FDA
Food and Drug Administration
PHILIPPINES

IMPLEMENTATION OF FOOD CONTROL SYSTEM IN THE PHILIPPINES

Charina May T. Tandas
Food Drug Regulation Officer III
FDA-Philippines
Symposium on Food Safety Management

Mandate

- RA 3720, Food, Drug and Cosmetic Act of 1963
- RA 5921 (1969), or The Pharmacy Law
- PD No. 881 (1972), or The Household Hazardous Act
- PD 856, or The Code of Sanitation of the Philippines
- PD 480, Creating A Radiation Health Office
- PD 1372, Amendment to PD 480
- EO No. 51 (1986), or The Milk Code of the Philippines
- RA 6675, (1988) or The Generics Act Of 1988
- RA 7394(1991), or The Consumer Act of the Philippines
- RA 7581 (1992) or The Price Act
- RA 8172 (1995), or The ASIN Law
- RA 8203 (1996), or The Special Law on Counterfeit Drug
- RA 8976 (2000), or The Food Fortification Law
- RA 9165, or The Comprehensive Dangerous Drugs Act of 2002
- RA 9211, or The Tobacco Regulation Act of 2003
- RA 9257, or The Expanded Senior Citizens Act of 2003
- RA 9502, or Universally Accessible Cheaper and Quality Medicine Act of 2008
- **RA 9711, The FDA Act of 2009**
- RA 10354, or The Responsible Parenthood and Reproductive Health Bill of 2012
- RA 10623 (2013), or The Price Act
- RA 10620, or The Toy and Game Safety Labeling Act of 2013
- RA 10611, or The Food Safety Act of 2013
- RA 10643, or The Tobacco Products Graphic Health Warnings Law (2014)

Food and Drug Administration (FDA): Its Mandates

- FDA- regulates the production, sale and traffic of health products
  - Regulatory Powers, Duties and Functions
  - Quasi-Judicial Powers, Duties and Functions
  - Administrative Powers, Duties and Functions

Food and Drug Administration (FDA): Its Mandates

- Regulatory Powers, Duties and Functions:
  - Require implementation of risk management plan
  - Issues certificates of compliance with technical requirements
    - Spot checks operation of establishments and facilities of health products
  - Issues appropriate authorizations

Food and Drug Administration (FDA): Its Mandates

- Regulatory Powers, Duties and Functions:
  - Institute and strengthen the postmarketing surveillance system in monitoring health products
  - Collection of samples of health products
  - Analyze, test and/or inspect health products
  - Order the ban, recall, withdrawal and/or destruction of any health product

Food and Drug Administration (FDA): Its Mandates

- Regulatory Powers, Duties and Functions:
  - Develops and prescribes policies, standards, regulations, and guidelines
  - Supervises, monitors and audits research studies
  - Establishment of bonded warehouses
  - Call on the assistance or deputize members of law enforcement

Food and Drug Administration (FDA): Its Mandates

- Quasi-Judicial Powers, Duties and Functions:
  - Renders decisions on actions or complaints
  - Issues cease and desist orders and orders of seizure of health products
  - Imposes administrative sanctions/penalties

Food and Drug Administration (FDA): Its Mandates

- Administrative Powers, Duties and Functions:
  - Calls upon other government and private testing laboratories.
  - Levy, assess, collect and increase appropriate fees
  - Creation of Units and Augmentation of Resources
  - Accept grants, donations and other endowments

Objectives

- Safeguard and promote public health by ensuring the efficacy, purity and quality of products under its jurisdiction
- Protect consumers and the public from false, deceptive and misleading information and health claims
- Ensure the scientific accuracy and soundness of all product information conveyed to the public.
- Guide and assist manufacturers, importers, distributors and retailers of products it regulates i.e. processed pre-packaged foods, drugs including vaccines and biological, in vitro diagnostic reagents, medical devices, cosmetics and hazardous substances used in the household.

Major Services

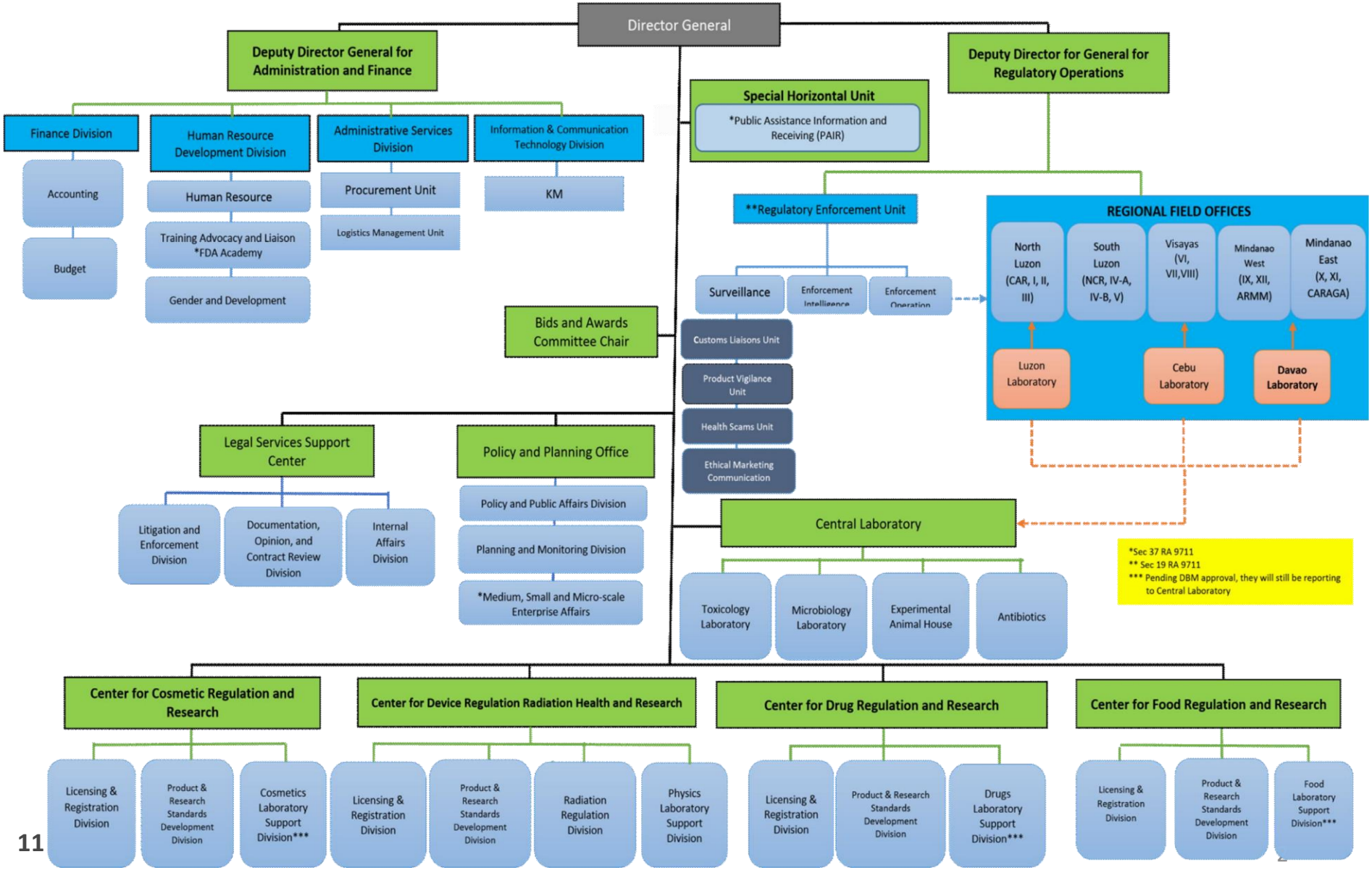
Inspection/ Licensing of Establishments

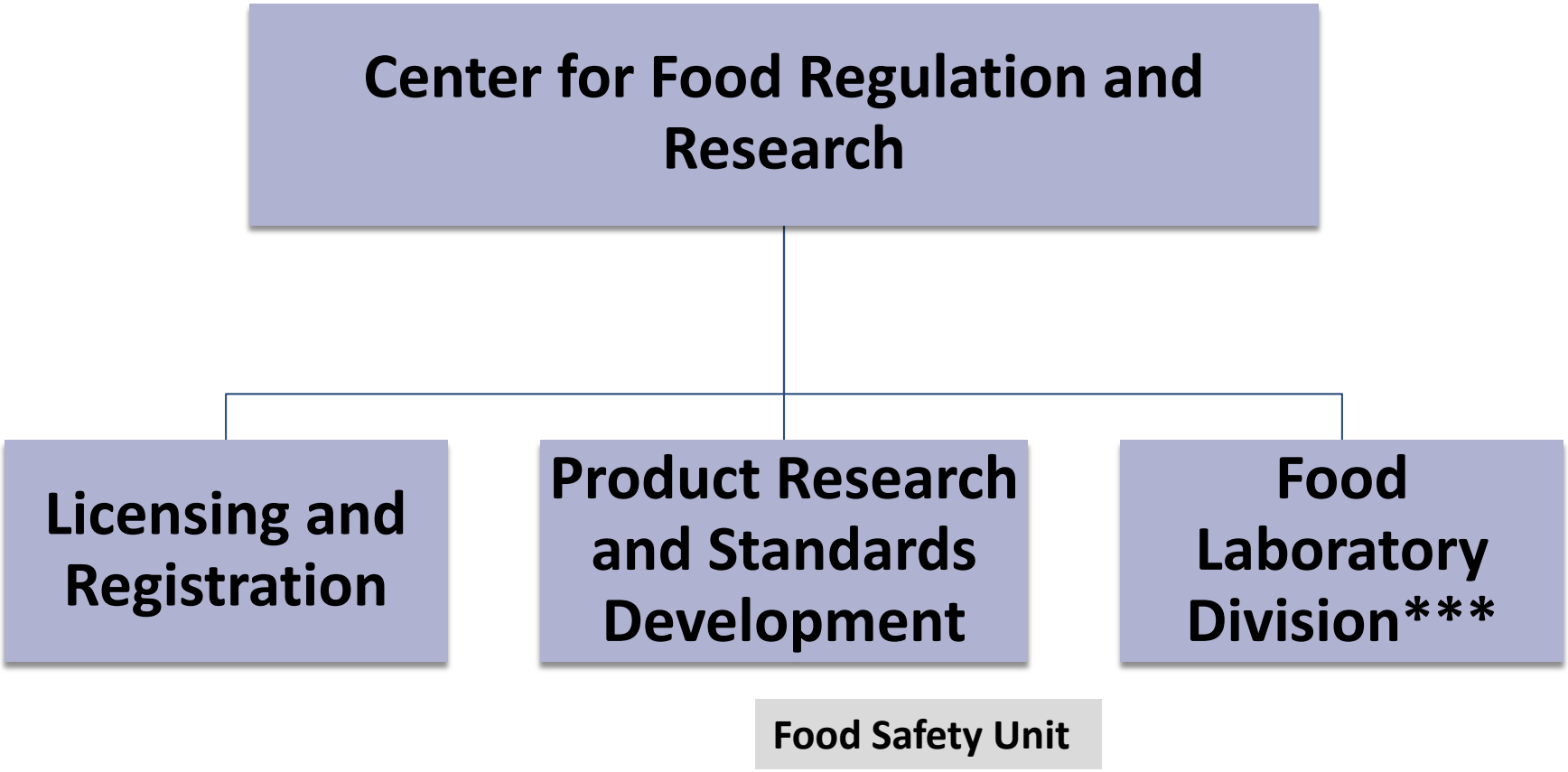
Issuance of Product Market Authorization-(LTO, CPR)

Issuance of Regulatory Policies and Technical Regulations, and Standards Development

Effective Post Market Surveillance

THE FDA (REORGANIZED)




Center for Food Regulation and Research
Licensing and Registration
Product Research and Standards Development
Food Laboratory Division***
Food Safety Unit

CFRR-Major Functions

- Product Market Authorization
  - Licensing of establishments
  - Registration of food products
  - Issuance of Sales Promotion Permit
- Standards/Policy Development
  - Conducts research in aid of regulation, PNS
  - Post Market Surveillance
  - Conducts audits with Regional Field Office
  - Sampling

CFRR-Major Functions

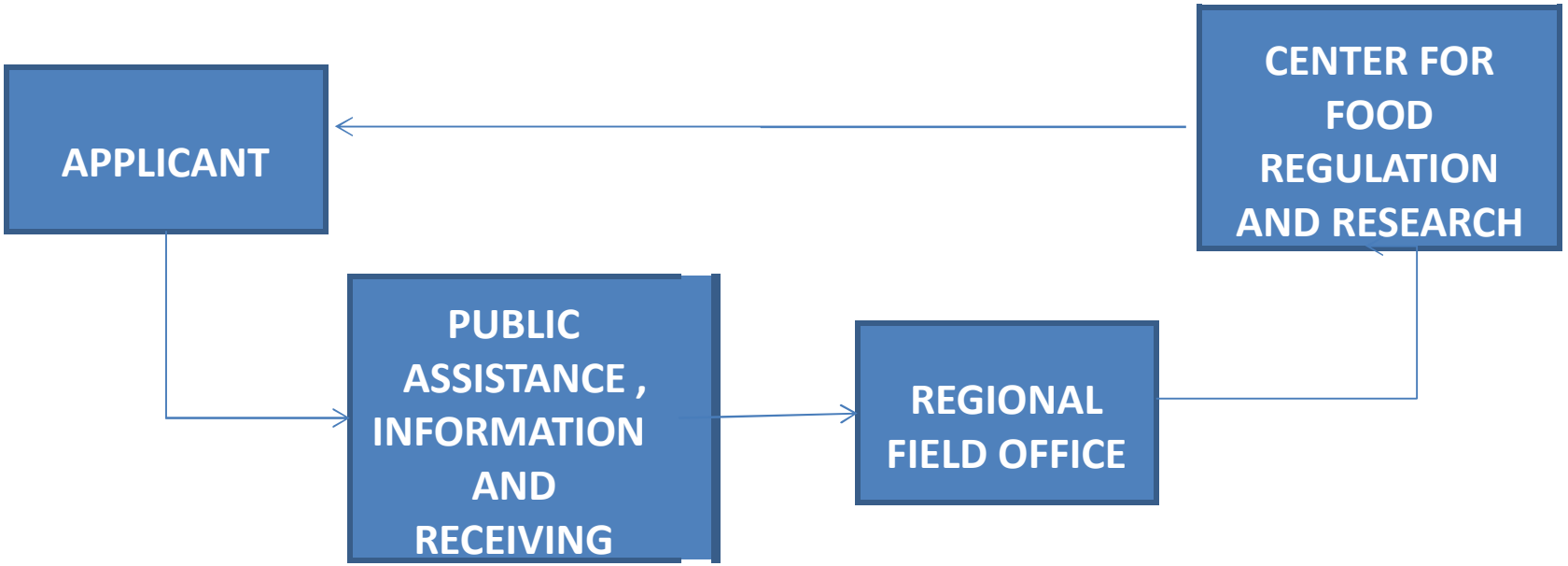
- Post Market Surveillance (cont)
  - Coordinates with other offices in conducting Post Market Surveillance
  - REU
  - Health Scam
  - Customs Liaison unit
- Laboratory Testing
  - Product recall
  - Complaints
  - Referrals from other officer
- Coordinates with other offices and agencies (e.g DTI, DOST)

Food products under FDA jurisdiction

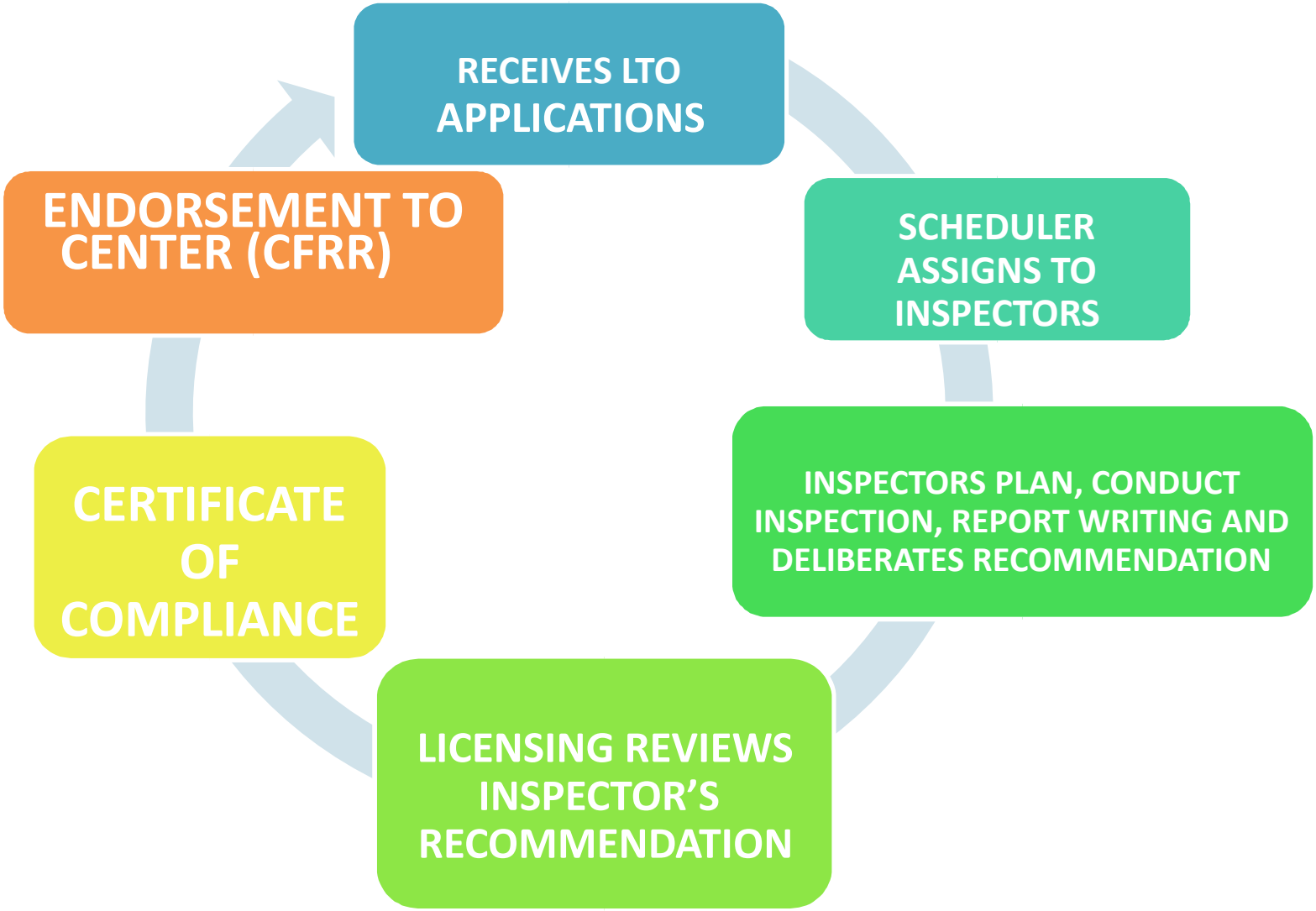
All processed food products which may be raw materials, finished bulk or finished products in original packaging

Licensing of establishments

Republic of the Philippines
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



Regional Field Office



General Requirements

1. Accomplished Integrated Application Form as prescribed by current FDA regulations
2. Proof of Payment of Fees
3. Proof of Business Registration
4. Proof of Occupancy (per facility and/or address declared as part of the establishment)
5. Product List
6. Location Map
7. Floor plan/ layout with dimensions

Specific Requirements

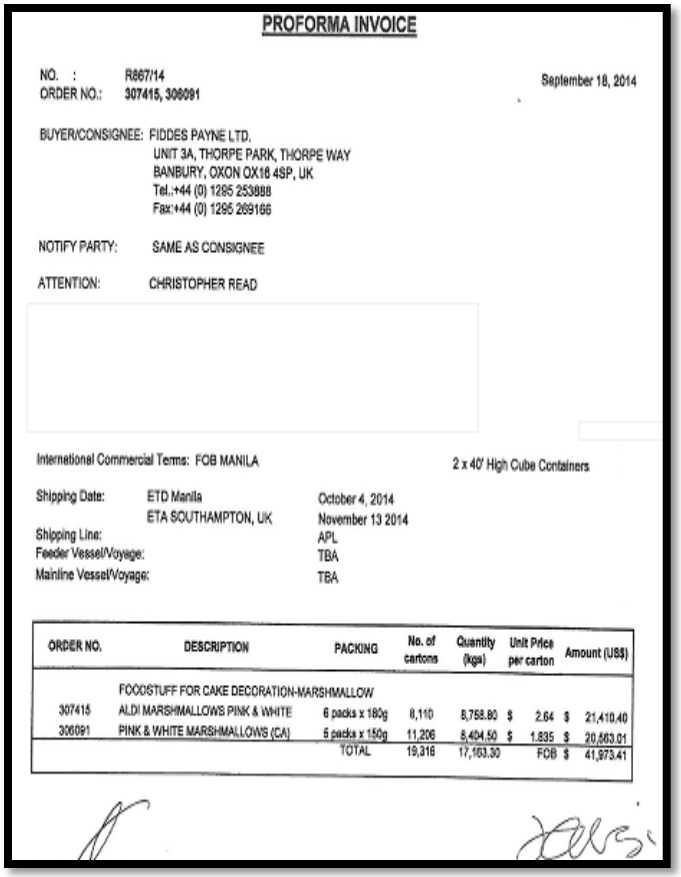
- Manufacturer/Processor
- Description of manufacturing process or food processing/preparation, including a flowchart with quality control points, as appropriate to the size of operation
- Quality control procedures, as appropriate to the size of operation
- Results of analysis of Finished Product /s showing compliance with applicable standards
- Facsimile of proposed product label, compliant with FDA standards
- Importer-Distributor of Raw Materials/Finished Products/Ingredients/Additives for Distribution and/or Retail

Specific requirements

Importer-Distributor of Raw Materials/Finished Products/Ingredients/Additives for Distribution and/or Retail

9.3.1 Each item declared in the list of food product(s) to be imported must be identified in <u>any</u> of the following:

- Pro forma invoice,
- Foreign agency agreement,
- Appointment letter, or
- Distributorship agreement



PROFORMA INVOICE

NO. : R867/14
ORDER NO.: 307415, 306091

September 18, 2014

BUYER/CONSIGNEE: FIDDES PAYNE LTD,
UNIT 3A, THORPE PARK, THORPE WAY
BANBURY, OXON OX16 4SP, UK
Tel.:+44 (0) 1295 253888
Fax:+44 (0) 1295 269166

NOTIFY PARTY: SAME AS CONSIGNEE

ATTENTION: CHRISTOPHER READ

International Commercial Terms: FOB MANILA

2 x 40' High Cube Containers

Shipping Date: ETD Manila October 4, 2014
ETA SOUTHAMPTON, UK November 13 2014
Shipping Line: APL
Feeder Vessel/Voyage: TBA
Mainline Vessel/Voyage: TBA

ORDER NO.	DESCRIPTION	PACKING	No. of cartons	Quantity (kgs)	Unit Price per carton	Amount (US$)
	FOODSTUFF FOR CAKE DECORATION-MARSHMALLOW					
307415	ALDI MARSHMALLOWS PINK & WHITE	6 packs x 180g	8,110	8,758.80	$ 2.64	$ 21,410.40
306091	PINK & WHITE MARSHMALLOWS (CA)	5 packs x 150g	11,206	8,404.50	$ 1.835	$ 20,563.01
		TOTAL	19,316	17,163.30	FOB	$ 41,973.41

Specific requirements

Importer-Distributor of Raw Materials/Finished Products/Ingredients/Additives for Distribution and/or Retail

All establishments from which the applicant **sources its imports** must be supported by at least one of the following documents **issued by the health or regulatory authority of the country of origin or of source**:

- Valid manufacturer's certificate of registration with GMP compliance, or its equivalent,
- Valid Sanitary Phyto-sanitary Certificate or Health Certificate,
- Valid ISO 22000 Certification,
- Valid HACCP Certificate, or
- Certificate of Free Sale

Note: All certification issued by a private organization should be attested by a recognized business association or chamber of commerce.

And must be authenticated by Philippine Consulate from the country of origin

FF1404911

AVA

Agri-Food & Veterinary Authority of Singapore

5 Maxwell Road #03-00 Tower Block MND Complex Singapore 069110
Fax: (65) 6220 6068 Website: http://www.ava.gov.sg

Date: 04 Jul 2014

TO WHOM IT MAY CONCERN

FREE SALE CERTIFICATE

This is to certify that ABC SINGAPOREAN COMPANY PTE LTD at 21 TUAS WEST DRIVE SINGAPORE 638411 is a food factory licensed by this Authority under the Sale of Food Act Chapter 283 to manufacture cup liquid beverages and non-dairy creamer. The licence is subject to annual renewal. The factory is graded 'A' which meets good hygienic, sanitary and manufacturing practices.

The following product manufactured by ABC SINGAPOREAN COMPANY PTE LTD is required to comply with the standards laid down in the Food Regulations and is allowed for sale in Singapore and for export for human consumption.

S/No.	Product Description	Packing
1	FOAMING CREAMER	10KG/BAG

Agri-Food & Veterinary Authority of Singapore

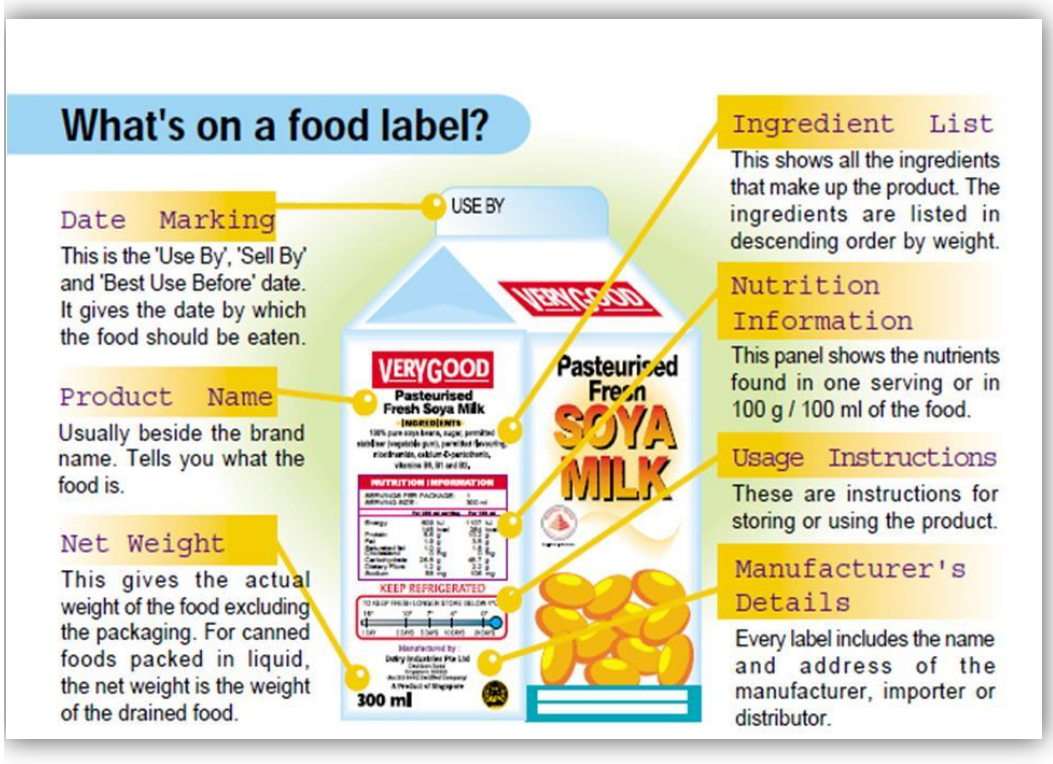
LEE WOEI SING
for Director-General
Agri-Food and Veterinary Services

Specific Requirements

PROCESS FLOW DIAGRAM

ICED CAKES (WITH IN-PROCESS) PRODUCTION
Process Area: Central Icing Section

CIS Personnel	(Depanning)/ Slabbing of basecakes	Basecake Height
CIS Personnel	Transfer to Assembly line	Standing time
CIS Personnel	(Wine spraying)	Amount of wine per slice (TMC only)
CIS Personnel	Addition of filling	Quantity per layer
CIS Personnel	Setting	Setting time, Chiller/Blast Freezer temperature
CIS Personnel	Boxing / Metal Detection	Expiry code, Metal Detector Calibration
Logistics Personnel	Storage	Chiller temperature
QA Specialist	Sampling & Evaluation	Periodic sampling: sensory, micro, shelf life monitoring
	END	



Mandatory Labeling Requirements Administrative Order No. 2014-030

1. Product Name/Name of the Food	1. Nutrition Facts/Nutrition Information/ Nutritive Value (mandatory)
2. Use of Brand Name and/or Trademark	2. Expiry or Expiration Date/ Use-by-date/Consume before Date
3. Complete List of Ingredients	3. Storage Condition (as applicable)
4. Net Contents and Drained Weight	4. Food Allergen Information (with ingredient)
6. Name and Address of Manufacturer, Repacker, Packer, Importer, Trader and Distributor	5. Direction/Instruction(s) for Use (as applicable)
6. Lot Identification	

Processing Time

Issuance of LTO/ Regular Renewal/ Issuance of GMP and HACCP Certificates	• 25 working days (CFRR)
Automatic Renewal of LTO/ Amendments without inspection –	• 14 working days

Validity of the LTO

- Unless revoked, the LTO shall have the following validity period:
  - An initial license issued shall be valid for two (2) years
  - A renewed license shall be valid for five (5) years.

Basis: Administrative Order 2014-0029

Registration of Food Products

Registration Requirements as per AO No. 2014-0029

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Registration No : FR-116505
Registration Status : [X] I [ ] R

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act No.3720, otherwise known as the Food, Drugs and Devices, and Cosmetic Act, as amended by Executive Order No. 175, Republic Act No. 9711, otherwise known as the Food and Drug Administration Act of 2009, and other applicable laws, rules and regulations, the registration of the food product described hereunder is granted approval.

Product Name : Lemon Flavor #73564 (Registered as Raw Material)
Brand Name :
Manufacturer : Blue Pacific Flavors and Flavors and Fragrances Inc. USA
Toll Packer : x x x x x x x x x x
Trader : x x x x x x x x x x
Exporter : x x x x x x x x x x
Importer : The First Enterprises, Inc. 200 Roosevelt Ave., SFDM, Quezon City
Distributor : x x x x x x x x x x
Packaging : White Galloon

This authorization shall be valid for **2** year(s) and shall expire on **31 March 2016** subject to the conditions listed on the reverse page and the product's continuing compliance to applicable standards and regulations.

WITNESS MY HAND and the Seal of this Office, this **31st** day of **March 2014**.

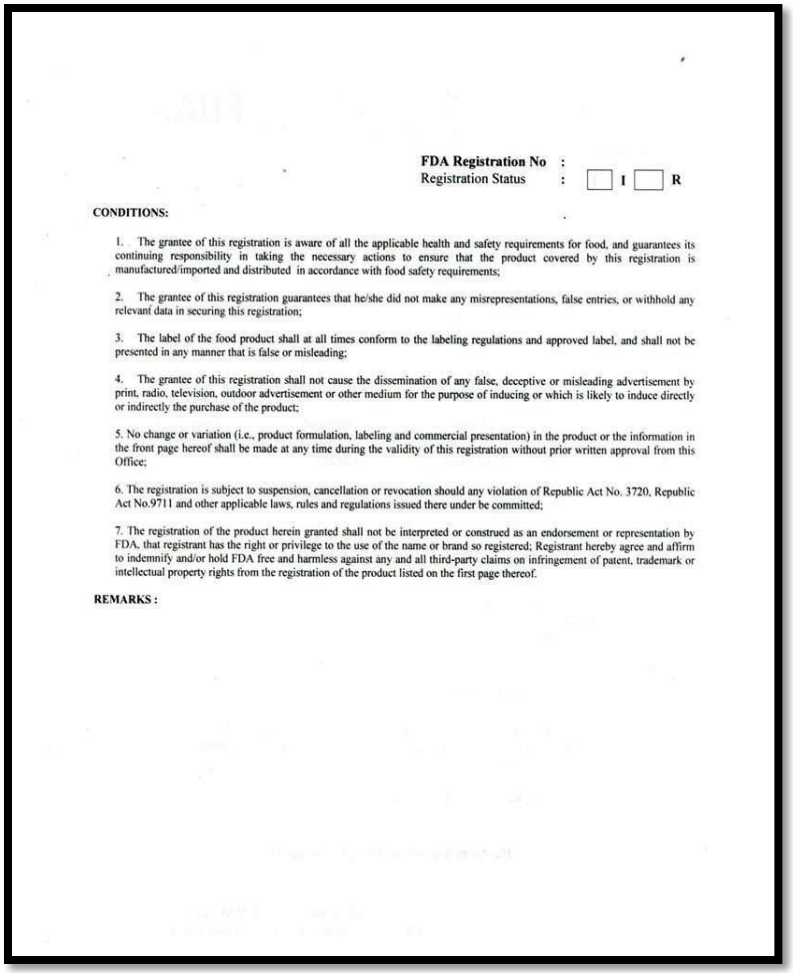
By Authority of the Director General

PILAR MARILYN M. PAGAYUNAN
OIC, Center for Food Regulation and Research

RSN	:	13F-14414	Additional Payment
O.R. No	:	0517883	0529871
Amount	:	Php 420	Php 100
Date Issued	:	25 Oct 2013	20 Feb 2014

DDR/CTTI/mrw

FDA-0024042



FDA Registration No :
Registration Status : [ ] I [ ] R

CONDITIONS:

1. The grantee of this registration is aware of all the applicable health and safety requirements for food, and guarantees its continuing responsibility in taking the necessary actions to ensure that the product covered by this registration is manufactured/imported and distributed in accordance with food safety requirements;

2. The grantee of this registration guarantees that he/she did not make any misrepresentations, false entries, or withhold any relevant data in securing this registration;

3. The label of the food product shall at all times conform to the labeling regulations and approved label, and shall not be presented in any manner that is false or misleading;

4. The grantee of this registration shall not cause the dissemination of any false, deceptive or misleading advertisement by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of the product;

5. No change or variation (i.e., product formulation, labeling and commercial presentation) in the product or the information in the front page hereof shall be made at any time during the validity of this registration without prior written approval from this Office;

6. The registration is subject to suspension, cancellation or revocation should any violation of Republic Act No. 3720, Republic Act No.9711 and other applicable laws, rules and regulations issued there under be committed;

7. The registration of the product herein granted shall not be interpreted or construed as an endorsement or representation by FDA, that registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property rights from the registration of the product listed on the first page thereof.

REMARKS :

LOW RISK FOOD PRODUCT AND RAW MATERIALS (FDA Circular 2014-029)

Electronic Registration (E-Registration) System

- File an initial registration using the e-registration system. Please refer to FDA Circular No. 2014-029 Procedure for the Use of Electronic (E-registration) System prior to filing for registration

Low risk

- Thru PAIR system of application

Medium risk

- Thru pair system of application

High risk

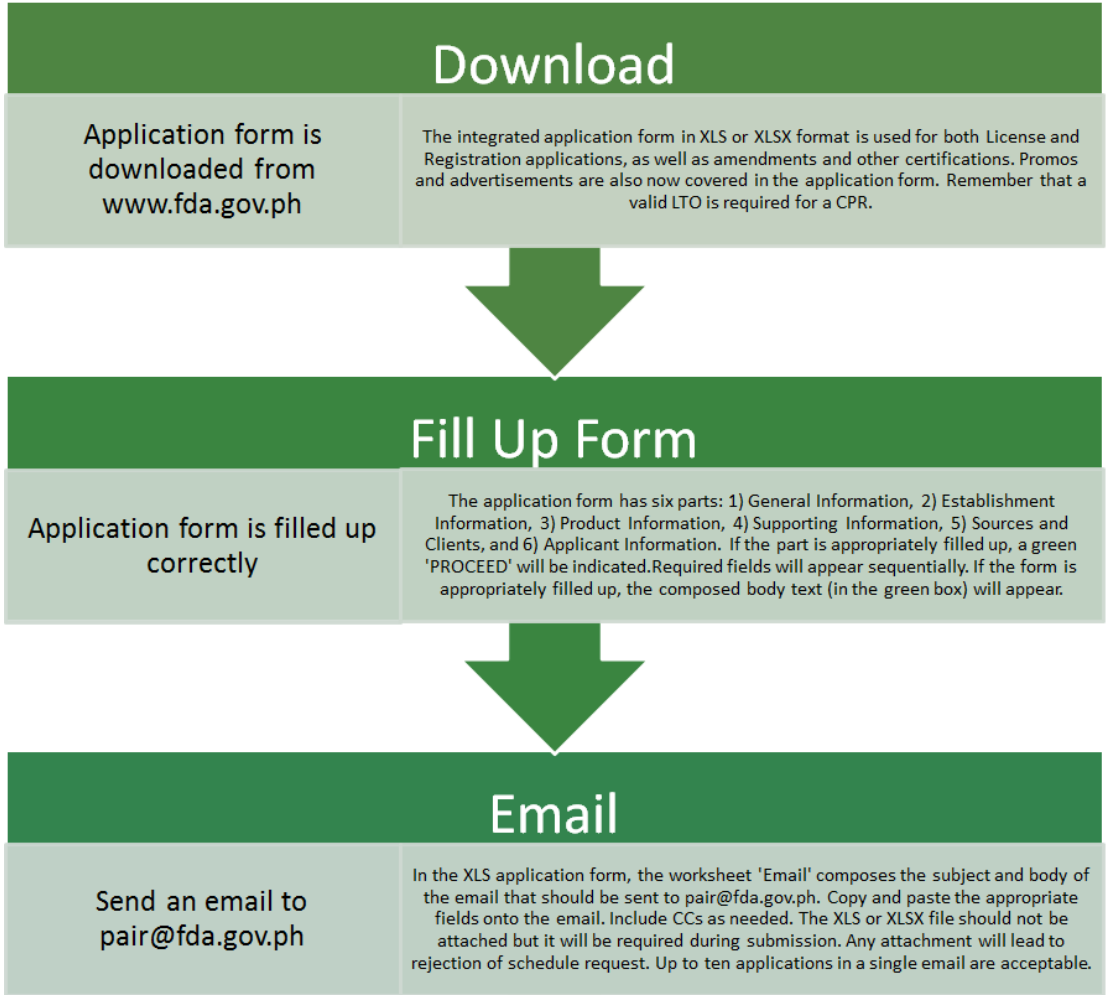
CERTIFICATE OF PRODUCT REGISTRATION (CPR) REQUIREMENTS FOR MEDIUM AND HIGH RISK FOOD PRODUCTS (FDA Circular 2014-0029)

INITIAL	RENEWAL	AUTOMATIC RENEWAL
1. **NOTARIZED AND COMPLETELY FILLED- UP Integrated Application Form** 2. **Proof of Payment of Fees as prescribed by current FDA regulations** 3. **Clear and complete loose labels or artworks of all packaging sizes, or equivalents as defined by FDA regulations.** 4. **Pictures of the product in all angles in different packaging sizes, and from at least two different perspective allowing visual recognition of a product as the same with the one being registered, as applicable.** 5. **For Food Supplement, a sample in actual**	1. NOTARIZED AND COMPLETELY FILLED- UP Integrated Application Form 2. Proof of Payment of Fees as prescribed by current FDA regulations (5 Years Validity) 3. Requirements in support of amendments included in the renewal application (Not applicable for automatic renewal) 4. Clear and complete loose labels or artworks of all packaging sizes, or equivalents as defined by FDA regulations. 5. As applicable, documents to substantiate claims. • Certificate or certification to support use of logo/seal on Sangkap Pinoy, Halal,	1. NOTARIZED AND COMPLETELY FILLED- UP Integrated Application Form 2. Proof of Payment of Fees as prescribed by current FDA regulations (5 Years Validity) CONDITIONS: 1. Renewal of the CPR may be automatic provided that the following conditions are met: a) The application should be filed before the expiration date of the CPR; b) The prescribed automatic renewal fee must be paid prior to filing of the application and c) If there is no condition stated at the back of the issued Certificate of Product Registration. However, in case there is a condition, a scanned copy of the acknowledgement letter from FDA indicating the condition stated in the CPR had been complied, should be submitted 1. Any application filed as automatic renewal registration shall be submitted with the FDA within 90 days before the date of its expiration. 2. Request for amendment shall not be allowed to be filed simultaneously with an application for

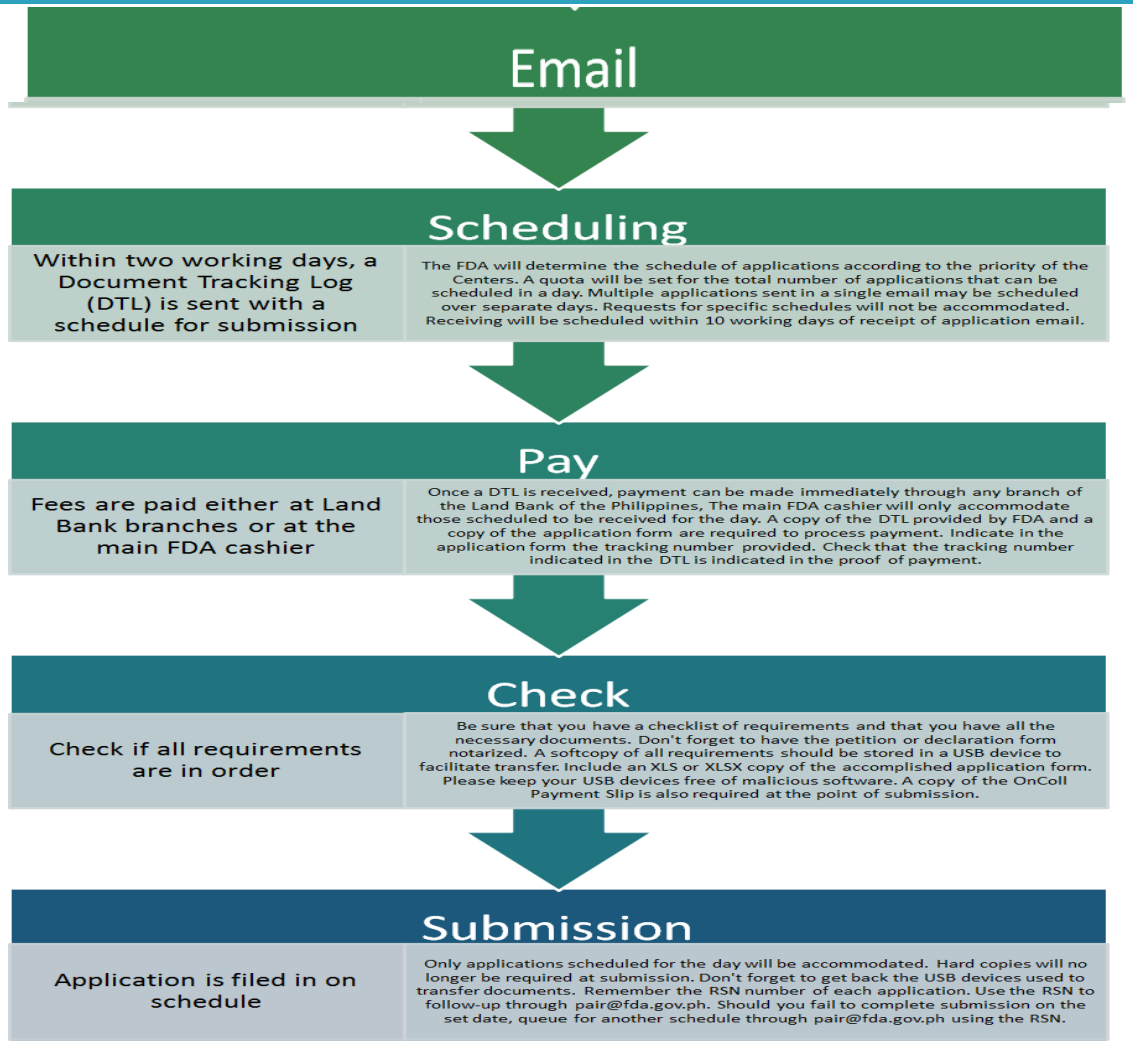
CPR Processing Time

Initial/ Regular Renewal-	• 88 working days
Automatic Renewal/ Re-application	• 45 working days

Application Process



Application Process



Inspection of (Regional Field Office)

CONTROL MEASURES TO ENSURE THAT BEST PRACTICES ON MEETING QUALITY AND SAFETY STANDARDS IN FOOD ARE MET (following QWP checklist and guidelines)

- Good Manufacturing Practice
- Hazard Analysis on Critical Control Points (HACCP)
- Import/ Export Control Certification
- Safety and Quality Standards
- Food Control System/Food Safety Act

Market Monitoring of Product Quality

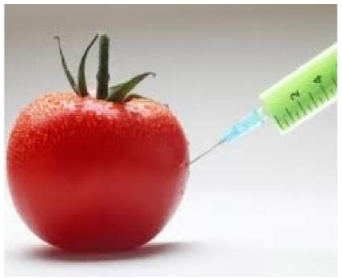
Upon order from Centers, Health Scam Unit, Legal

- Unregistered Products
- Adulterated Products
- Expired Products/No integrity
- Misbranded/Mislabelled

And upon order from Centers, Health Scam Unit, Legal

Post Monitoring Alert System

- PRSDD coordinates with RFO in identification of processed foods samples for collection per month/year or as the need arises
- Continuous monitoring of unauthorized processed food products in the market
  - non-compliance with labeling requirements and product
  - standards
  - Inconsistent information with CP- e.g., misdeclaration, falsification of documents



MONITORING AND SAMPLING OF FOOD PRODUCTS

All processed food products classified which may be raw materials, finished bulk or finished products in original packaging

Vienna, Austria?

Conduct Monitoring & Sampling

- Licensed Manufacturer's site
- Warehouse of licensed food distributors
- BOC warehouse/containers vans
- Store outlets such as supermarkets, groceries etc.

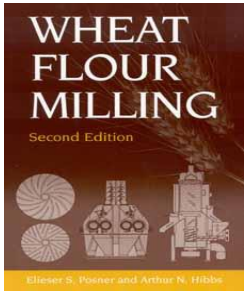
Monitoring Checklist/Requirements

- Compliance to label requirements
- Product registration (valid)
- Certificate of analysis

Required to:

a. fortified food (flour, cooking

b. iodized salts



Products Tested

Processed foods

- e.g Alcoholic and non-alcoholic beverages
- food supplement
- condiments and seasonings
- snack food
- dairy products

Staples such as oil, rice, sugar and flour

Consumer complaint samples

Collected samples/ Monitored

Product Recall

Referrals

Post market monitoring /Collected from other regions

Products tested

Sampling

- Physico-chemical analysis

  At least 2 units of prepackaged food products (in its commercial presentation) whose composite weight is not less than 250 grams (B.C. No. 6-A series 2001)

- Microbiological analysis

  2 units of at least 100 grams of prepackaged food products (in its commercial presentation)

  at least 3 units of prepackaged products (with same lot code) for thermally processed low acid or acidified packed in hermetically sealed container. 6 units if <100g

- Performs the following:
  - composite sampling
  - duplicate samples
  - % Recovery in every analysis

Product recall

- Team

Chair-OIC Director

Co-chair-Division head of PRSDD

Members: Laboratory

Regional Field Office

Legal

REU/Health Scam Unit

Product Recall Team Function (FDA Personnel Order No. 2013-064)

- Conduct and evaluation of the health hazard presented by a food product recalled or considered for recall
- Recommended a recall order of the food product to the FDA Director General
- Prepare a product recall advisory in the form of an FDA Circular for public information
- Request the RFO to conduct an in-depth inspection of responsible establishment where the violation occurred as well as collect adequate samples for the Central Laboratory to conduct appropriate test
- Issue a termination advisory of the product recall for public information

Product Recall Classes (BC No. 8 s. 2001)

Class 1

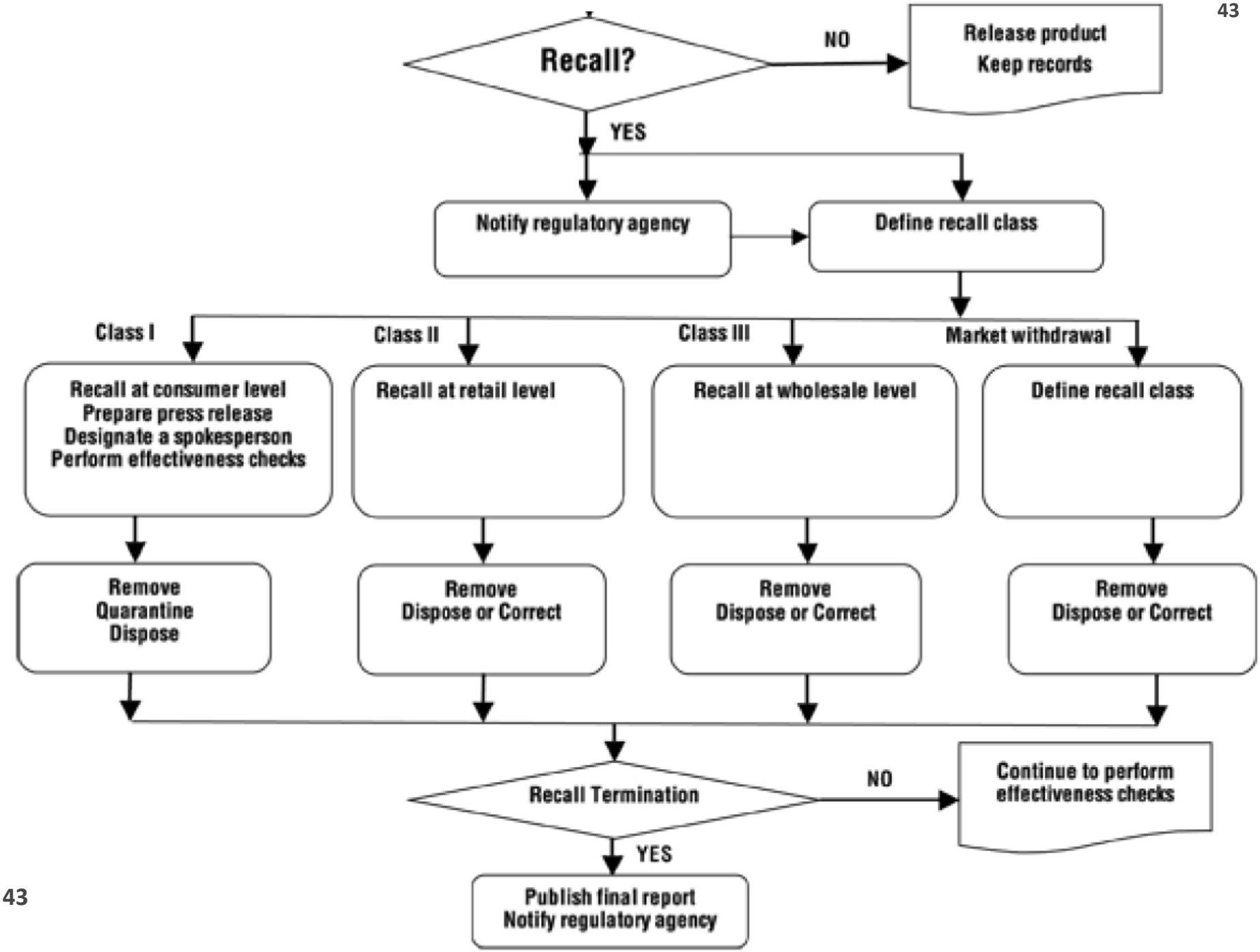
- Notices and warnings shall be issued by tri-media to the general public, health professionals, health institutions, industry associations, distribution outlets for such products and all other concerned parties

Class II

- Notices and warnings shall be issued to 1) groups and institutions that are identified as those who generally use or are exposed to the product 2) those who could help remove such violative products from the market or prevent such products from being used

Class III

- Notices and warnings shall be issued to concerned parties and distribution outlets


Recall?
NO
Release product
Keep records
YES
Notify regulatory agency
Define recall class
Class I
Class II
Class III
Market withdrawal
Recall at consumer level
Prepare press release
Designate a spokesperson
Perform effectiveness checks
Recall at retail level
Recall at wholesale level
Define recall class
Remove
Quarantine
Dispose
Remove
Dispose or Correct
Remove
Dispose or Correct
Remove
Dispose or Correct
Recall Termination
NO
Continue to perform
effectiveness checks
YES
Publish final report
Notify regulatory agency

Product Complaints

Receiving of food product complaint either through a phone call, walk-in or referral from another government unit.

Assess the nature of the complaint and determine the qualification of the complaint/complainant whether it merits further assistance or an outright rejection

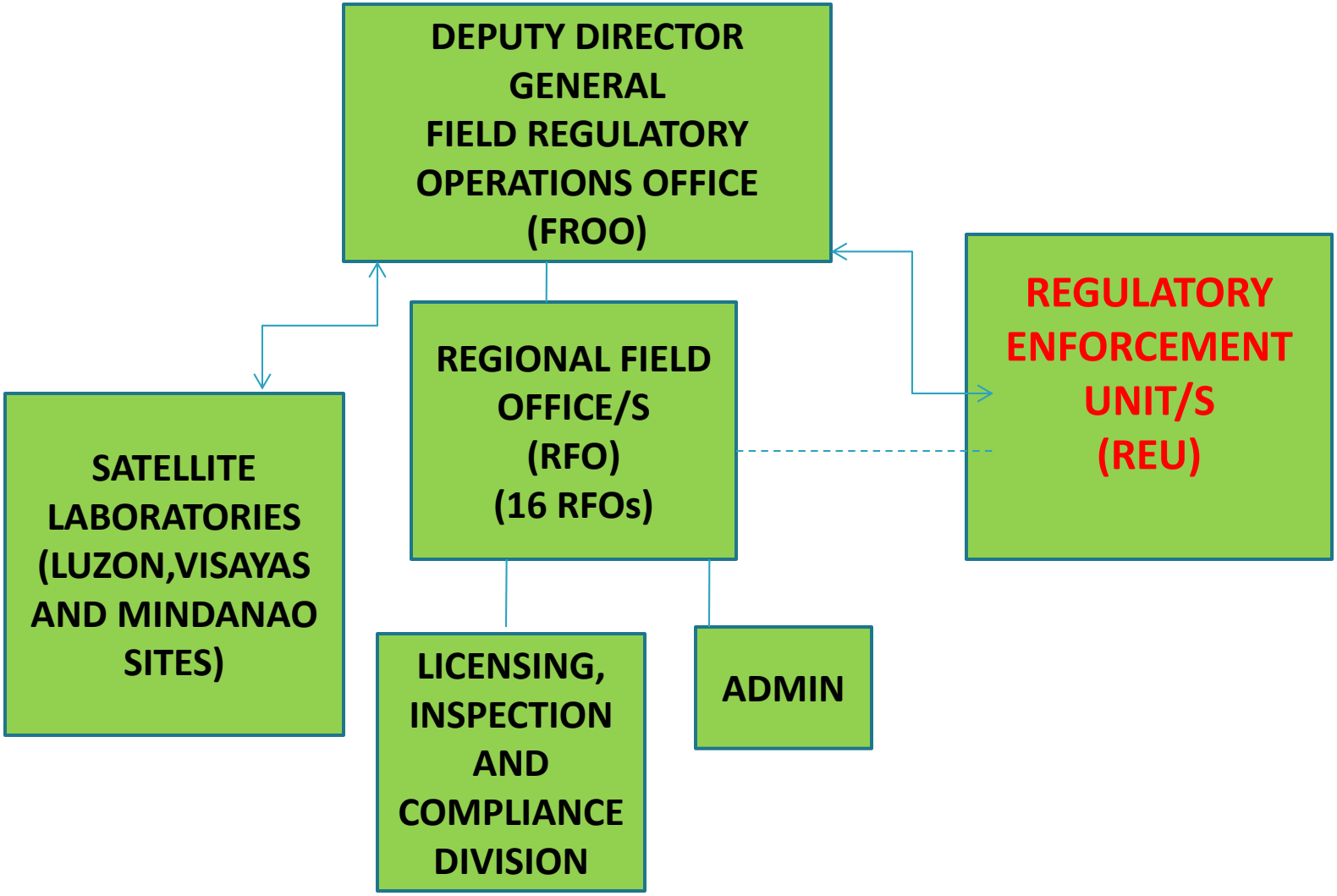
Complete a written report whether accepted or rejected

Product Complaints

- If complaint qualifies further action fill up the product complaint form and the accompanying request for analysis form if necessary for forwarding a complaint food product requiring lab analysis by the FDA Food Lab
- If complaint requires action aside from analysis by the FDA Food Lab, such actions that will verify and/or further validate the genuine nature and/or gravity of the cause of the complaint a referral to the concerned Regional Field office through the Field Regulatory Regulations office should be done
- Collate feedback from referrals made: Food Lab and RFO and evaluate the results to decide on the next action of the complaint
- Inform the complainant on the outcome of the complaint

Regulatory enforcement Unit

Support-FDA Field Regulatory Office (FROO)



Regulatory enforcement Unit

- RA 9711 Book 1, Article VIII, D Section 12
  - There shall be established, in each region of the country, including the National Capital Region and the Autonomous Regions, a Regulatory Enforcement Unit (REU) composed of at least five (5) qualified personnel who shall be under the control and supervision of the Deputy Director-General for Field Regulatory operations and shall be administratively supported by the field offices.

Regulatory enforcement unit

- RA Act No. 9711
- Protect and promote the right to health of the Filipino people, and
- Help establish and maintain an effective health product regulatory system and undertake appropriate health human resource development and research, responsive to the country's health needs and problems.

Objectives

- To protect the consumers in ensuring that the health products they take are of quality, safe and effective.
- To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction are efficient, benchmarking international best practices.

Strategies

- Vigilant and strong monitoring and surveillance of all health products.
- Strict enforcement of FDA's orders and ensure compliance with standards and guidelines.
- Strong linkage with other local enforcement agencies as to access in database and other relevant information.

Duties and Functions

- Bear arms/ wear official uniforms and insignias and shall be classified as law enforcement agents;
- Serve and execute rulings, orders, and decisions of the Regional Field Director or the Director-General;
- Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under the FDA Act of 2009, these Rules and Regulations, and related laws concerning the regulation of health products; and
- To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities in support of the objectives of the Law and this IRR.

Other Functions (REU)

- Consolidate reports from intelligence/ surveillance unit and submit to FDA for appropriate action
- Provide all necessary equipment and gadgets to the subordinate units
- Coordinate future actions to other LEA's limited to their task only

Target groups

- Unlicensed health product establishments
- Counterfeit health products
- Unauthorized health products
- Adulterated health products
- Expired health products
- Mislabeled/misbranded health products

Health Scams Unit

- To ensure that all media advertisements comply and adhere to the standards, guidelines, and regulations of the FDA and to protect the consumer against misleading, deceptive, false, erroneous impression regarding any health product.
- To continuously educate the public through the issuance of Advisories facilitating sound choice in the proper exercise of their rights as consumers.

Scope and Focus

- The HSU shall conduct monitoring of all advertisement in violation of R.A. 3720, as amended by R.A. 9711, otherwise known as the FDA Act of 2009.
- The HSU shall focus mainly, but not limited to, on the violative advertisement found in the social media and the internet.

Objectives

- To protect the public from misinformation coming from all kinds of advertisements
- To promptly inform and educate the public on the correct and accurate information regarding health products
- To monitor advertisements that may potentially violate laws, rules and regulations of the FDA
- To investigate further and report the source of the violative advertisements

Advertising and Sales Promotions

- ART. 116. PERMIT TO CONDUCT SALES PROMOTION
- No person shall conduct sales campaigns, including beauty contest, national in character, sponsored by and promoted by manufacturing enterprises without first securing a permit from the concerned department at least thirty (30) calendar days prior to the commencement thereof. Unless an objection or denial is received within fifteen (15) days from the filing of the application, the same shall be deemed approved and the promotion campaign or activity may be conducted.

Memorandum of Agreement Between DOH and DTI

DTI shall issue the permit for the sales promotion activities of:

- Food Service Establishment classified as service firms like restaurants and food chains.
- Devices which are not included in the list of devices required to be registered.
- Joint promotions of Department Stores and Food/Drug/Devices/Cosmetics/HHS manufacturers/sellers – provided that a copy of Certificate of Product Registration (CPR) shall be submitted to DTI as a pre-requisite to the DTI-Permit.

Post Marketing Surveillance

- The Center in coordination with FDA Laboratory prepares the PMS Annual monitoring program and database containing the following information:
  - Target products for PMS collection based on the risk assessment result;
  - Target area where the PMS samples will be collected, where applicable;
  - Target schedule of collection;
  - Provisions on test parameter, laboratory test result, the actions taken and/or the remarks, where applicable.
- The Center provides copy of the Annual Monitoring Program to the Field Regulatory Operations Office to collect samples and/or inspect establishment of the target product/s.
- The FRO collects sample of the target product and/or inspects establishment (based on the guidelines for the minimum number of samples required for each test analysis and QSP on collection of samples for laboratory analysis).
- The FRO refers the collected sample:
  - To the Center for verification of product registration status
    - The Center verifies the product's registration status.
    - The Center releases result of Product Verification.
  - And/or to the FDA Laboratory for testing
    - The FDA laboratory analyst performs analysis on the submitted samples
    - The FDA Laboratory releases the result of laboratory test

Post Marketing Surveillance

METHOD OF COLLECTION

<u>At the site of licensed manufacturers/distributors:</u>

a. Finished product:

- 5 pieces of the same kind and of each lot/batch

b. Raw materials

Composite sampling:

-5 containers/sacks for each lot/batch

- 250 Grams per container/sack

<u>At the store outlets (unlicensed)</u>

Through Purchasing

Post Marketing Surveillance

- For passed results, FDA Laboratory releases test report to the requesting party.
  - 5.4.2.2.2 For failed/OOS results, FDA Laboratory releases test report to the requesting party. Likewise, FDA Laboratory provides copy of the test results directly to the concerned Center.
- The Center reviews result for appropriate regulatory action/s
- RFO-FDRO prepares ROV and submits to LSSC for appropriate legal action/s.
- The REU Special Investigator serves and/or executes the legal order from the LSSC.
- The Center updates the PMS Annual Monitoring Program as often as possible.

Customs Liaison Unit

- Serves as linkage between the FDA and the Bureau of Customs (BoC) on matters of mutual concern and where importation and exportation of health products passing thru all portal entries should be of uncompromised quality, safety, and legit source

Functions

- Focal point and clearing authority for the agency on matters requiring FDA-BoC linkage
- Attends and participates in related meetings, dialogues, and info-sharing for closer collaboration

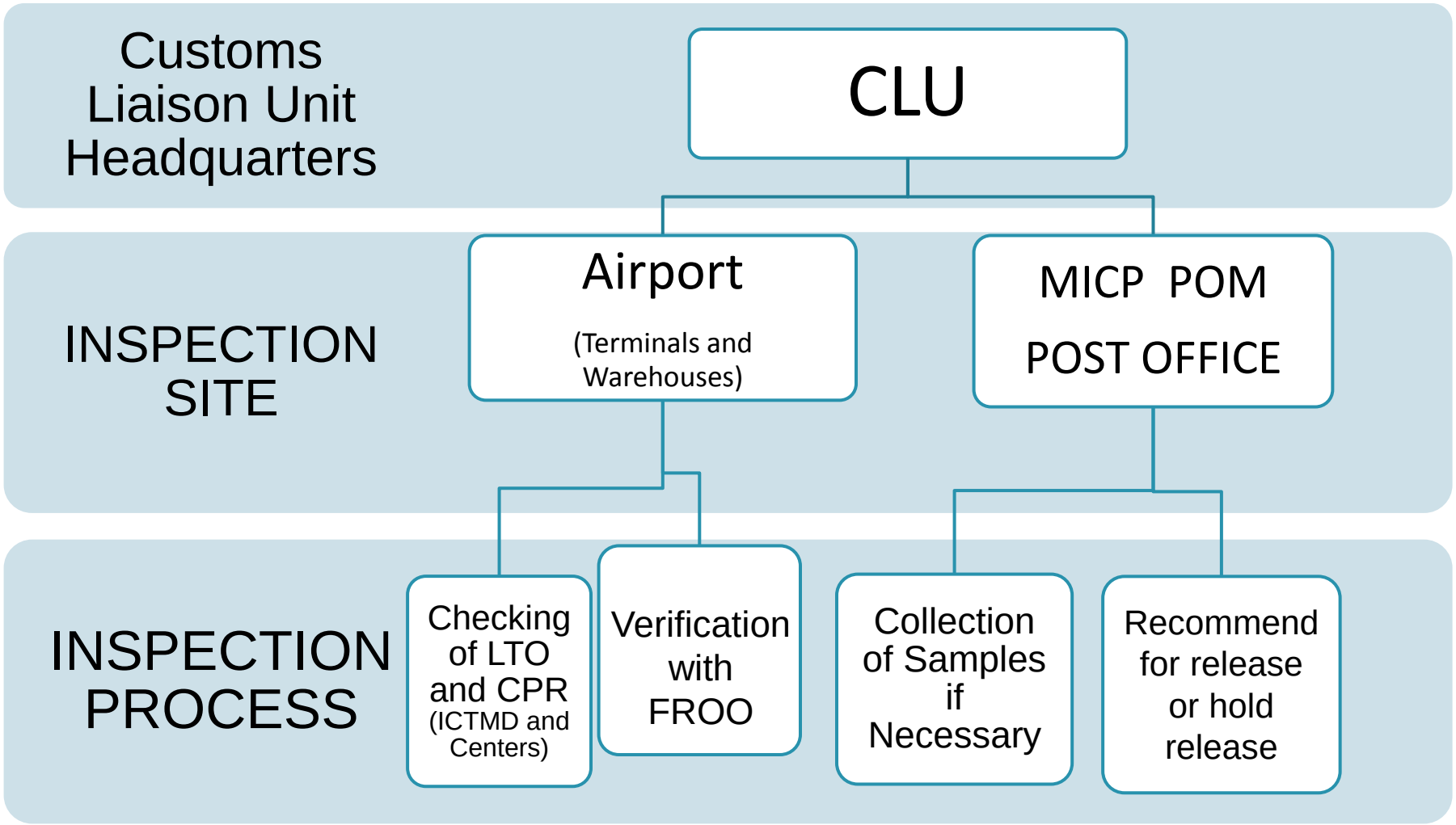
- Works horizontally in conjunction with the Centers/Offices on BoC-related issues towards a strengthened coordination and regulatory actions

- Posting of FDA inspectors to work closely with Customs and Quarantine to safeguard entry of imports thru a unified border inspection and enforcement control

Scope of work

- Receives/acts on queries from regulated industry, referrals from centers and BoC on matters that need coordination and regulatory action
- Coordinates with ICTM/Centers/Offices on status of license and product registration or notification
- Attends meeting, dialogue, information sharing as necessary

FDA Border Inspection Strategy



Customs Liaison Unit

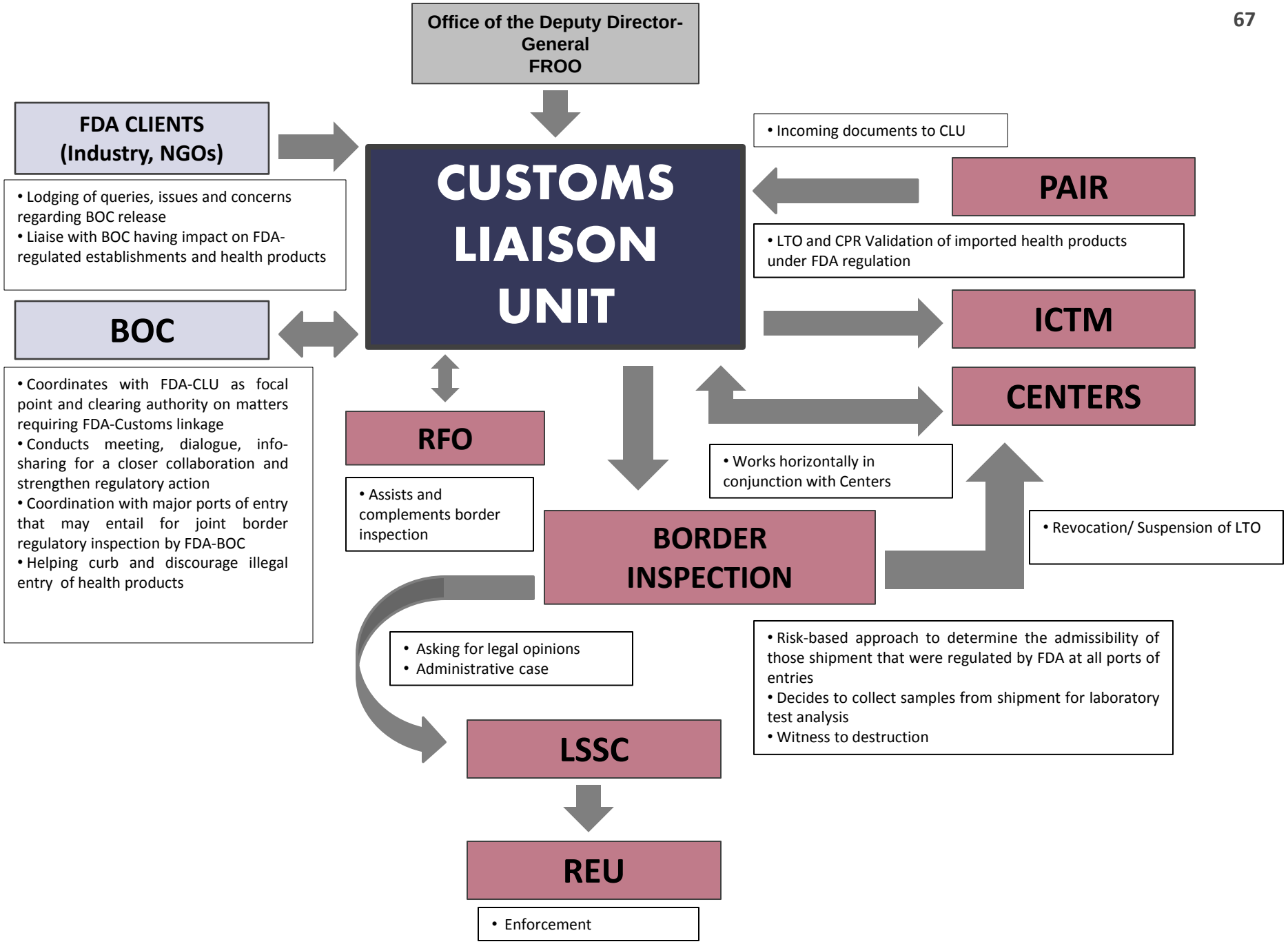
CLU

CLIENTS

- Official Visit PAIR (Rm 106)
- Landline Calls
- Mobile Texts
- E-mails

Customs Liaison Unit

Bureau of Customs


Office of the Deputy Director-General
FROO
FDA CLIENTS (Industry, NGOs)
• Lodging of queries, issues and concerns regarding BOC release
• Liaise with BOC having impact on FDA-regulated establishments and health products
CUSTOMS LIAISON UNIT
• Incoming documents to CLU
PAIR
• LTO and CPR Validation of imported health products under FDA regulation
BOC
• Coordinates with FDA-CLU as focal point and clearing authority on matters requiring FDA-Customs linkage
• Conducts meeting, dialogue, info-sharing for a closer collaboration and strengthen regulatory action
• Coordination with major ports of entry that may entail for joint border regulatory inspection by FDA-BOC
• Helping curb and discourage illegal entry of health products
ICTM
CENTERS
RFO
• Assists and complements border inspection
• Works horizontally in conjunction with Centers
BORDER INSPECTION
• Revocation/ Suspension of LTO
• Asking for legal opinions
• Administrative case
• Risk-based approach to determine the admissibility of those shipment that were regulated by FDA at all ports of entries
• Decides to collect samples from shipment for laboratory test analysis
• Witness to destruction
LSSC
REU
• Enforcement

FDA Legal procedures

- Complaint
- RA 9711 prohibited acts

Sec. 3. Complaint or Petition by a Party

- The Complaint or Petition shall indicate the:
  - full name and addresses of the parties, and shall set forth in concise manner, the claims, the relief prayed for, and the date of the pleading.
  - must be signed by the party or counsel representing him/her, stating in either case his/her address which should not be a post office box.
  - must likewise be supported by an affidavit that the affiant has read the pleading and that the allegation therein are true and correct of his/her personal knowledge or based on authentic documents;

Sec. 3. Complaint or Petition by a Party

- Must contain a sworn certification:
  - that he/she has not theretofore commenced any action or filed any claim involving the same issues in any court, tribunal or quasi-judicial agency and to the best of his/her knowledge, no such similar action or claim is pending therein;
  - if there is such other pending action or claim, a complete statement of the present status thereof; and
  - if he/she should hereafter learn that the same or similar action or claim has been filed or is pending, he/she shall report that fact within five (5) days therefrom.

Prohibited Acts Under RA9711

- "(a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded.
- "(b) The adulteration or misbranding of any health product.
- The manufacture, **importation**, exportation, **sale, offering for sale, distribution**, **transfer**, non-consumer use, promotion, advertisement, or sponsorship of **any health product** which, although requiring registration, is **not registered with the FDA** pursuant to this Act.

Prohibited Acts Under RA9711

- "(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to health products if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded: Provided, That a retailer may sell in smaller quantities, subject to guidelines issued by the FDA.
- k) The manufacture, **importation**, exportation, **transfer or distribution** of any food, by any natural or juridical person **without the license to operate from the FDA** required under this Act.

Grounds for Disapproval of Application and Suspension or Cancellation of License, Registration, or Authorization

The application requirements submitted show that the establishments does not meet the required technical requirements or appropriate standards

The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law, these Rules and Regulations or appropriate standards

The owner has **violated** any of the **terms and conditions** of its license

Such other analogous grounds or causes as determined by the FDA

Thank you