FOOD AND DRUG ADMINISTRATION

Ensuring Safety, Efficacy, and Quality of Drug Products

Presentation Outline

I. The FDA and the CDRR
II. FDA Directives and CDRR Objectives
III. Special Topics
    A. ASEAN Harmonization
    B. Bioequivalence
    C. Biosimilars
    D. Mexico City and Kuala Lumpur Principles

FOOD AND DRUG ADMINISTRATION

Regulatory office under the Department of Health

FDA MANDATE

PROTECT
THE GENERAL PUBLIC

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

MISSION

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

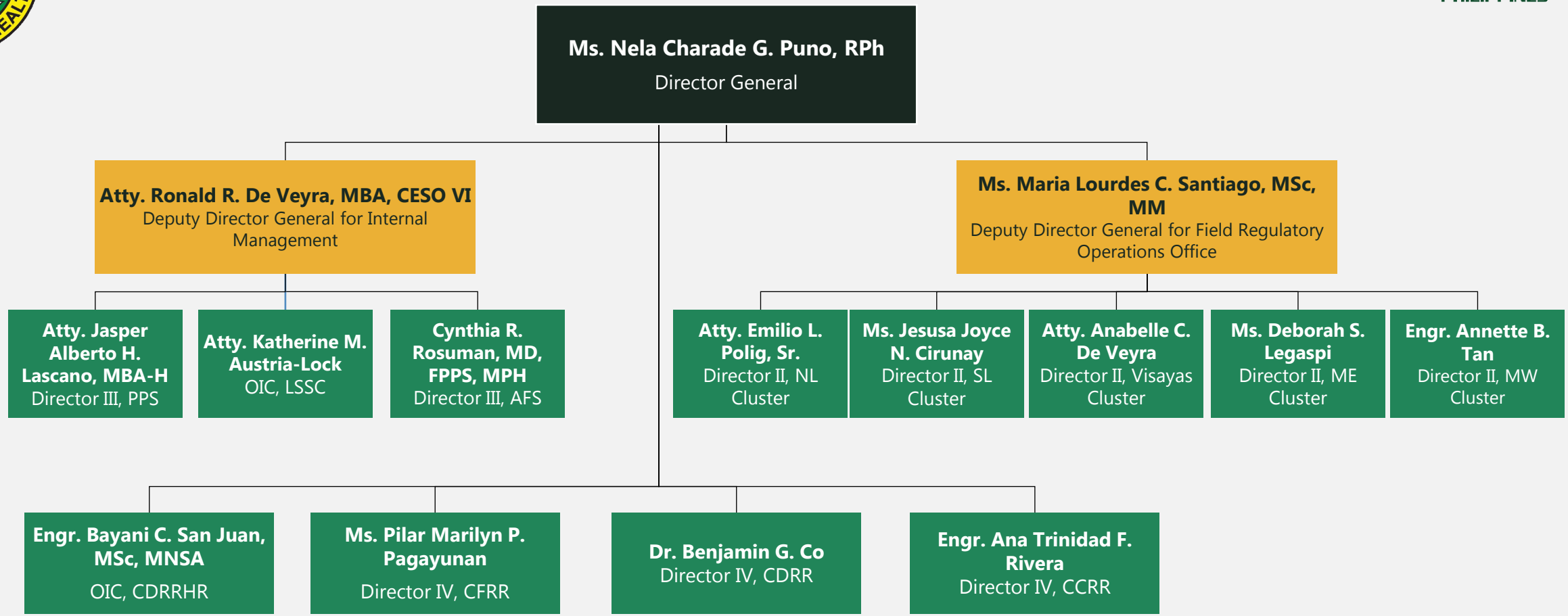
VISION

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

Quality Policy

Our highest commitment is to ensure the safety, efficacy and quality of health products.

Toward this end, we commit to maintain and establish science-based policies based on national and international standards as the basis for regulatory policies, to continually improve and maintain our competencies in relation to our regulatory function, and to deliver quality public service with integrity and efficiency.



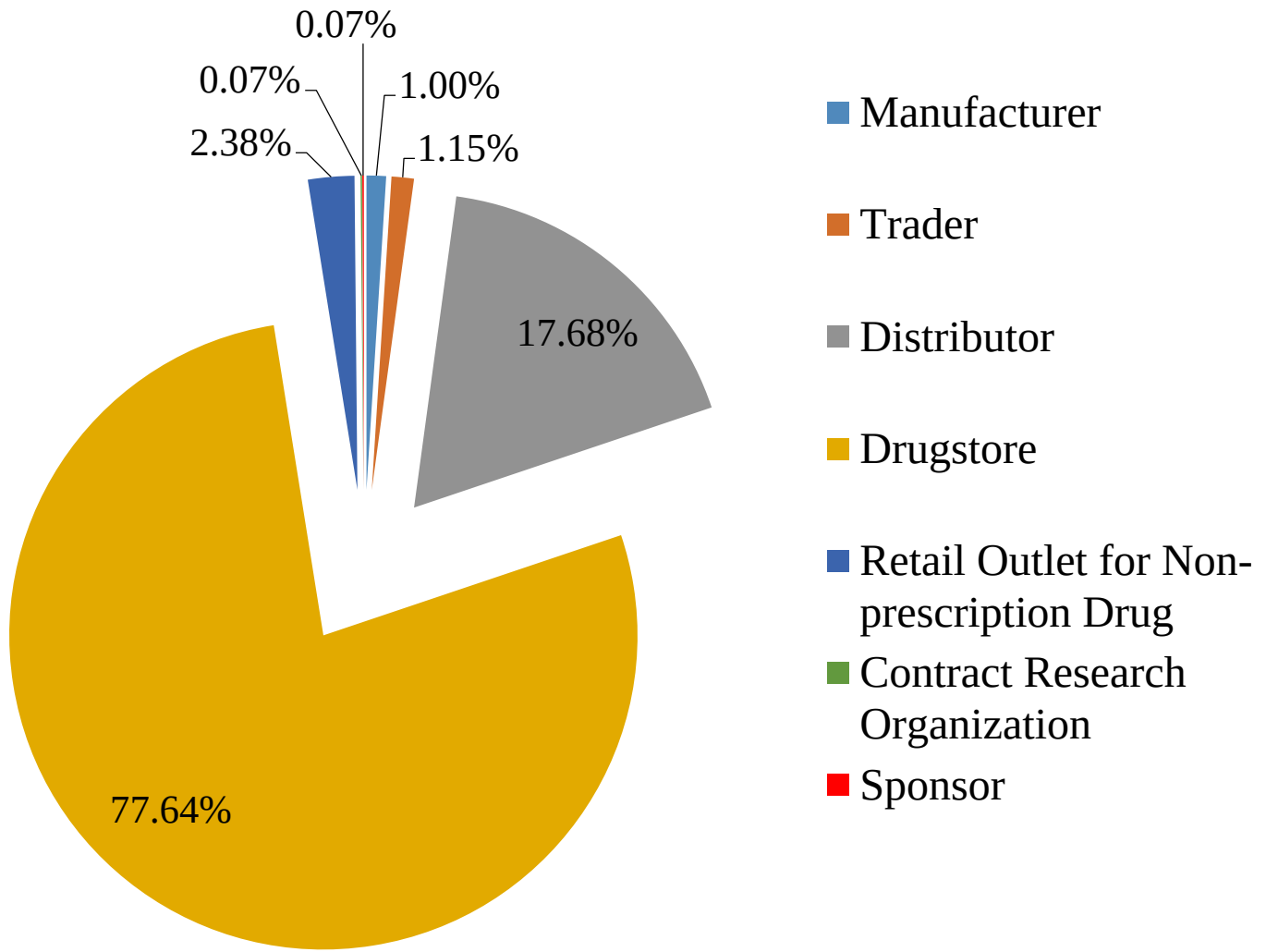
KEY OFFICIALS

The Center for Drug Regulation and Research

Ensures the **safety, efficacy**, and **quality** of **drug products**

1. New chemical entities
2. Generic products
3. Biological products (including biosimilars and vaccines)
4. Household remedies
5. Over-the-counter products
6. Traditionally-used herbal products
7. Herbal medicines
8. Medical gases
9. Veterinary Drugs
10. Stem Cell Products

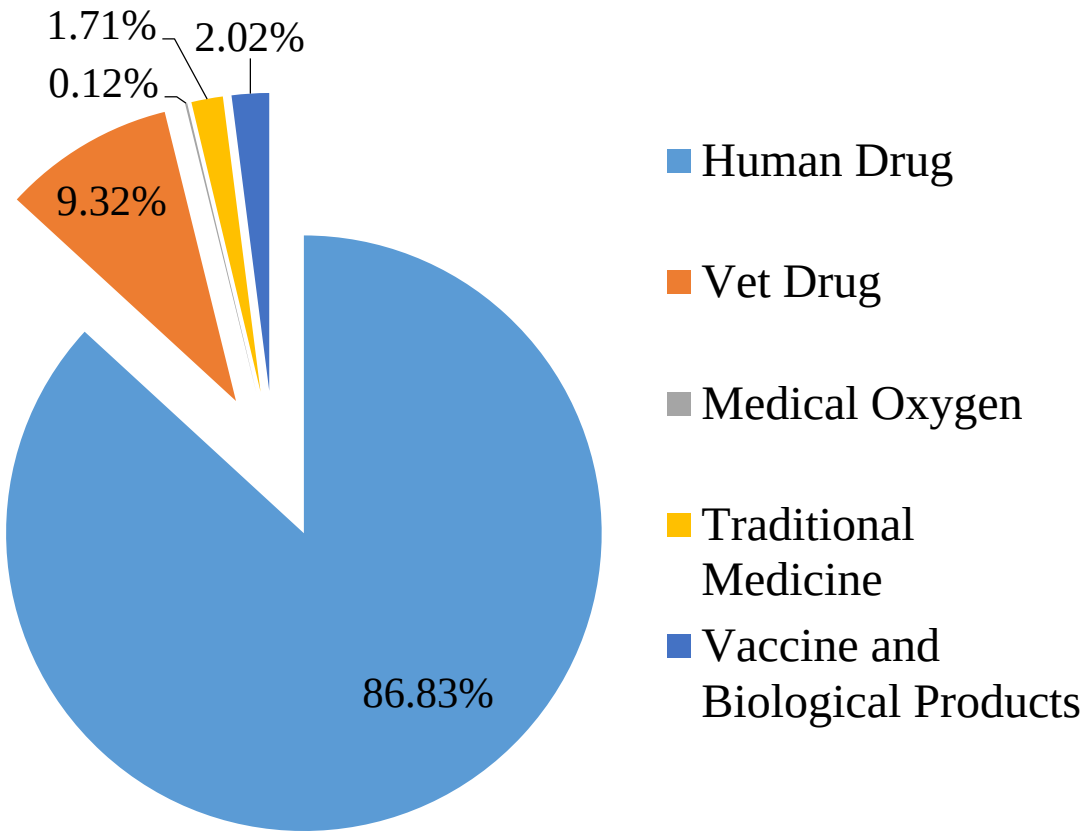
Licensed Drug Establishments



Establishment Type	Number
Manufacturer	351
Trader	403
Distributor	6195
Drugstore	27204
Retail Outlet for Non-prescription Drug	834
Contract Research Organization	26
Sponsor	26
TOTAL	35039

As of December 2016

Registered Drug Products



Product Type	Number
Drug (Human)	20512
Drug (Vet)	2201
Medical Oxygen	28
Traditional Medicine	404
Vaccine and Biological Products	478
TOTAL	23623

As of December 2016

Benjamin G. Co, MD, FPPS, FPSECP
Office of the Director

FDA Food and Drug Administration PHILIPPINES

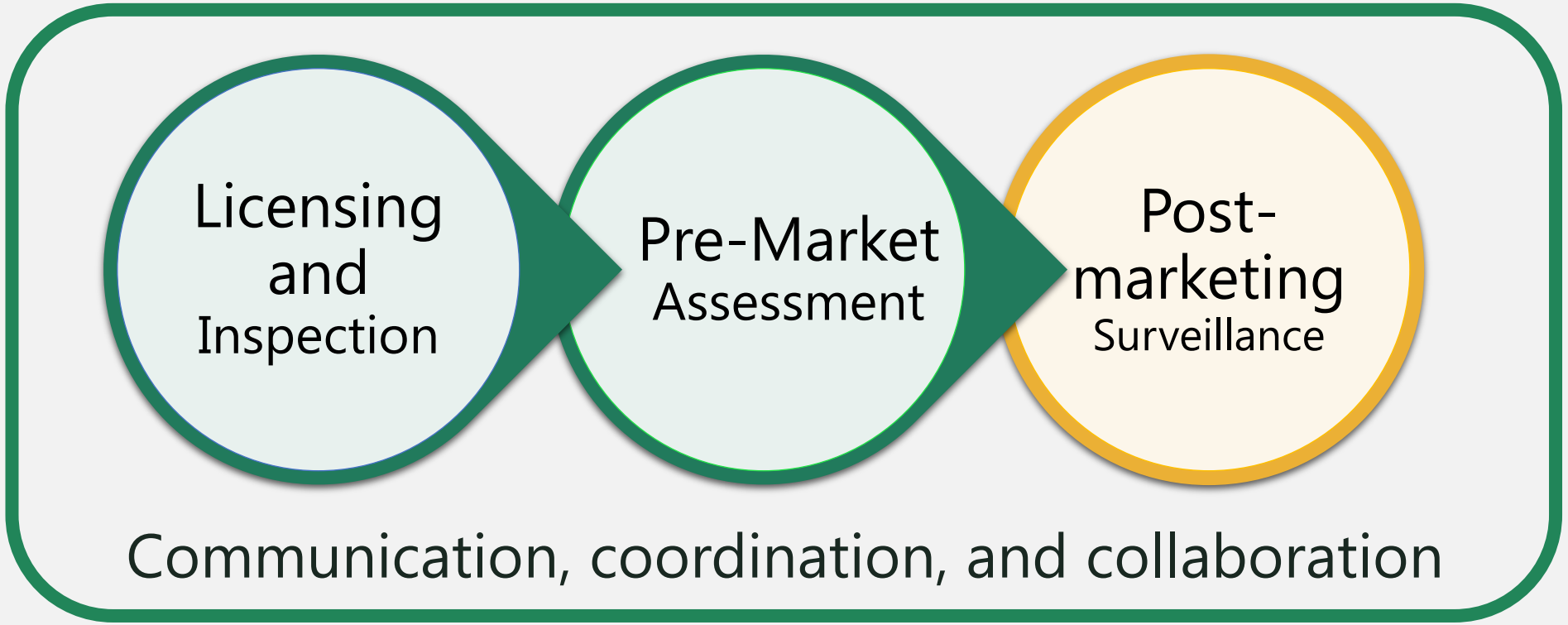
Ma. Theresa Pia C. Yap, RPh
Product Research and Standards Development Division (PRSDD)

- Policy/Standards Development and Advocacy Section
- Clinical Research Section
- Post-marketing Surveillance 1 Section
- Post-marketing Surveillance 2 Section
- Pharmacovigilance Section
- PRSDD Support Section

Melody M. Zamudio, RPh, MGM-ESP
Licensing and Registration Division (LRD)

- Licensing Section
- Registration Section
  - L1 Unit
    - New Drug and Prescription Generics Unit
  - L2 Unit
    - Vaccines and Biologics Unit
    - OTC and Herbal Preparations Unit
    - Veterinary Drugs Unit
    - Post-Approval Unit
- LRD Support Section

Regulatory Framework



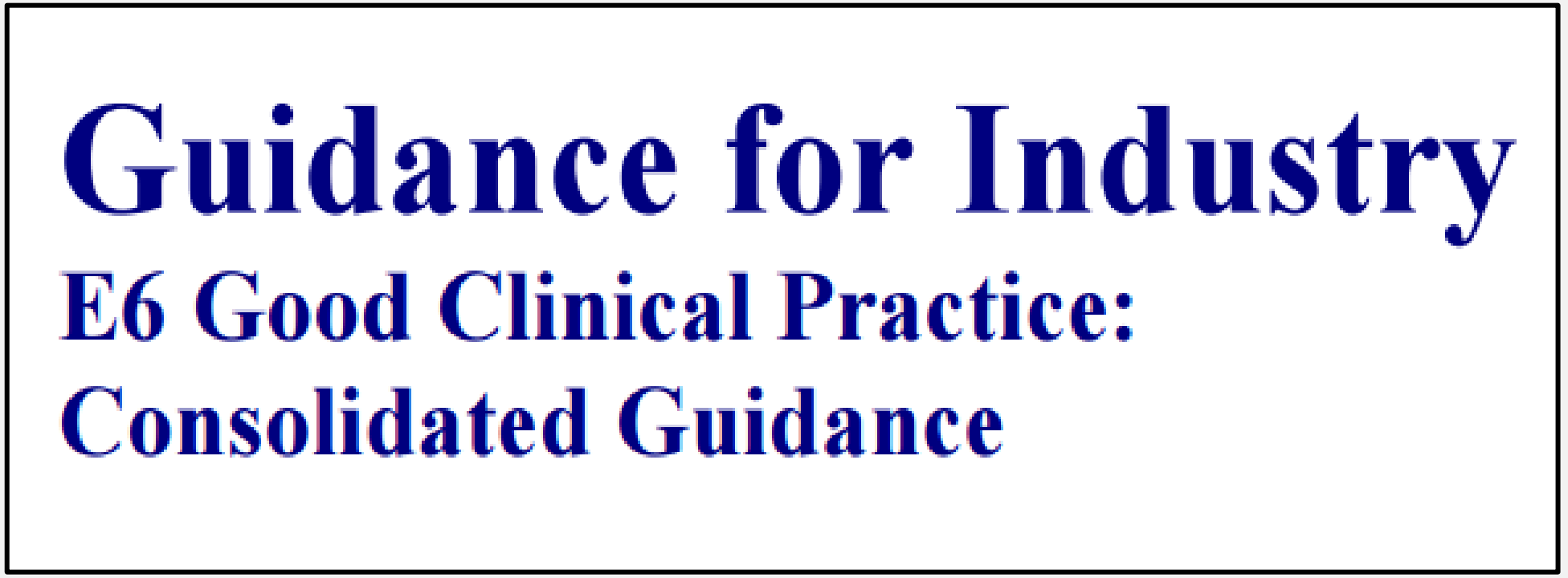
“standards of safety, efficacy, and quality”

Licensing and Inspection:
at par with international standards

Good Manufacturing Practice	→ AO 2012-0008	PIC/S	✓ 52 Countries
Good Distribution Practice	→ AO 2013-0027	World Health Organization	✓ Worldwide
Good Storage Practice	→ AO 2013-0027	World Health Organization	✓ Worldwide
Good Clinical Practice	→ FC 2013-018	ICH harmonisation for better health	✓ Worldwide

Pre-Market Assessment:
at par with international standards

1. The conduct of clinical trials must comply with ICH GCP



Pre-Market Assessment:
at par with international standards

2. Proof of safety, efficacy, and quality must pass the requirements of FDA

Pre-Market Assessment:

at par with international regulatory schemes

Inspection of foreign drug manufacturers	→ Eliminates "backyard manufacturing"	→ AO 2013-0022
Conduct of Bioavailability and Bioequivalence Studies	→ Generic proof of interchangeability	→ FC 2016-019

Postmarketing Surveillance
strengthened enforcement

1. Pharmacovigilance

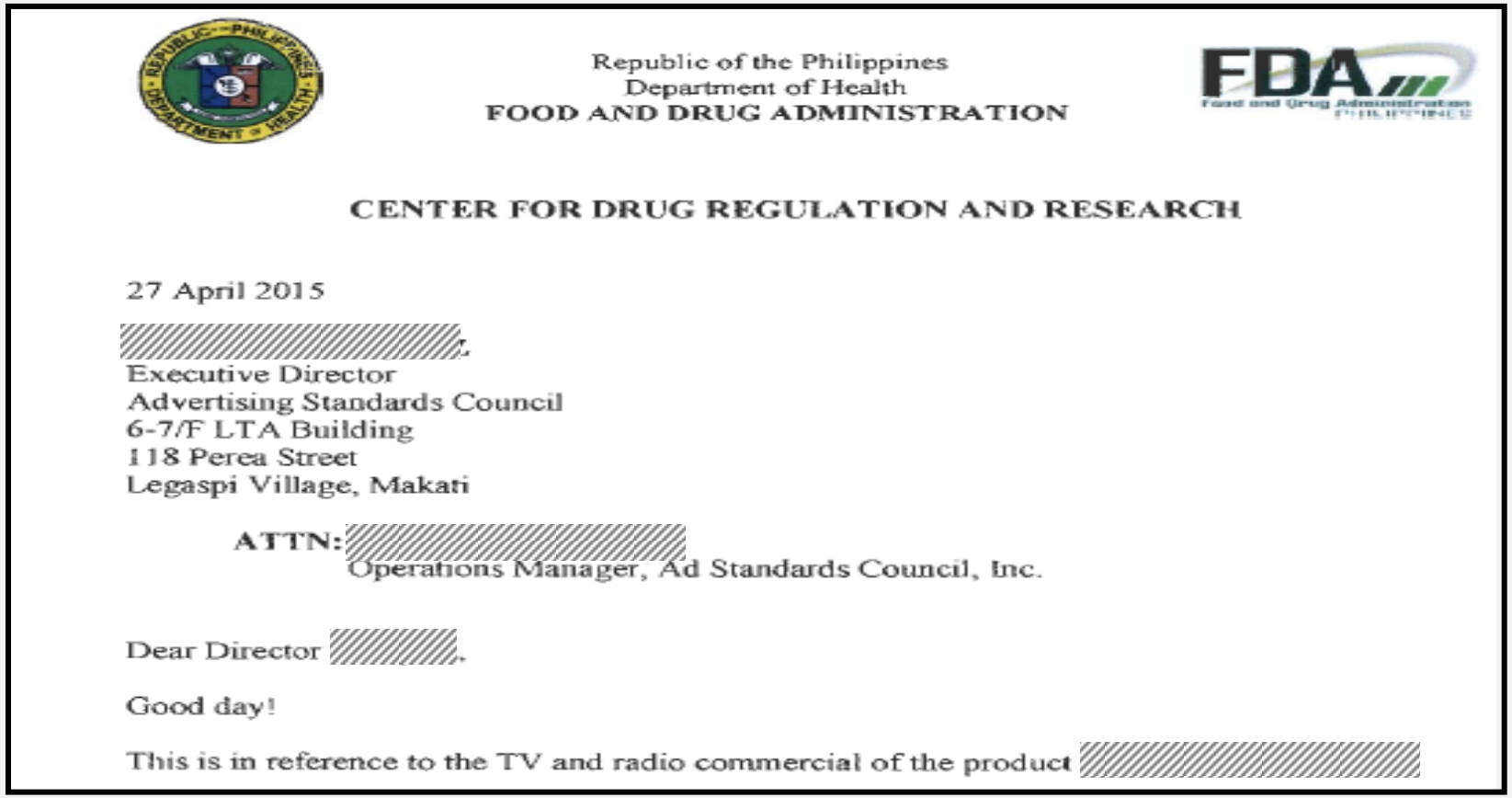
Safety monitoring of drugs on the market for unexpected health risks and informing the public of risks posed by specific drugs and other health products

Postmarketing Surveillance
strengthened enforcement

2. Monitoring, collecting, sampling and testing of drugs
3. Audits and inspection of manufacturers/ distributors/ retail outlets

Postmarketing Surveillance
strengthened enforcement

4. Advertisements and claims monitoring



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

27 April 2015

[redacted]
Executive Director
Advertising Standards Council
6-7/F LTA Building
118 Perea Street
Legaspi Village, Makati

ATTN: [redacted]
Operations Manager, Ad Standards Council, Inc.

Dear Director [redacted].

Good day!

This is in reference to the TV and radio commercial of the product [redacted]

Postmarketing Surveillance
strengthened enforcement

5. Consumer reporting of ADR/complaints processing

National Pharmacovigilance Center

"Saving Lives Through Vigilant Reporting"

Send completed form to: ADR Unit, FDA, Civic Drive, Filinvest Estate, Alabang, Muntinlupa ,1781.
Or fax to: (02) 807-85-11, c/o The ADR Unit. **Send sample, if any, of suspect drug for analysis.**
Website: www.fda.gov.ph

Postmarketing Surveillance
strengthened enforcement

6. Recall, labeling revision, restrictions on use, and other enforcement action

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 November 2013

FDA Advisory
No. 2013 - 055

SUBJECT: RECALL OF UNREGISTERED PRODUCTS MARKETED BY [redacted]

Based on the results of the recent investigations conducted by the Food and Drug Administration, it was found that there are products marketed by [redacted] Inc. without valid Certificates of Product Registration (CPR), hence unregistered.

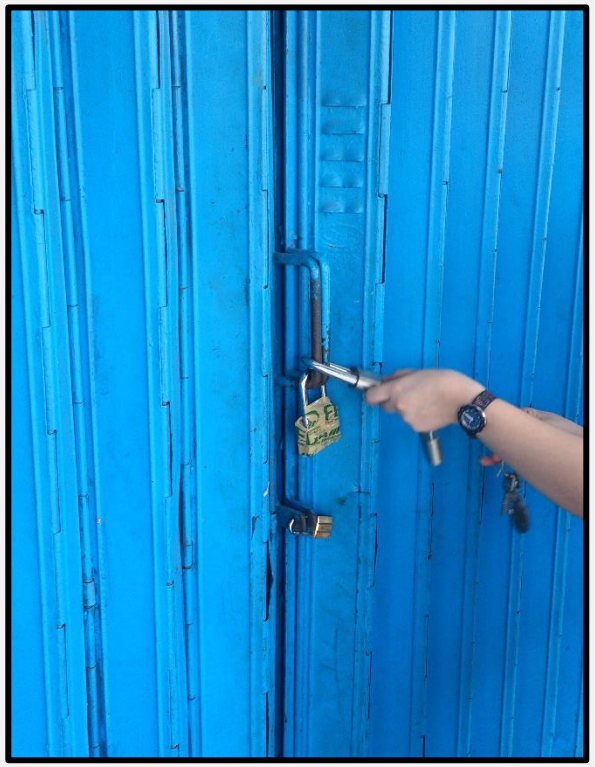
12 May 2011

DOH-FDA Advisory
No. 2011- 004

SUBJECT: SAFETY ON THE OFF-LABEL USE OF GLUTATHIONE SOLUTION FOR INJECTION (IV)

WARNING TO THE PUBLIC:

The use of glutathione IV as a skin whitener is not approved by the FDA. The public is strongly warned to refrain from using glutathione for this purpose in light of potential harm associated with such use.



Communication, Coordination, and Collaboration

1. International Collaboration

World Health Organization

FDA 食品藥物管理署 Food and Drug Administration

USAID FROM THE AMERICAN PEOPLE | USP

PROMOTING THE QUALITY OF MEDICINES

APEC

MFDS KOREA

ICH harmonisation for better health

asean

pmda

Communication, Coordination, and Collaboration

2. Alignment with other government agencies

Communication, Coordination, and Collaboration

3. Partnerships with professional associations and private institutions


FDA
STRAT PLAN
2017

5-Year Strategic Structure (2017-2021)

The FDA Strategic Structure 2017–2021 is divided into two phases:

2017-2019

Restructure Agency's Foundation

- Establish MIS and Operational System
- Organizational Reform and Development
- Strengthen Enforcement
- Facility Upgrade and Improvement
- Smart Regulation
- Strengthen Public Information and Service

2020-2021

New Strategies to accelerate Growth

- Inter-Agency Partnerships
- Globalization
- Digital Enforcement Initiatives
- Laboratory Presence and Capabilities
- FDA Academy Service Portfolio

FDA

CDRR Objectives and Goals

Objective 1: To render efficient and quality services meeting the TAT

A. Process applications within the TAT
B. Administrative support activities are done in less than one day
C. Eliminate backlog

CDRR Objectives and Goals

Objective 2: To proactively conduct PMS, responsive to the needs of the public

A. Empowering the public through information
B. Conduct of advocacy activities
C. Strengthened monitoring

CDRR Objectives and Goals

Objective 3: To create a healthy working environment and train competent regulatory staff

A. Competent staff
B. Succession and endorsement plan
C. Manpower expansion
D. Performance recognition activities

Policy Targets

Type	Number
Administrative Order	22
FDA Circular	15
FDA Personnel Order	3
Internal Memo	1
Others	3
Total	**44**

Policy Targets

A. Licensing-related

1. AO 2016-0003 updates
2. RMP for establishments
3. Foreign GMP revision

Policy Targets

B. Registration-related

4. Revised registration guidelines
5. Policy on HR and POM
6. Drug schedules
7. BE comparator product updates
8. Vaccines and Biologics
9. RBP Products
10. Exemption from Registration
11. Collaborative Registration Procedure CRP
12. Streamlined PACs
13. Prioritized review guideline
14. Revised Principal Certificate of PCPR and CLIDP
15. Post-approval changes for vaccines
16. SBP scope, Renewal of SBPs and RBPs
17. Expedited review of WHO Prequalified SBPs
18. RMP for drug products
19. Flu vaccine validity
20. Homeopathic drug products
21. Radiopharmaceuticals
22. Blood and blood products
23. Reproductive Health Product Registration

Policy Targets

C. Clinical trial-related

24. Clinical Trial

Policy Targets

D. PMS-related

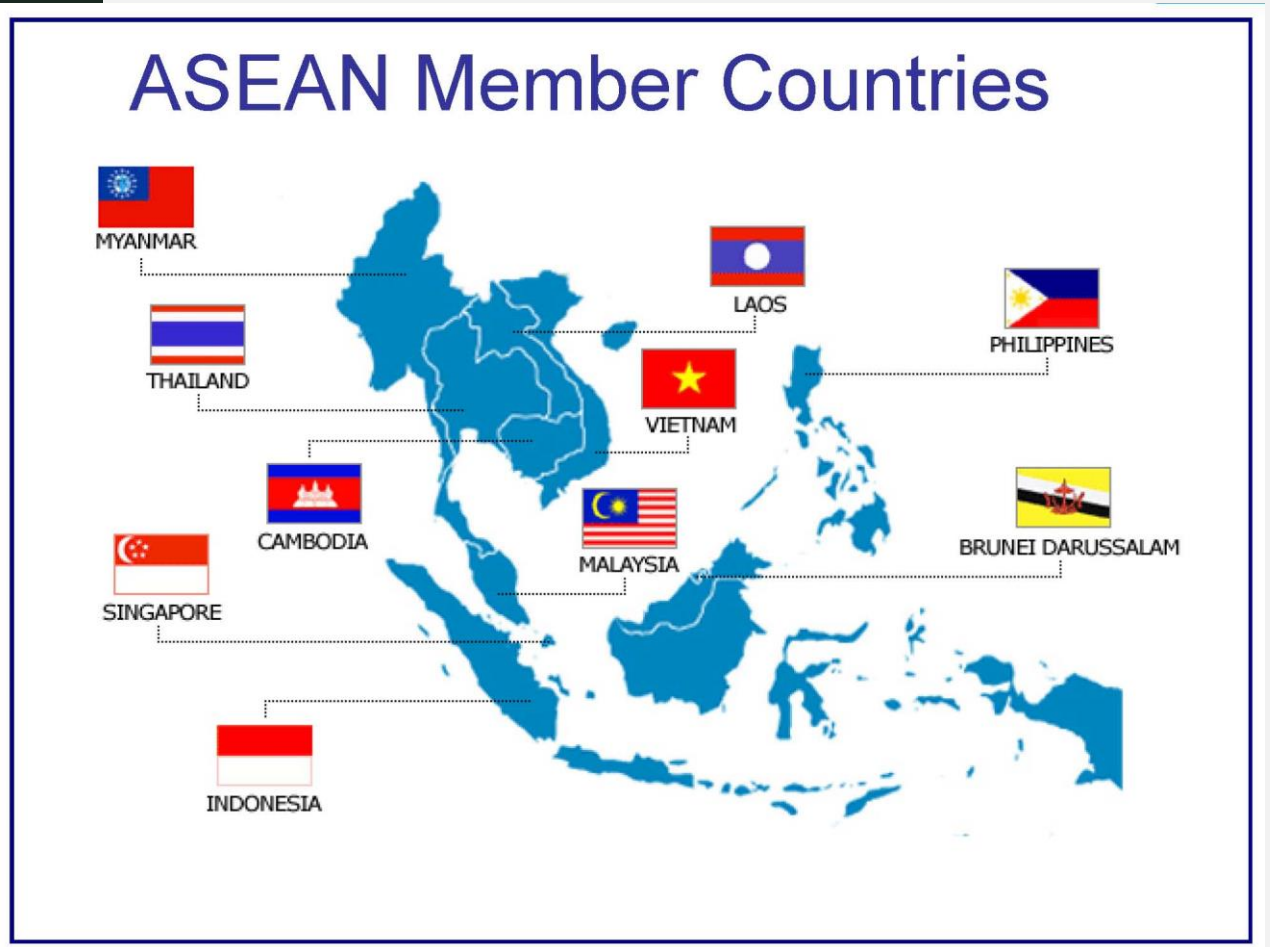
25. Advertisements and promotions of OTC and other products
26. PV program
27. Drug Recall Committee
28. WHO RAS Drug Focal
29. ASEAN PMAS Focal
30. PMS for drugs
31. Veterinary Advertisements
32. Dispensing doctors

Policy Targets

E. Others

33. Streamlined permits
34. Compassionate Special Permit (CSP)
35. Voluntary cancellation of CPR
36. Stickering guidelines
37. NDAC creation
38. Veterinary API Importation clearance
39. Brand name
40. Receiving and follow-up
41. Medical director
42. Stem cells
43. P100 Policy reiteration
44. Fees and Charges

Special Topics: ASEAN Harmonization on Pharmaceuticals



Objectives:

Elimination of technical barriers to trade posed by regulations, without compromising the quality, efficacy and safety of pharmaceuticals

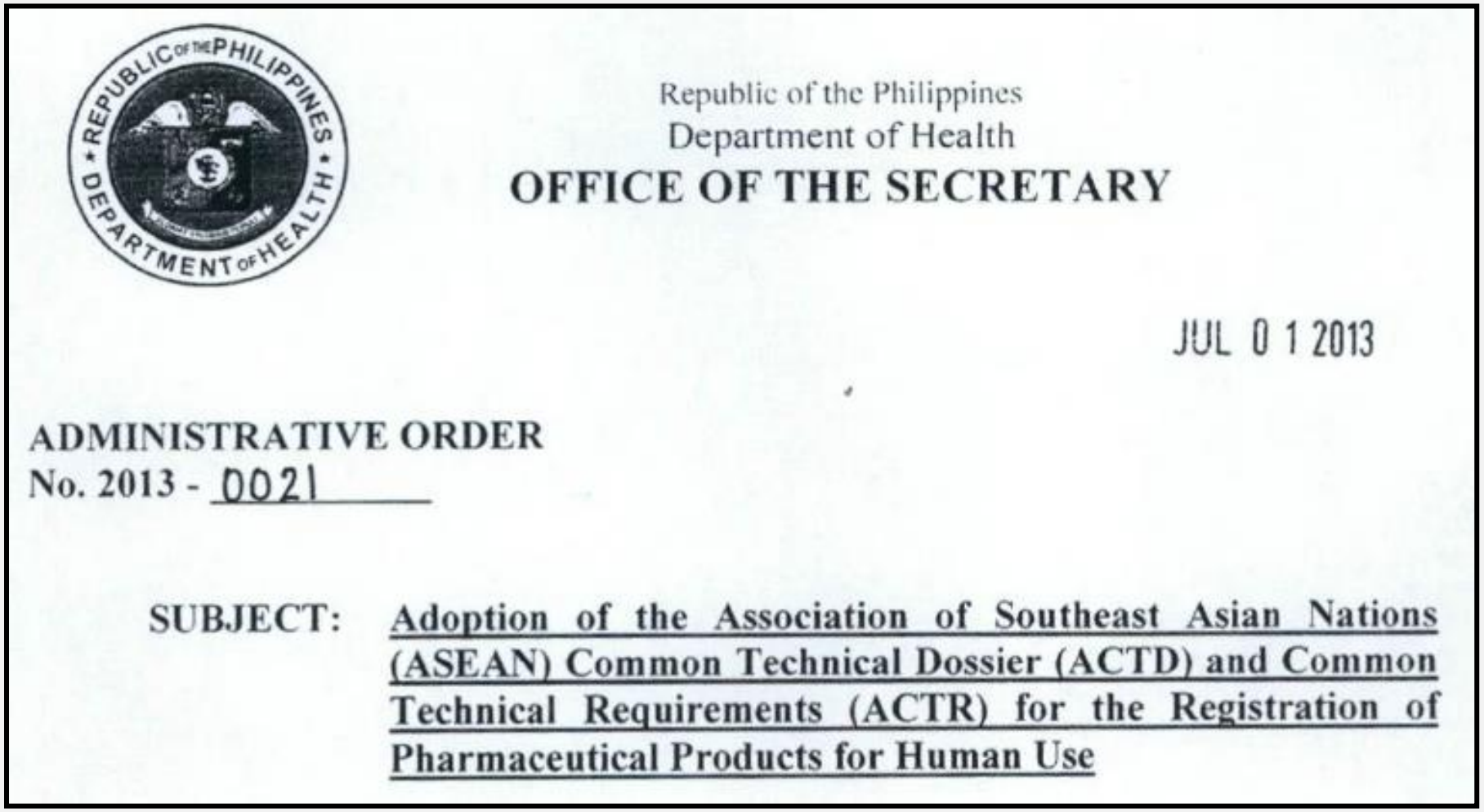
Special Topics: ASEAN Harmonization on Pharmaceuticals

	Level	Function	Meeting, output
ASEAN Summit	President Prime Minister	Highest decision-making body	Annual meeting
ASEAN Ministry	Minister of Economy, Trade, Foreign Affairs	Coordinate the work of Association	Joint Ministerial Meeting (JMM)
Committees	ASEAN Consultative Committee for Standards and Quality (ACCSQ)	Facilitate the objectives of the Free Trade Area / Implement the mutual recognition agreement	Harmonized sectors: pharmaceutical, electrical, telecommunications, cosmetics, foodstuff
Working Group	Pharmaceutical Product Working Group (PPWG)	Develop harmonization scheme of pharmaceuticals regulations	Harmonized guidelines, requirements, Glossary of Terms

Special Topics: ASEAN Harmonization on Pharmaceuticals

Country	Committed	Actual Implementation
Singapore	December 2005	December 2005
Malaysia	December 2005	December 2005
Thailand	December 2006	December 2007
Vietnam	December 2007	December 2007
Indonesia	December 2007	October 2011
Brunei	December 2008	December 2008
Cambodia	December 2008	March 2010
Philippines	December 2008	July 2013
Laos	December 2008	August 2011
Myanmar	December 2008	2009 (?)

Special Topics: ASEAN Harmonization on Pharmaceuticals



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUL 0 1 2013

ADMINISTRATIVE ORDER
No. 2013 - 0021

SUBJECT: **Adoption of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the Registration of Pharmaceutical Products for Human Use**

Special Topics: ASEAN Harmonization on Pharmaceuticals

ASEAN Common Technical Dossier (ACTD)

Part I: Administrative Data and Product Information

Part II: Quality

Part III: Nonclinical Document

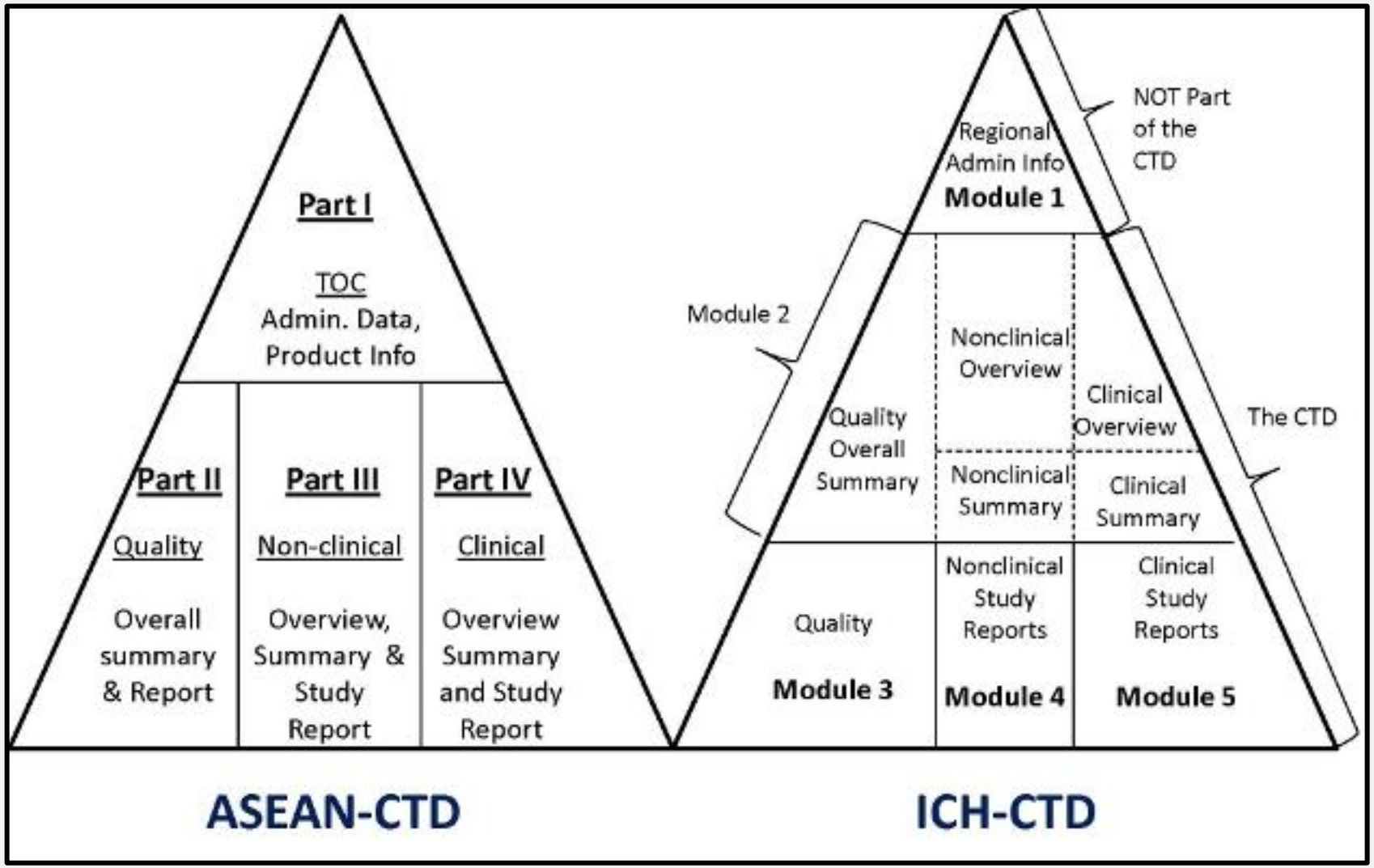
Part IV: Clinical Document

Special Topics: ASEAN Harmonization on Pharmaceuticals

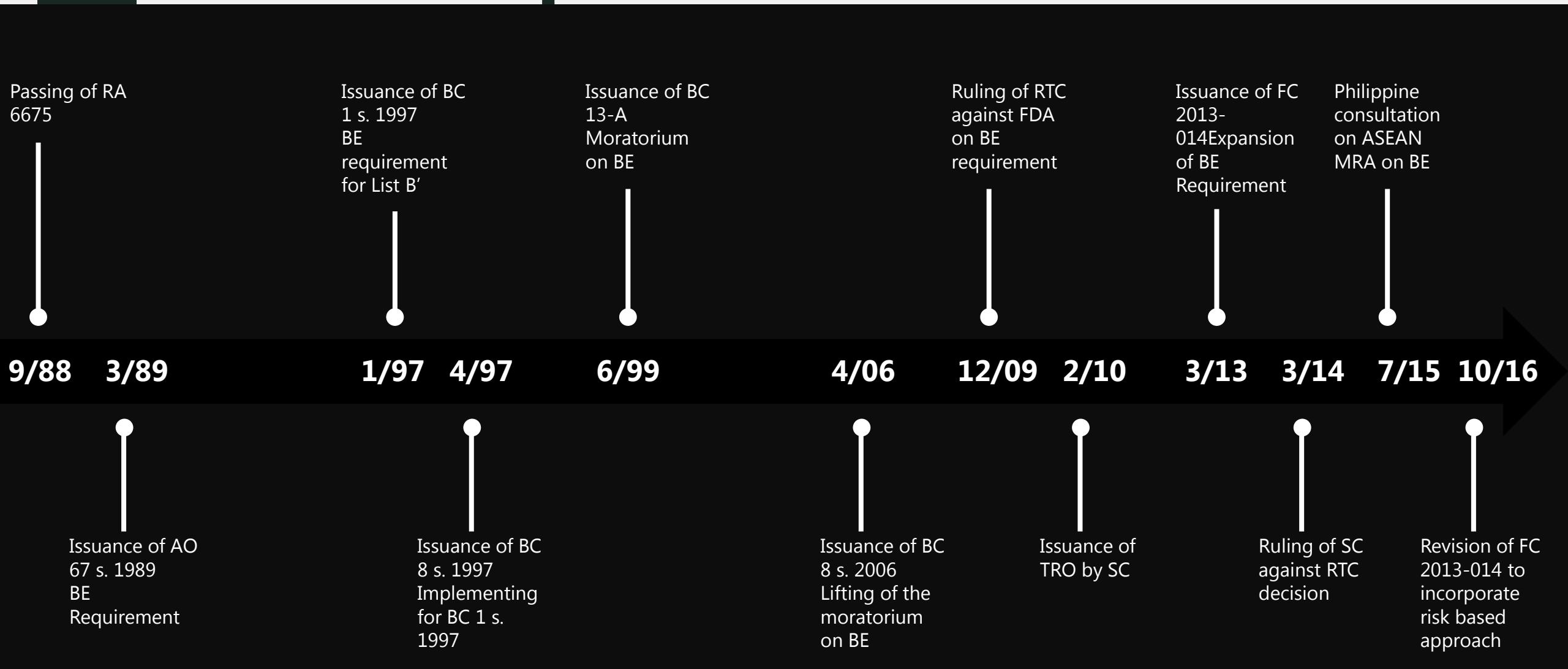
ASEAN Common Technical Requirements (ACTR)

1. ASEAN Guidelines on **Stability** of Drug Product
2. ASEAN Guideline on Submission of **Manufacturing Process Validation** Data for Drug Registration
3. ASEAN Guidelines for **Validation of Analytical Procedures**
4. ASEAN Guideline for the Conduct of Bio**availability and Bioequivalence Studies**
5. ASEAN Guidelines on **Nonclinical (Safety) Docu**ment
6. ASEAN Guidelines on **Clinical (Efficacy) Document**
7. ASEAN **Variation Guideline** for Pharmaceutical Products

Special Topics: ASEAN Harmonization on Pharmaceuticals



Special Topics: Bioavailability and Bioequivalence Studies



Special Topics: Bioavailability and Bioequivalence Studies

ASEAN GUIDELINES FOR

THE CONDUCT OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES

FINAL DRAFT : 21 JULY 2004

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2016-019

25 OCT 2016

SUBJECT: **Revised Guidelines on the Submission of Equivalence Evidence for Registration of Pharmaceutical Products**

Special Topics: Bioavailability and Bioequivalence Studies

A. *For Renewal Applications:*

All applications for renewal registration shall be issued a CPR with a validity of five (5) years, *provided* that the following conditions shall be fulfilled:

1. *Mandatory submission of in vivo/in vitro equivalence study (whichever is applicable) upon renewal shall apply to the following:*

2. *Conditional approval of incoming renewal applications shall be applicable to the following:*

   a) Pharmaceutical products containing a Class 1 or 3 drugs based on the BCS; and
   b) FDC products containing substances under BCS Class 1 and/or 3 only

3. *Approval of renewal registration shall be allowed without the upfront submission of BE study or biowaiver to the following renewal applications:*

   a) Over-the-Counter (OTC) drugs;
   b) Single and multi-component vitamin and mineral preparations;
   c) Single and multi-component preparations containing amino acids; and
   d) Household Remedies (HR)

Special Topics: Reference and Similar Biotherapeutic Products

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

APR 1 1 2014

ADMINISTRATIVE ORDER
2014 - 0016

SUBJECT: **Adoption of the World Health Organization "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" for the Registration of Biosimilar Products**

Special Topics: Reference and Similar Biotherapeutic Products

World Health Organization

ENGLISH ONLY
FINAL

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 19 to 23 October 2009

GUIDELINES ON EVALUATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS (SBPs)

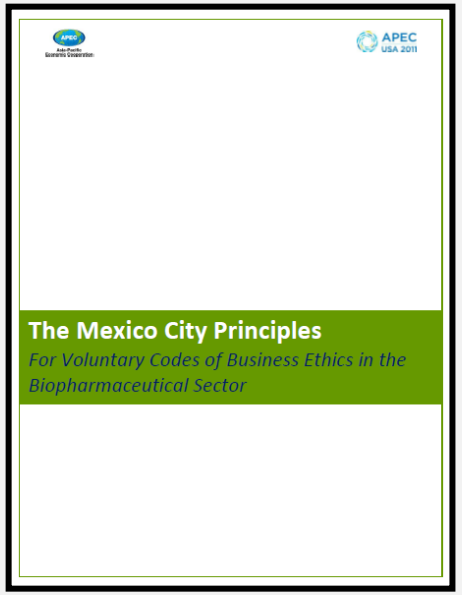
Special Topics: Reference and Similar Biotherapeutic Products

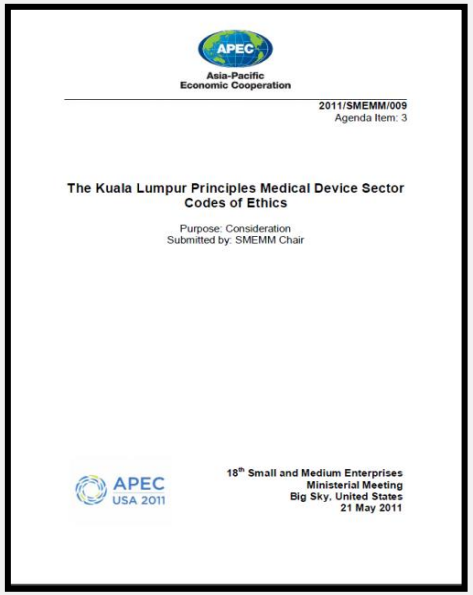
Received	Approved
10	3

Monoclonal antibodies, insulin products, etc

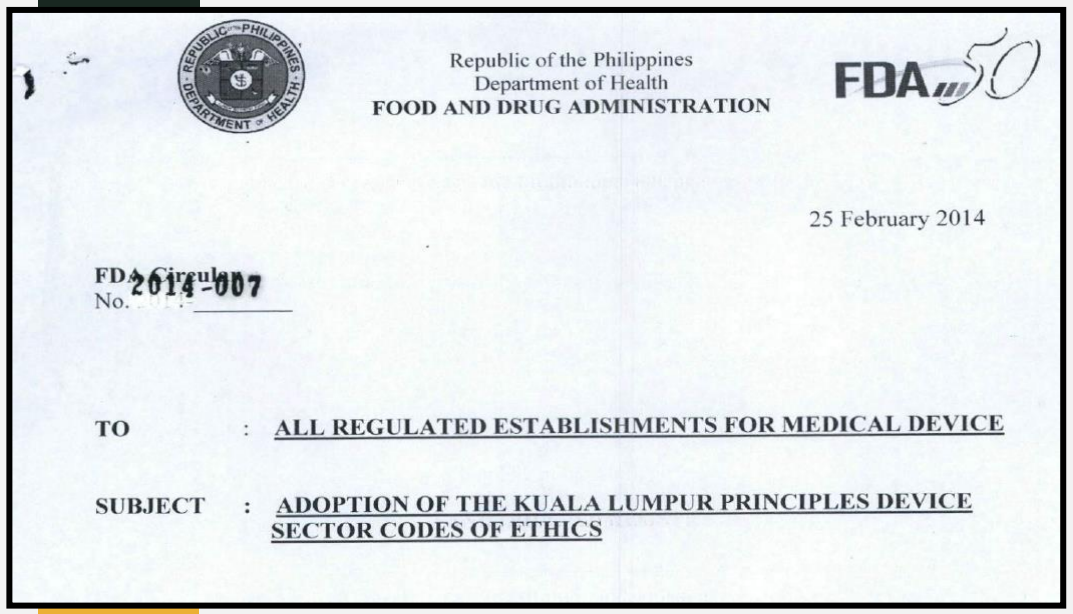
Special Topics: Mexico City and Kuala Lumpur Principles

- 17th APEC SME Ministerial Meeting:
  - Joint statement: **corruption** imposes a significant **market access barrier** and **high costs** for SMEs
  - Business Ethics for APEC SMEs Project
- KL and MC Principles





Special Topics: Mexico City and Kuala Lumpur Principles



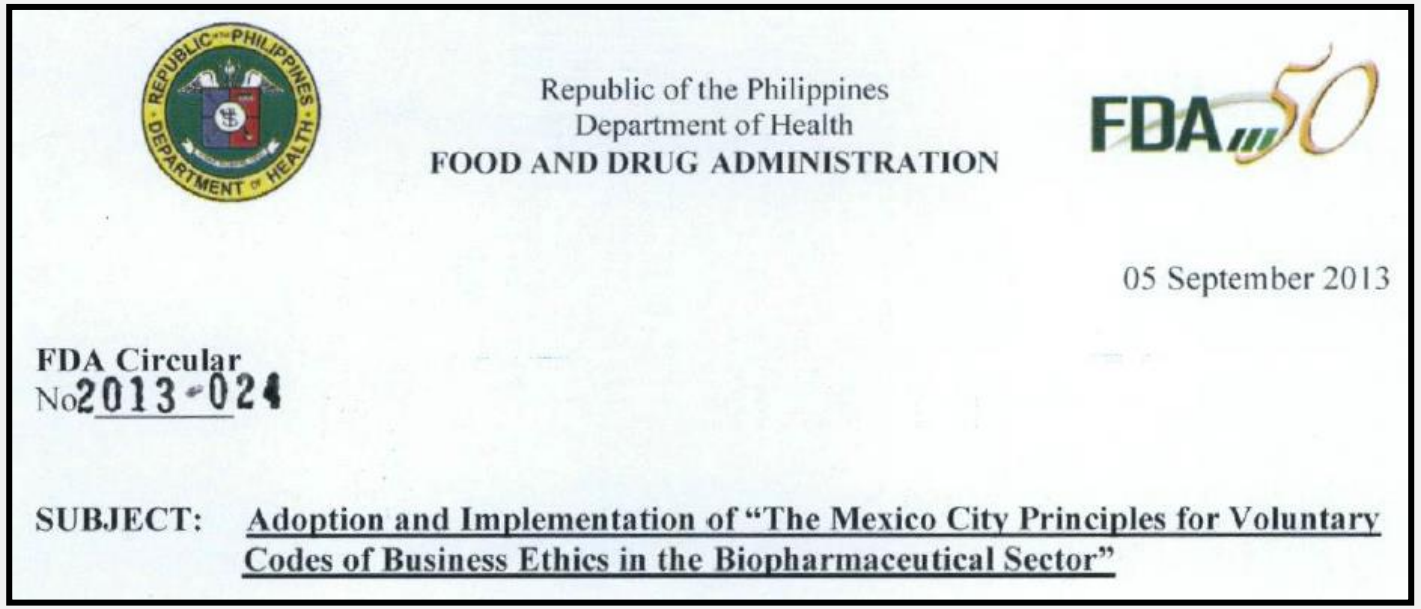
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 February 2014

FDA Circular
No. 2014-007

TO : ALL REGULATED ESTABLISHMENTS FOR MEDICAL DEVICE

SUBJECT : ADOPTION OF THE KUALA LUMPUR PRINCIPLES DEVICE SECTOR CODES OF ETHICS



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

05 September 2013

FDA Circular
No2013-024

SUBJECT: Adoption and Implementation of "The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector"

Special Topics: Mexico City and Kuala Lumpur Principles

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 2 1 2015

ADMINISTRATIVE ORDER
No. 2015- 0053

SUBJECT: Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices

Special Topics: Mexico City and Kuala Lumpur Principles

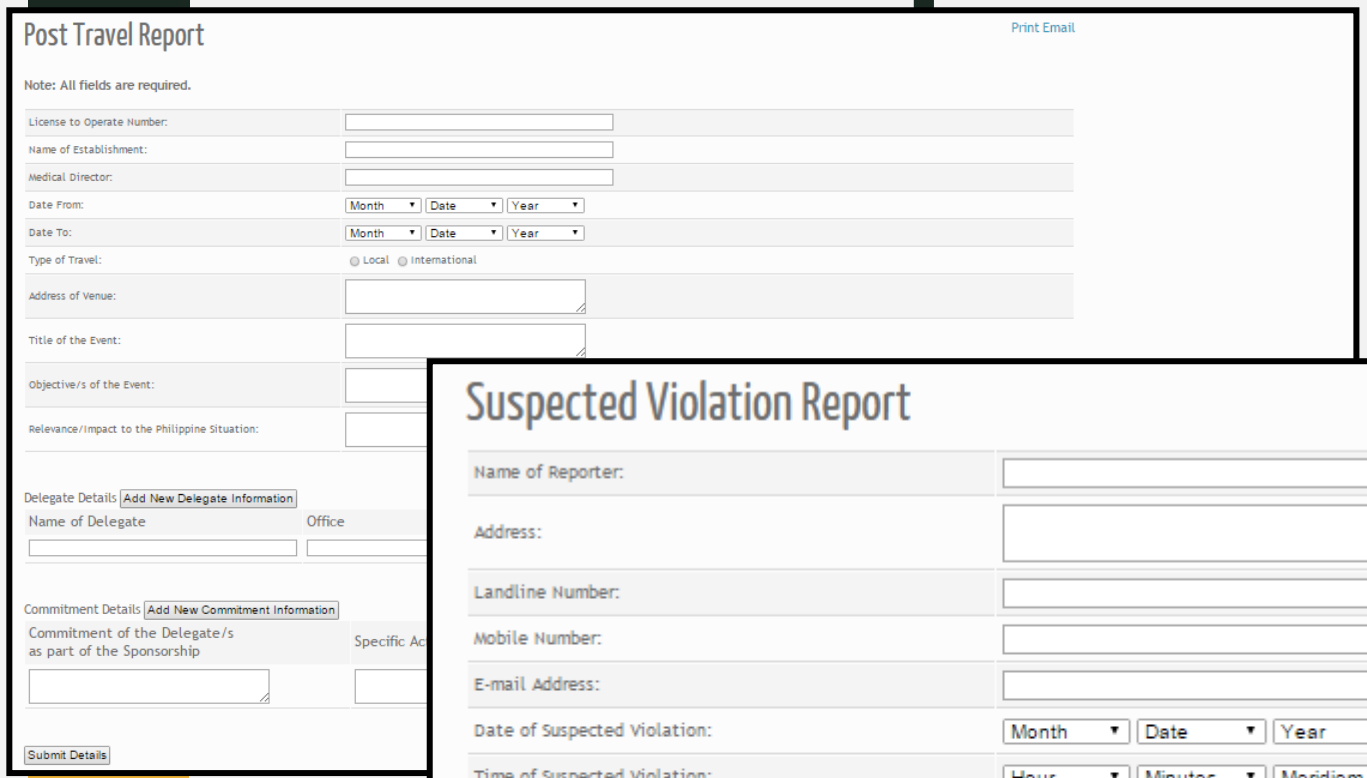
Administrative Order No. 2015-0053

Special Topics: Mexico City and Kuala Lumpur Principles

Monitoring and Compliance

1. **DOH** through the **FDA** as the **lead** agency
2. **Reports/violations** shall be submitted to FDA
3. **Not within FDA jurisdiction** – filed with **Office of the Secretary** or **other agencies**
4. **Filing fee and Bond** for company to company complaints

Special Topics: Mexico City and Kuala Lumpur Principles



Post Travel Report

Print Email

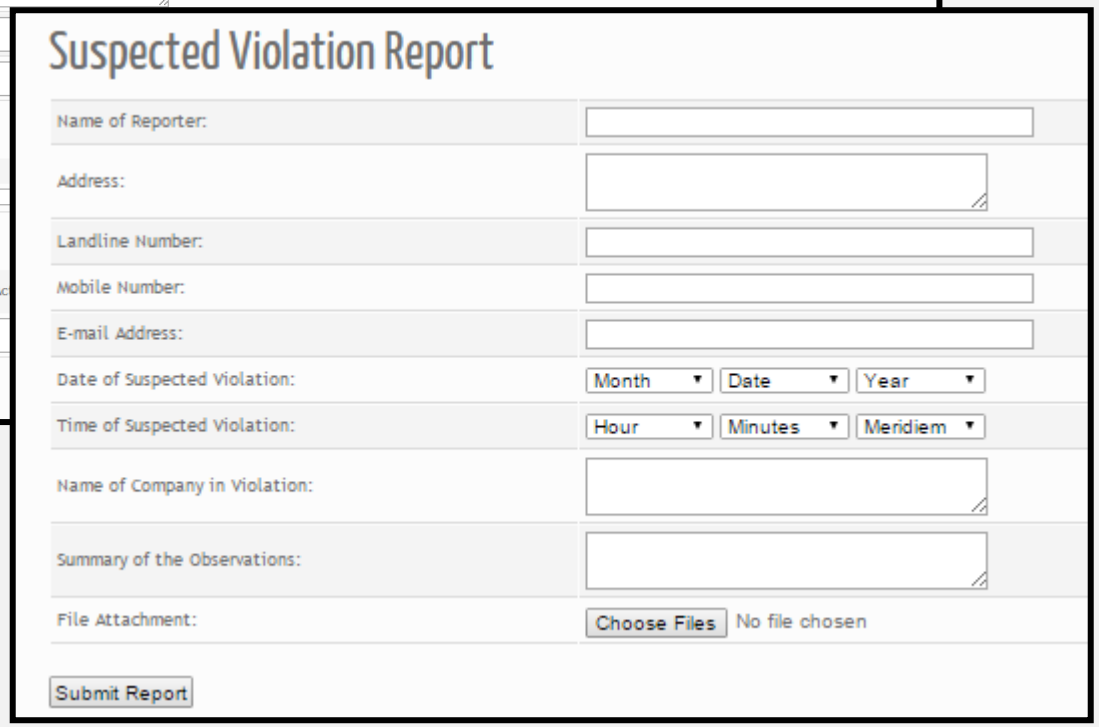
Note: All fields are required.

License to Operate Number:
Name of Establishment:
Medical Director:
Date From: Month Date Year
Date To: Month Date Year
Type of Travel: Local International
Address of Venue:
Title of the Event:
Objective/s of the Event:
Relevance/Impact to the Philippine Situation:

Delegate Details Add New Delegate Information
Name of Delegate | Office

Commitment Details Add New Commitment Information
Commitment of the Delegate/s as part of the Sponsorship | Specific Ac

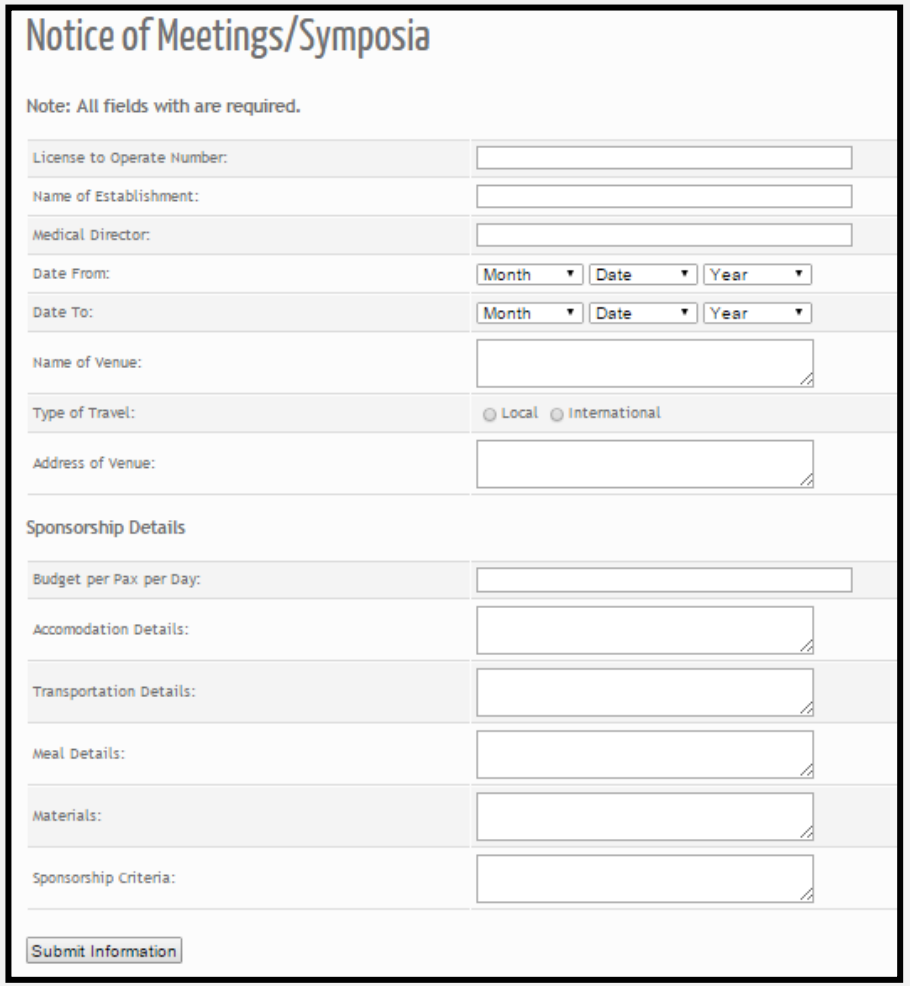
Submit Details



Suspected Violation Report

Name of Reporter:
Address:
Landline Number:
Mobile Number:
E-mail Address:
Date of Suspected Violation: Month Date Year
Time of Suspected Violation: Hour Minutes Meridiem
Name of Company in Violation:
Summary of the Observations:
File Attachment: Choose Files No file chosen

Submit Report



Notice of Meetings/Symposia

Note: All fields with are required.

License to Operate Number:
Name of Establishment:
Medical Director:
Date From: Month Date Year
Date To: Month Date Year
Name of Venue:
Type of Travel: Local International
Address of Venue:

Sponsorship Details

Budget per Pax per Day:
Accomodation Details:
Transportation Details:
Meal Details:
Materials:
Sponsorship Criteria:

Submit Information

Special Topics: Mexico City and Kuala Lumpur Principles

- ✓ **Committee for Networking**
  - ➢ Strong network among stakeholders
  - ➢ Conduct of advocacy activities
  - ➢ Recommendation of individual code of ethics
- ✓ **Committee for Effective Enforcement**
  - ➢ Development of regulatory tools
  - ➢ Development of coordination and decision-making mechanism between and among enforcement agencies.
- ✓ **Committee for Regulatory Impact Assessment and Research**
  - ➢ Carrying out of fitting research studies on ethical practices in the country.
  - ➢ Completion of a regulatory impact assessment two years after implementation