“We will work together more than you’ve ever seen before.

This is our TIME.
Intention + Investment + Effort Will all equate to RESULTS.”

NELA CHARADE G. PUNO, RPh
FDA Director-General
FDA NEWSLETTER

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EDITORS NOTE
This is the FDA Newsletter for the 1st Quarter of 2018.
Our deepest thanks to all our contributors.
The 3 Marching Orders, namely Zero Backlog, 72-hour Response Time, and Strengthened Enforcement, are the backbones of the Agency's institutional reforms, which allow us to focus our efforts towards administrative efficiency and increased regulatory coverage for better consumer safety and welfare protection.

The FDA is steadily moving forward with our 5-Year Development Plan, and in 2018 we will continue to build critical systems to support critical public services.

The TUV Rheinland’s issuance of a new and upgraded ISO9001:2015 Certificate after their 2nd surveillance audit with upgrade underscores the FDA milestones and achievements in 2017. Our progress from ISO9001:2008 to ISO9001:2015 has been a challenge, but one that we meet head-on. We stand together as one FDA. The regulatory Centers for drugs, food, cosmetics, and devices, the laboratories, the administrative, legal, and policy support, and our enforcement arm together make the Agency strong.

It has only been 19 months since I assumed the office as FDA Director-General. We have shown that investment and effort coupled with good intentions and modest ambition produces results. We will work together more than you’ve ever seen before. This is our TIME.

An average Filipino household spends more than half of every one hundred pesos earned on FDA-regulated products. It is in the DNA of the FDA to serve the interest of the Consumers.

The FDA is committed to greater transparency. We have launched a new FDA Website (www.fda.gov.ph) to ensure that users from the consumer, industry and government sectors will have access to timely, useful and relevant information. However, it is still a work in progress.

The FDA Regulatory Enforcement Unit has been doing an immense job in protecting the consumers from fake, unregistered, harmful and toxic health products that are being peddled by unscrupulous businessmen and criminals. The FDA will remain relentless against violators. I enjoin all well-meaning entrepreneurs to secure their License to Operate and product market authorizations.

“It is in the DNA of the FDA to serve the interest of the Consumers.”

FDA DG Puno as Guest of Honor in ceremonial military uniform during the PNP Flag Raising Ceremony
FDA Director General, Ms. Nela Charade G. Puno, was accorded Arrival Honors befitting a Guest of Honor during the Philippine National Police (PNP) Flag Raising Ceremony last February 26. She was welcomed by PNP DG Bato del Rosario at the PNP Headquarters. DG Puno expressed her profound gratitude to the PNP for its continuous support to FDA in getting rid of counterfeit, unregistered, and misbranded health products in the market, through FDA-PNP Joint Task Force D-PUNCH (Destroy Products Unfit for the Consumption of Humans).
The Regulatory Enforcement Unit (REU) in collaboration with the PNP has so far seized over P75M worth of unregistered and fake drugs and medicines, cosmetics, medical devices and violative hazardous urban household substances products. It has so far padlocked 53 establishments, initiated 16 criminal cases, with 21 cases still under preliminary investigation. Three search warrants have been served, and 17 entrapment operations have been carried out. Around 35 seizure operations have been conducted.

The relentless pursuit of the REU against erring establishments, unscrupulous businessmen and gross violators of RA 9711 will continue and intensify in 2018. Well-meaning establishments are encouraged to secure their License to Operate and Certificates of Product Registration and Notifications to avoid FDA penalties and sanctions.
Six Strategic Imperatives

- **Smart Regulation**
  - Focuses on closing the policy gap – investing more in policy evaluation and simplification

- **Establish MIS & Operational System**
  - Enabling improved systems and processes to bring better value to our stakeholders

- **Facility Upgrade & Improvement**
  - Continuous improvement of facility to keep up with the changing times

- **Strengthen Public Information & Service**
  - Differentiate by delivering a distinct customer experience across all channels

- **Strengthen Public Information & Service**
  - Commitment to create a positive work environment and invest in the infrastructure needed as we put our growth and speed into practice

2018 ANNUAL PLAN SNAPSHOT

**Overall Objective**

- To achieve at least 20% REVENUE GROWTH for year 2018

**Goals**

- Zero Backlog
- Decentralization
- Consumer Protection & Advocacy

**Overall Strategies**

- Policy Reform
- Administrative Reform Phase 1
- Strengthen Food & Drug Safety System
- Improve FDA Action Center
- Implement Performance Governance System
- Strengthen Enforcement
- International Cooperation with High Impact Activities
- Outsource Services
- Organizational Transformation
The following are some of the major national laws (so far) that are currently implemented and enforced by the FDA, with other government agencies:

- Republic Act (RA) 9711, FDA Act of 2009
- RA 3720, Food, Drug and Cosmetic Act of 1963,
- RA 5921 (1969), or The Pharmacy Law,
- Presidential Decree No. 881 (1972), or The Household Hazardous Act,
- Executive Order No. 51 (1986), or The Milk Code of the Philippines
- RA 6675, or The Generics Act Of 1988,
- RA 7394(1991), or The Consumer Act of the Philippines,
- RA 7581 (1992 ) or The Price Act, and
- RA 8172 (1995), or The ASIN Law,
- RA 8203 (1996), or The Special Law on Counterfeit Drug, and
- RA 8976 (2000), or The Food Fortification Law
- RA 10611, or The Food Safety Act of 2013
- PD 856, or The Code of Sanitation of the Philippines
- RA 9502, or The Universally Accessible Cheaper and Quality Medicine Act of 2008,
- RA 9257, or The Expanded Senior Citizens Act of 2003
- RA 10354, or The Responsible Parenthood and Reproductive Health Bill of 2012
- RA 9165, or The Comprehensive Dangerous Drugs Act of 2002
- RA 10623 (2013), or The Price Act
- RA 9211, or The Tobacco Regulation Act of 2003
- RA 10843 or the Graphic Health Warnings Law
- PD 1372, Amendment to PD No. 480 Which Created The Radiation Health Office

The FDA is migrating to a new FDA Website. Once completed, it will be more accessible, functional, faster and friendly to users.
The FDA passed the TUV Rheinland 2nd follow-up audit surveillance. Its accreditation was upgraded to ISO9001:2015 last February 12 to 14. The FDA’s Scope of Accreditation was expanded to include Post-Market Surveillance, in addition to Licensing of Health Product Establishments and Registration of Health Products.

Under the strong leadership of DG Nela Charade G. Puno, the FDA passed the audit without any nonconformity findings. However, there were minor observations that need to be addressed for improvement.

The FDA audit site included the FDA offices in Alabang and 17 FDA Regional Offices, and 2 Satellite Laboratories.

The FDA Quality Management System (QMS) was verified by means of random sampling. Verifications were made on the FDA’s workflow—compliance to the sets of standard requirements and documentation of the management system, taking into account the special features of the organization’s business activities and the applicable statutory and regulatory requirements. Extensive interviews were conducted.

Upon the recommendation of the auditors, TUV Rheinland awarded the ISO9001:2015 Certificate of Accreditation.

The next surveillance audit will be in February 2019.
Last March 15, the FDA Management Team, led by the Director-General Nela Charade G. Puno, reviewed the FDA’s performance during the 1st Quarter of the year. The different offices and centers presented their accomplishments based on their targets. Issues and concerns were also discussed during the meeting.

As part of the monitoring and evaluation, DG Puno reminded all participants to work on the 3 Marching Orders and the 6 Imperative Strategies. She requested all Centers to continuously improve their efficiency in issuing License to Operate (LTO) and Certificate of Product Registration (CPR)/Notification based on Anti-Red Tape Act - Citizen’s Charter Commitment (ARTA-CCC) of the FDA.

She enjoined the Center Directors to continue its collaboration with the Regulatory Enforcement Unit (REU) in safeguarding public health and consumer safety.

The OIC of the Office of the Deputy Director General (DDG) for Field Regulation Operations Office, Atty. Emilio Polig, Jr., gave the Opening Remarks, while the DDG for Internal Management, Atty. Ronald R. De Veyra, delivered the Closing Message.

- **Licensing of Establishments**
  6,646 License to Operate (LTO) were issued; **92.75%** (6,164) LTOs were processed within the ARTA-CCC.

- **Product Registration**
  21,130 CPR/Notification were issued; **75.18%** (15,887) were issued within the ARTA-CCC.

- **Certificates and Certification**
  (Batch Certification, Lot Release Certificate, Export Certificate, Certificate of Free Sale, among others)
  74.90% of the Certificates were issued within ARTA-CCC.

- **Laboratory Analysis**
  94.02% (16,21) samples of the products tested passed the analysis for safety, potency or quality; only 5.97% (103) were found to be out of the specifications.

- **Post-Market Surveillance and Routine Inspection**
  - Health Products. Out of the 3,510 health products that were subjected to PMS, **75%** (2,633) were found compliant with the FDA pre-approved specifications.
  - Establishments. Out of the 7,079 establishments inspected, **89.77%** (6,355) were found to have remained compliant with FDA requirements as Manufacturer, Distributor (importer, exporter, wholesaler), Traders or Drug Outlet.

Submission of complete and correct licensing and registration requirements during initial application almost always ensure issuance of license and product certification within ARTA-CCC.
Republic Act No. 9711 (FDA Act of 2009) was signed into law in recognition of the FDA’s vital role in ensuring public health and consumer safety. It authorized the FDA to retain its income to attain financial stability. The provisions of RA 9711, however, have yet to be fully realized before FDA can attain financial independence.

The current FDA administration gave high priority to consumer protection.

Proactive programs for public health and consumer protection have costs. The activities cannot be delayed, suspended, compromised or interrupted due to budgetary constraints, or even due to external influences.

The business and industry sectors are ultimately responsible and accountable for the performance of their products and brands in the market. They are called upon to cooperate and collaborate with the FDA in ensuring public health and consumer safety.

It must be emphasized that the role of the FDA does not end in the issuance of licenses to regulated establishments and pre-market approval of health products to the business sector. FDA must assure the consumers that the licensed establishments maintain the safety, efficacy and quality of their product as pre-approved by the FDA. The FDA must ensure that establishments and health products, especially in the food and medical device sectors, that are not yet under the regulatory folds comply with the FDA licensing and registration requirements. Product and brand owners should adhere to the standards of fair trade practices. Product labels and health claims, as well as advertisement and promotional materials, should not be misleading and deceive the consumers.

All these, among others, are covered by the Post-Market Surveillance (PMS) and Enforcement. Failure to comply with FDA-approved product specifications may result in product recall to protect the consumers. PMS, more than anything else, is applicable to FDA-registered products. For unregistered and contraband products, the FDA's response is strict Enforcement - the D-PUNCH (Destroy Products Unfit for the Consumption of Human).

Health products that enter through the national borders must be pre-approved by the FDA before they are shipped or exported to the Philippines.

All unregistered, harmful, toxic, hazardous, spurious, falsified, falsely labelled, and counterfeit health products are seized, confiscated and destroyed by the FDA.

CONSUMERS MATTER

FDA Budget: PRIMACY OF PUBLIC HEALTH AND CONSUMER PROTECTION

- The current administration increased the 2017 budget by 52.69% over the past administration in 2016

In 2016 and 2017, the government allotted to FDA the budget of P698,521,344.44 and P1,325,635,993.06, respectively, which translates to P6.98/consumer in 2016 and P13.25/consumer in 2017.

- The FDA revenue from the Industry Sector in 2016 and 2017 was P409,307,261.93 and P394,737,104.69, respectively.

These figures represent the cost recovered by the FDA for legitimizing business operators and their products. The 2017 collection was P14,570,157.24 less than in 2016. In effect, the government subsidized the amount of P289,214,082.51 in 2016 and P930,898,888.36 in 2017.

Reliance on legislated budget is not enough, given the thrust of the current Administration and the FDA 5-Year Development Plan to increase consumer safety and welfare protection, on top of supporting the “ease of doing business” and investment in the country.

- The existing schedule of fees is based on the 2001 guidelines.

Seventeen years ago, the Philippine population was only 79.67M. The peso-dollar exchange rate was P38. The number of FDA employees was only around 300, which has now tripled. The FDA was an agency operating only in Alabang, but it now includes 5 Regional Clusters composed of 18 regions, 81 provinces and 2 satellite laboratories. The licensing and registration systems were manually processed. The FDA Centers are currently enhancing or migrating to online licensing and registration system, and the ideal ratio of computer to employees is now 1:1.

The Philippine economy was not as robust then as it is today. The number of establishments and health products being regulated has increased logarithmically to more than 302,452, and is still increasing. The number of national laws (Republic Acts, Presidential Decrees or Executive Orders) that need to be implemented stood at only 11 in 2001, but has now more than doubled. The agency needs to cope with demands of further liberalization of trade through regional and inter-regional free trade agreements. Today, social media has firmly established its influence on consumers’ behavior and decisions. Consumers are now more demanding than ever.
CONSUMERS MATTER

⇒ The FDA is accountable to the health and well-being of all Filipino consumers, around 106 million and still growing. This number includes highly susceptible sectors of the population like infants, children, pregnant mothers, senior citizens, and those who are ill.

⇒ The consumers spent on health products reached Php 1.4 T for pharmaceutical and healthcare products and Php 5.8 T in food and drinks (2011). *

* other products regulated by the FDA include household hazardous substances, like toys, childcare articles, urban pesticides, and medical devices, like diagnostic kits, equipment and instruments, among others

New Schedule of Fees on June 2018

The FDA issued FDA Advisory No. 2018-117 announcing that it will be implementing a new schedule of fees for licensing and registration, among other FDA services, effective 30 June 2018. Further to this, the FDA announced that will no longer accept cash payments starting on the same date.

All payments to FDA shall be done through the following:

- Bancnet Online Payment
  www.bancnetonline.com

- Landbank of the Philippines (LBP) Oncoll Payment

The specific details on the Collection Policy and Procedure are found in FDA Circular 2017-010, which can be accessed at the FDA website. Interested parties may call the FDAC at (02) 821-1176 / (02) 821-1177 for more information. You may also e-mail us at info@fda.gov.ph.

The new schedule of fees is based on the provision of RA 9711 and existing DBM guidelines.

Legal Basis

Section 54, Chapter 12, Book IV of Executive Order No. 292 (Administrative Code of 1987) authorizes the Heads of Bureaus, Offices and Agencies, upon approval of the Secretary, to charge and collect fees to recover the cost of services rendered.

The Office of the President issued Administrative Order No. 31, s. 2012, which authorizes all heads of departments, bureaus, commissions, agencies, offices and instrumentalities of the national government, including government-owned and controlled corporations to rationalize the rates of their fees and charges and increase the existing rates and impose new fees and charges. AO No. 31, s. 2012, repealed Memo Circular No. 137, s. 2007, which required clearance from the NEDA Board before imposing new fees or increases in existing fees.

In spite of a clear legal basis, the FDA consulted the stakeholders, the industry and business sectors, over the last 9 years to come up with a final guidelines. Six BFAD Directors and FDA OIC or Acting DG, including the current full-pledged DG conducted public consultations at different levels of the organization.

As mandated by RA 9711, the FDA funds will be used for public health and consumer safety and welfare protection, and to assure fair trade practices, among others.
The creation of the FDAC is pursuant to FDA Order No. 2017-010.
Human Resource Development is about helping employees develop their personal and professional organizational skills, knowledge, and abilities. In line with the HRD Program, the HRDD invites resource speakers per month to address the FDA employees and management during the Flag Raising Ceremony. The activity is meant to uplift and inspire the FDA employees in their work and in their personal lives.

Public service is performed by employees called civil servants. Government agencies are not profit-oriented organizations. The employees are motivated differently. The services that they render require high level of education, training and experiences. Civil servants are different breed with strong public ethos—to give something to the public and community through their works.

INTEGRITY. On February 05, 2018, Mr. Mario P. Contemprato talked about “Integrity”. Mr. M. P. Contemprato is a graduate of 3 courses, namely Bachelor of Theology, AB History and Bachelor of Laws. He is the Associate Pastor and Outreach Department Head of Church of God in Dasmarias, Cavite.

TRANSPARENCY. On March 05, 2018, Mr. Rodelio C. dela Cruz, Ordained Minister and Associate Pastor of the Church of God in Dasmarias, Cavite, discussed the importance of “Transparency”. He is the Chairman of the Board and School Director, Kerusso Christian Academy. He is a Licensed Civil Engineer with MBA degree. He used to be a Manager of the Metropolitan Waterworks and Sewerage System and Maynilad Water Services, Inc.

**HRD Matters**

Pastor Mario P. Contemprato and DDG-IM Atty. Ronald R. De Veyra

Pastor Rodelio C. dela Cruz with FDA DG Nela Charade G. Puno

The staff of HRDD with Mr. Rodelio C. dela Cruz (6th from left) with his wife (8th from left)
Women's Month

2018 LINE UP OF EVENTS

February 28, 4pm, FDA Main Lobby Launch and Pledge of Commitment

March 8, Time TBA, around FDA International Women’s Day Mob
  *March 5, 4-5pm, Main Lobby: Placards & Streamers Prep

March 9, 1-3pm, Conference A GAD Committee Meeting
  A round table discussion to strengthen GAD plans for 2018

March 12, 4-6pm, ODG Conference Room SH Out!
  A forum on Sexual Harassment

March 22, 4-6pm, ODG Conference Room Women’s Cycle
  Understanding women’s bodies and their processes

March 28, 4-6pm, FDA Main Lobby Film Showing & Fellowship
The FDA is accepting interns for the whole year. Around 68 interns were accepted this quarter and were deployed in key FDA Centers and Offices, in various divisions and sections.

At the end of their program, the interns will be evaluated. Interns will also be asked to provide feedback on the FDA intern program for continuous improvement. Some FDA interns in the past have already gained employment at the FDA.

<table>
<thead>
<tr>
<th>No. of Interns</th>
<th>School</th>
<th>Course</th>
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<tbody>
<tr>
<td>1</td>
<td>Technical University of the Philippines</td>
<td>Chemical Engineering</td>
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<tr>
<td>3</td>
<td>De La Salle Health Sciences Institute</td>
<td>BS Biochemistry</td>
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<td>1</td>
<td>Adamson University</td>
<td>BS Information Technology</td>
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<td>11</td>
<td>Pamantasan ng Lungsod ng Muntinlupa</td>
<td>BSBA Human Resource Management</td>
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<td>Pamantasan ng Lungsod ng Muntinlupa</td>
<td>BS Psychology</td>
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<td>1</td>
<td>AMA Computer College</td>
<td>BS Information Technology</td>
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<tr>
<td>2</td>
<td>Pamantasan ng Lungsod ng Muntinlupa</td>
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<td>Polytechnic University of the Philippines</td>
<td>BS Information Technology</td>
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<td>Pamantasan ng Lungsod ng Muntinlupa</td>
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<td>7</td>
<td>Eulogio &quot;Amang&quot; Rodriguez Institute of Science and Technology</td>
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<tr>
<td>3</td>
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On February 28, 2018, students from the Institute of Clinical Laboratory Sciences, Silliman University, a private research university in Dumaguete, Negros Oriental, visited the FDA in Alabang for a field trip.

The FDA Director-General, Ms. Nela Charade Puno, personally welcomed the Dean, the B.S. Medical Technology students, and the faculty. DG Puno engaged the students for more than an hour of discussions, motivating them to continue to follow their dreams and passions in life.

The students were divided into 3 batches for the quick guided tour of the Central Service Laboratory. They proceeded to the Research Institute for Tropical Medicine in the afternoon.

The field trip was coordinated by the Policy Dissemination and Training Division, Policy and Planning Service with the Common Services Laboratory.
On March 26, 2018, right after the General Assembly, the FDA Coop elected four new Members of the Board of Directors, namely Ms. Lanette Lee Querubin, Ms. Maria Essa Tuason, Ms. Grace Medina, and Ms. Thelma Perez.

The FDA Coop is chaired by Ms. Emelita Delmiguez. The rest of the Members of the BOD who has so far served for a year are Ms. Marivic Paulino, Mr. Daniel Joren, Mr. Timothy Moises Mendoza, and Dr. Oscar G. Gutierrez, Jr.
The FDA Mindanao West Cluster in Zamboanga City passed the Civil Service Commission (CSC) Anti-Red Tape Act-Report Card Survey (ARTA-RCS) with a rating of 90.73%, which is equivalent to Excellent. The survey was held on September 26 to 29, 2018.

The FDA Mindanao West Cluster (MWC) puts them a step away from receiving the coveted CSC Seal of Excellence Award. It needs to pass the two-phase validation process to finally qualify for the Seal of Excellence Award.

Republic Act 9485, otherwise known as the Anti-Red Tape Act (ARTA) of 2007, aims to improve efficiency in the delivery of government service by reducing red tape and preventing graft and corruption. All government offices are mandated to take appropriate measures to promote transparency with regard to the manner transacting with the public.

On Feb 23, 2018 the Chief of the CCRR Licensing and Regulation Division, Ms. Maria Theresa M. Gutierrez, and the OIC of the CCRR Product Research and Standards Division, Ms. Melody M. Zamudio, oriented the participants from the Dermatologists of the Asian Hospitals on the licensing and product notification requirements of the Food and Drug Administration. The professional group of dermatologists organized the seminar to increase compliance of their members to FDA regulatory requirements. The role of the manufacture, trading, distribution and retailing of cosmetic products in quality and safety assurance were discussed.

Consumers, including the patients, have the right to be informed about the status of cosmetic products used on them.

The CCRR welcomes invitations from the cosmetic industry sectors and professional organizations to increase awareness and advocacy on the importance of securing FDA authorizations, with the end view of ensuring the safety and quality of health products made available to consumers, especially the naïve and unsuspecting consumers.

The orientation was held at the Café Breton located in Westgate, Alabang, Muntinlupa City.
CCRR Completes e-Learning Course

The Center for Cosmetics Regulation and Research (CCRR), upon the invitation of the Development Academy of the Philippines (DAP) in cooperation with Asian Productivity Organization (APO), participated in the E-Learning Course on Management Innovation in SMEs on 15-18 January 2018 at the DAP Conference Center, San Miguel Ave., Pasig City.

The E-Learning course aims to: (1) enhance participants’ understanding of the concept and basic principles of management innovation in SMEs for higher productivity, (2) increase capacity of SMEs to achieve long-term sustainability through the use of appropriate models of management innovations, and (3) share knowledge in implementation strategies for successful application of management innovation in SMEs.

The cyber-learning opportunity was conducted by Dr. Nomita Sharma and Mr. Hideyuki Ezaki through interactive lectures (video conference), group discussion, and field visit. An assessment test was conducted simultaneously with participants from Cambodia, Japan, Malaysia, Mongolia, Sri Lanka and Thailand.

Other government agencies, namely DTI, SUCs, TESDA, PSA, DOST, Muslim Affairs Commission, and the private sector were also represented.

CCRR Subject Matter Expert

Ms. Ofelyn Cabrido, Food and Drug Regulation Officer IV of the Product Research and Development Division, Center for Cosmetic Regulation and Research (CCRR) was invited by the Cosmetic Toiletries Fragrances Association of the Philippines (CTFAP) to act as subject matter expert or resource person to their seminar/workshop on Product Information File (PIF).

PIF is one of the important Post-Market Surveillance requirements of the CCRR. It is one of the ASEAN Cosmetic Directives agreed requirement to ensure protection of consumers against harmful cosmetics. Ms. Cabrido discussed the provisions of FDA Circular 2018-001 on Reiteration on the Requirement for (PIF) Product Information File.

The workshop was conducted at the Palms Country Club, Filinvest, Alabang, Muntinlupa City.

UNREGISTERED GOREE WHITENING CREAM

Ms. Ofelyn Cabrido was also interviewed by TV Channel 7, GMA 24 Oras News field reporter on March 26, 2018 in connection with the unregistered Goree Skin Whitening Cream that caused serious skin burn of the armpit of a woman. The product was tested and was found to contain more than 2,000 ppm mercury (Hg), way beyond the standard of 1 ppm. The FDA issued an advisory to warn the public and consumers. The FDA inspectors were ordered to seize and confiscate the said product.
Upon the invitation of DTI Bureau of Domestic Trade Promotion, the Policy and Planning Service (PPS) coordinated the participation of the Center for Food Regulation and Research (CFRR) and the FDA Academy in the 2018 Sikat Pinoy National Food Fair. The 5-day event was held at the Megatrade Halls 1-3, SM Megamall, Mandaluyong City from March 14 to 18.

A booth was assigned to the FDA which were manned by the FDA representatives from CFRR and the PPS.

It was an excellent opportunity for the FDA to reach out to the MSMEs who have not yet secured their FDA licenses and product registrations. The FDA authorizations are also important in ensuring competitiveness of locally produced products, and possibly to gain access to the international market or be part of the global value chain.
Mga kailangang permit mula sa Food and Drug Administration (FDA) License to Operate (LTO) Certificate of Product Registration (CPR) o Notification

Ang LTO ay permit na ibinigay ng FDA sa mga Business Operators tulad ng Manufacturer, Trader, Distributor, (Importer/ Exporter/ Wholesaler), kasama na ang mga Drug Outlets, matapos masuri ang mga isinumiteng Licensing Requirements o dokumento.

Ang CPR o Notification ay permit na ibinigay ng FDA sa mga lisensyadong Business Operators para mailagay ang isang produktong pang kalusugan sa merkado matapos masuri ang mga isinumiteng Registration Requirements o dokumento.

Bakit Kailangan ang mga FDA Permit?

Para sa proteksyon ng kalusugan ng mamimili, kailangan ang LTO at CPR sa pag manufacture, import, export, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, o sponsorship ng lahat ng produktong pang kalusugan upang masiguro ang safety, efficacy, at quality. (Republic Act 9711)

Bakit Importante na Rehistrado sa FDA ang Inyong Ginagamit na Produktong Pang Kalusugan?

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<tr>
<th>Rehistradong Produkto</th>
<th>Hindi Rehistradong Produkto</th>
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<td>Dumaan sa pagsusuri ng FDA ang produkto.</td>
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<tr>
<td>Makakasiguro na legítimo ang source at lisensyado ang manufacturer</td>
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<tr>
<td>Makakasigurong naglalarangan ng litas na sangkap</td>
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<tr>
<td>Tamang impormasyon ang nakalakip sa label o etiketa tungkol sa wastong pag-gamit ng produkto</td>
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</tbody>
</table>

Ano ang Parusa sa Paglabag sa Probisyon ng Republic Act 9711?

- Ang sino mang lumabag sa probisyong Republic Act 9711 ay maaring mapapatawan ng parusa ng pagkakakulong mula isang taon (1) at hindi hihigit sa sampung taon (10) o multa na hindi bababa sa limampung libong piso (P50,000.00) at hindi hihigit sa limandaang libong piso (P500,000.00).

- Kung ang nagkasala ay isa sa manufacturer, importer, o distributor ng produktong pang kalusugan, ang multa ay limang taong pagkakakulong (5) at hindi hihigit sa sampung taon (10) at multa na hindi bababa sa limangdaang libong piso (P500,000.00) at hindi hihigit sa limang milyong piso (P5,000,000.00).