the bureaucratic procedures, processes and systems, to address the backlogs and improve the quality and efficiency of evaluation. Full application and utilization of ICT in the FDA core processes foster a business friendly environment and ease the cost of doing business in the country.

Several suggestions have been put forward in the past, such risk-based approach to evaluation or non-evaluation, triage approach (as done in hospitals receive and treat patients according to the severity of the case), sequential decking and evaluation into a parallel system. For example, initial applications (that need voluminous data and dossiers) are separated from renewals/automatic renewals (without changes in anything) and other routine non-technical tasks (amendments that are not technical in nature, but merely require change in business addresses or telephone numbers and can be facilitated by an administrative assistant under technical supervision).

An automated PAIR is currently under development. There is a need to field PAIR-trained FDOs to instruct and assist DTI offices in our provinces and regions when FDA set up its "ATM" application kiosks for product registration and LTO applications, especially for MSMEs. The three Centers in Alabang will have to provide technical information and assistance by fielding some of the FDOs in the PAIR Unit, as necessary. The current PAIR officers can focus on accepting applications and releasing certificates and permits.
The FDA should develop further its quality control laboratory system and strengthen the FDA inspectorate, Regulatory Enforcement Unit and the Legal Support Service Center to sustain vigilance in post-marketing surveillance.

The FDA should continue to issue and disseminate useful, timely, and relevant policies and information through advisories. A firm control on claims made by advertisers and establish ethics and mechanics on promotion of health products in collaboration with ASC and DTI, including the IPOPhil.

As a science-based regulatory agency, the FDA should pursue policies that are based on the WHO recommendations and health principles for other health products. For food products, the FDA should support free trade agreements, but should be aligned with the UN FAO/WHO SPS/TBT Agreement and Codex Alimentarius.

There are still FDA initiatives, activities, projects and programs as well as mandates that need to be continued, supported, sustained, or implemented, some of which are on food safety, responsible parenthood and reproductive health, MSMEs, stem cell therapy, blood and blood products, biopharmaceutical marketing, promotions and sponsorships, intellectual property rights, advertisement and promotion, urban pesticides and operators/applicators, tobacco graphic materials, electronic cigarettes, among other ASEAN and APEC initiatives and commitments.

Financial stability and independence as provided by the two legislative landmarks, namely RA 9711 and RA 9502, should be attained by the FDA as soon as possible. The approval of the 5-year Business Plan and the draft Administrative Order on restructuring of fees remain as the major stumbling block to the FDA strengthening program. With the current budget of the FDA and its inability to fully use the retained income, the FDA will continue to over promise and yet under deliver.