FOOD AND DRUG ADMINISTRATION

Ensuring Safety, Efficacy, and Quality of Drug Products in the Philippines

Presentation Outline

I. The Food and Drug Administration
II. The Center for Drug Regulation and Research
III. Drug and Drug Products
IV. Regulatory Framework
V. The Way Forward

Legal Bases

Republic Act No. 3720 (as amended) – Foods, Drugs and Devices, and Cosmetics Act

FIFTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
Second Session

H. No. 3052

REPUBLIC ACT No. 3720

[1]**AN ACT TO ENSURE THE SAFETY AND PURITY OF FOODS, DRUGS, AND COSMETICS BEING MADE AVAILABLE TO THE PUBLIC BY CREATING THE FOOD AND DRUG ADMINISTRATION WHICH SHALL ADMINISTER AND ENFORCE THE LAWS PERTAINING THERETO.**

Legal Bases

Republic Act No. 6675 – The Generics Act of 1988

Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Second Regular Session
Begun and held in Metro Manila, on Monday,
the twenty-fifth day of July, nineteen hundred and eighty-eight

[REPUBLIC ACT NO. 6675]

AN ACT TO PROMOTE, REQUIRE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION, USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES

Legal Bases

Republic Act No. 7394 – Consumer Act of the Philippines

Republic of the Philippines
Congress of the Philippines
Metro Manila
Fifth Regular Session
Begun and held in Metro Manila, on Monday,
the twenty second day of July, nineteen hundred and ninety-one

Republic Act No. 7394
THE CONSUMER ACT OF THE PHILIPPINES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Legal Bases

Republic Act No. 8203 – Special Law on Counterfeit Drugs

[REPUBLIC ACT NO. 8203]

AN ACT OF PROHIBITING COUNTERFEIT DRUGS, PROVIDING PENALTIES FOR VIOLATIONS AND APPROPRIATING FUNDS THEREFOR

Legal Bases

Republic Act No. 9502 – Universally Accessible Cheaper Quality Medicines Act of 2008

Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Fourteenth Congress
First Regular Session

Begun and held in Metro Manila, on Monday, the twenty-third day of July, two thousand seven.

[Republic Act No. 9502]

AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES

Legal Bases

Republic Act No. 9711 – Food and Drug Administration (FDA) Act of 2009

[REPUBLIC ACT NO. 9711]

AN ACT STRENGTHENING AND RATIONALIZING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME, RENAMING IT THE FOOD AND DRUG ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND APPROPRIATING FUNDS THEREOF

Legal Bases

Republic Act No. 10354 – The Responsible Parenthood and Reproductive Health Act of 2013

[REPUBLIC ACT NO. 10354]

AN ACT PROVIDING FOR A NATIONAL POLICY ON RESPONSIBLE PARENTHOOD AND REPRODUCTIVE HEALTH

Legal Bases

Republic Act No. 10918 – Philippine Pharmacy Act

[REPUBLIC ACT NO. 10918]

AN ACT REGULATING AND MODERNIZING THE PRACTICE OF PHARMACY IN THE PHILIPPINES, REPEALING FOR THE PURPOSE REPUBLIC ACT NUMBERED FIVE THOUSAND NINE HUNDRED TWENTY-ONE (R.A. NO. 5921), OTHERWISE KNOWN AS THE PHARMACY LAW

Legal Bases

Republic Act No. 7277 (as amended by RA 10754) – Magna Carta for Disabled Persons

Republic Act No. 9165 – Comprehensive Dangerous Drugs Act of 2002

Republic Act No. 9994 – Expanded Senior Citizens Act of 2010

Republic Act No. 10532 – Philippine National Health Research System Act of 2013

Republic Act No. 10747 – Rare Diseases Act of the Philippines

Republic Act No. 10767 – Comprehensive Tuberculosis Elimination Plan Act

FDA MANDATE

PROTECT
THE GENERAL PUBLIC

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

BRIEF HISTORY

1963

RA 3720
Creation of FDA

1982

EO 851
BFAD

2009

RA 9711
FDA Strengthening

FOOD AND DRUG ADMINISTRATION

Currently, FDA is headed by

Ms. Nela Charade Galang-Puno

as appointed by President Rodrigo Duterte.

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.

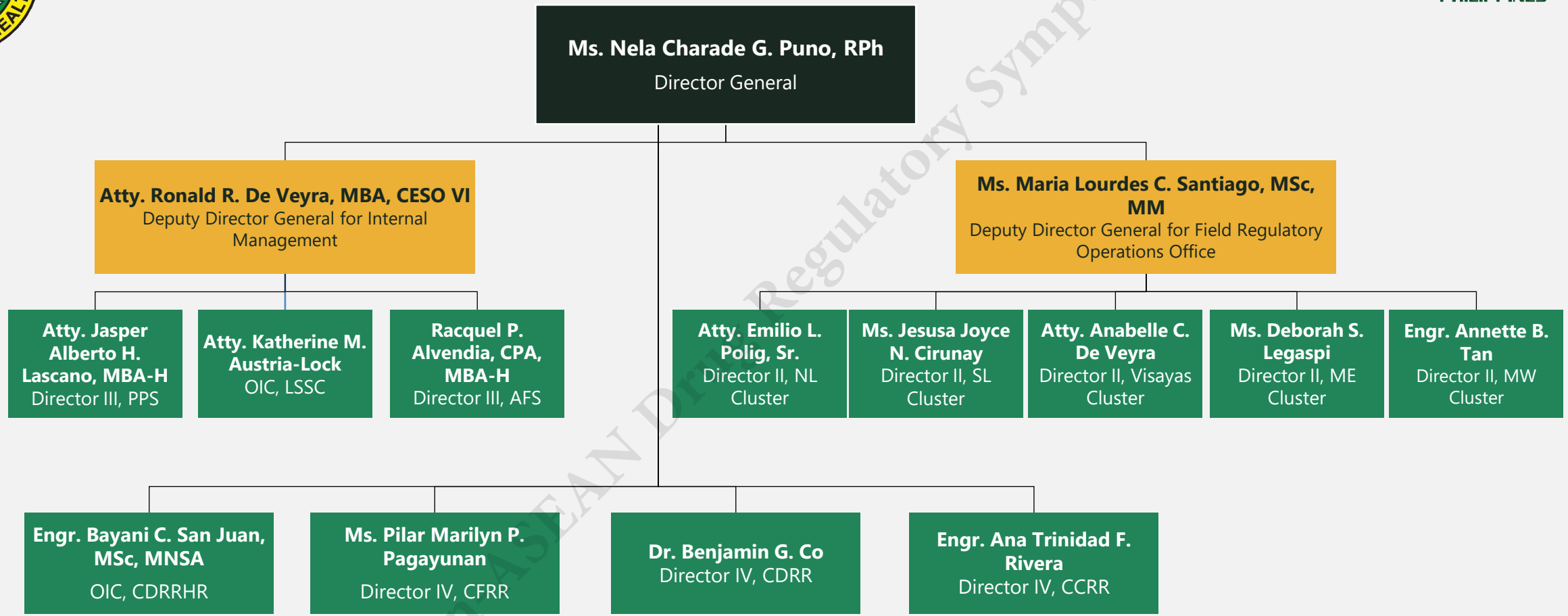
VISION

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**

"Drug Products"

1. any article **recognized** in the official **USP-NF, official HPUS, PP, PNDF, BP, EP, JP, IP**, any **national compendium** or any supplement to any of them;
2. any article intended for use in the **diagnosis, cure, mitigation, treatment or prevention of disease** in humans or animals;

"Drug Products"

3. any article **other than food intended to affect** the structure or any function of the human body or animals;
4. any article intended for use as a **component of any articles specified** in clauses (1), (2) and (3) not including devices or their components, parts or accessories;

"Drug Products"

5. **herbal and/or traditional drugs** which are articles of plant or animal origin used in folk medicine which are:
   i. recognized in **PNF**
   ii. intended for use in the **treatment or cure or mitigation of disease symptoms, injury or body defects** in humans

"Drug Products"

5. **herbal and/or traditional drugs** which are articles of plant or animal origin used in folk medicine which are:

iii. other than food, intended to **affect the structure or any function** of the human body

iv. in **finished or ready-to-use** dosage form; and

v. intended for use as a **component** of any of the articles specified in clauses (i), (ii), (iii) and (iv)

"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

Drug Class

1. **New Chemical Entities under Monitored Release**

   Not previously authorized for marketing for any pharmaceutical use

2. **Biotechnological Products (including biosimilars and vaccines)**

   Any product **of biological origin**, prepared with biological processes, derived from human blood and plasma, or manufactured by biotechnology consisting of substances of high MW whose purity, potency, and composition cannot readily be determined by chemical or physicochemical analysis

3. **Generic Drugs**

   Intended to be **interchangeable** with the innovator product

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUL 0 1 2013

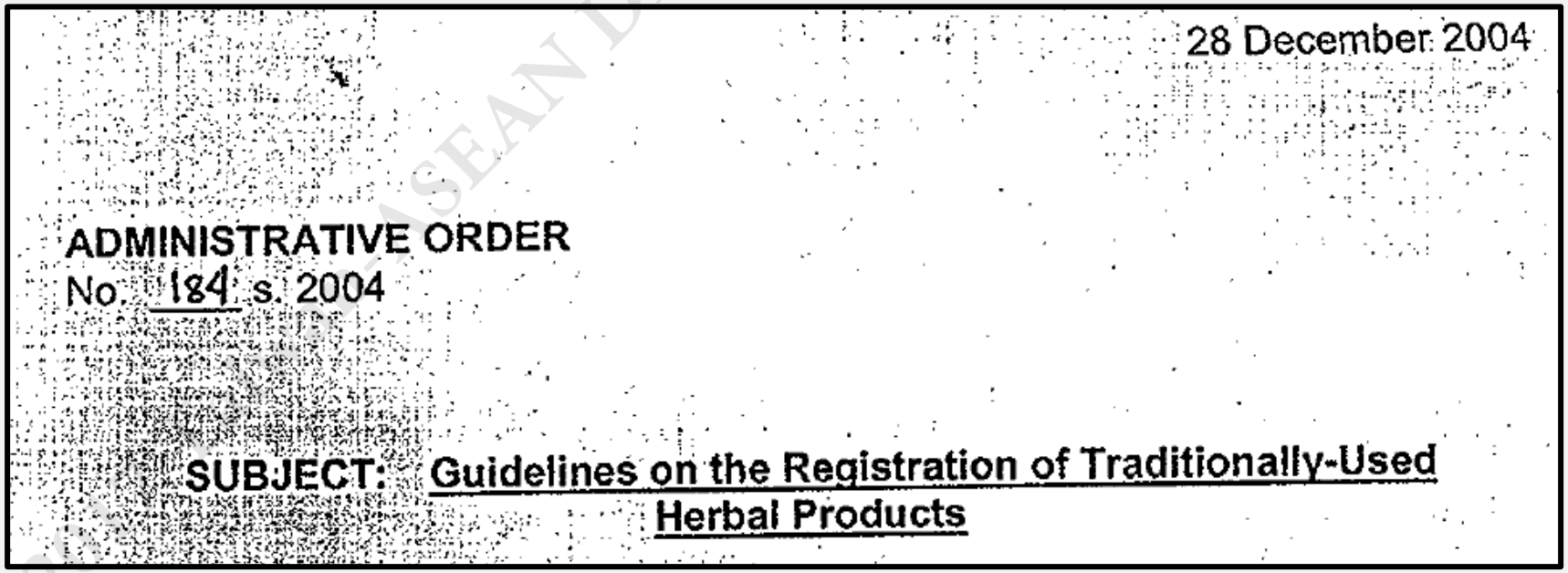
ADMINISTRATIVE ORDER
No. 2013 - 0021

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**

Drug Class

4. Traditionally-used Herbal Products

preparations from plant materials whose **claimed application/s** is/are **based only on traditional experience** of long usage which should be at least five (5) or more decades as documented in medical, historical and ethnological literature



28 December 2004

ADMINISTRATIVE ORDER
No. 184 s. 2004

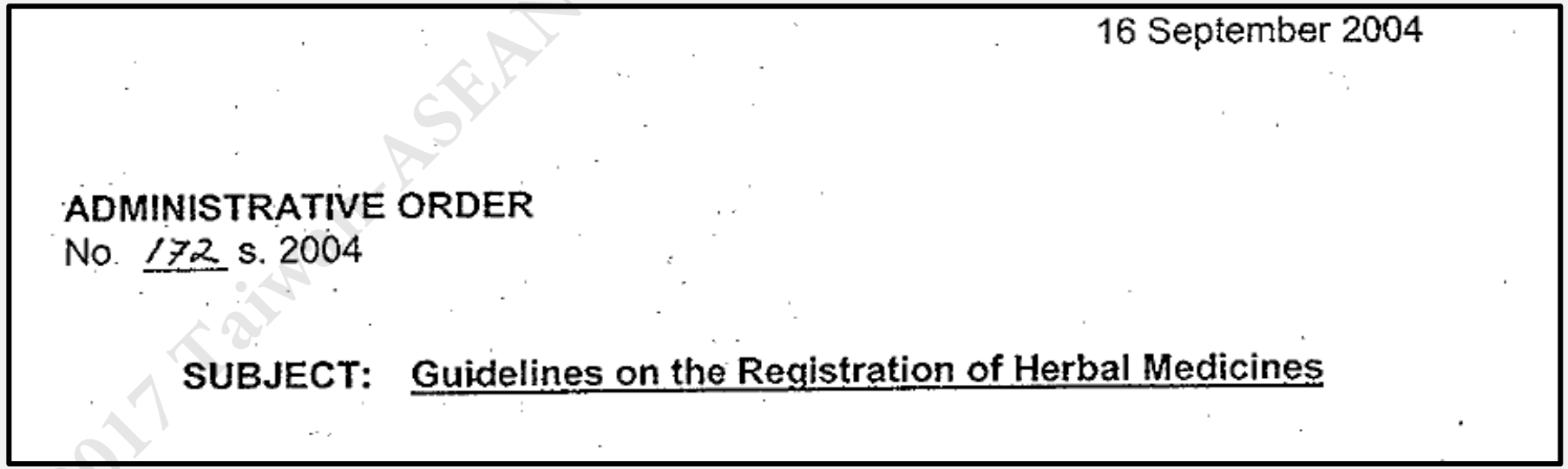
SUBJECT: Guidelines on the Registration of Traditionally-Used Herbal Products

Drug Class

5. Herbal Medicines

finished, products that contain as active ingredient(s) aerial or underground part(s) of plants or any other plant material, or combination thereof, whether in the crude state or as plant preparations

have specific therapeutic claim(s) intended for use in the diagnosis, alleviation, cure or treatment of disease, promotion of health or intended to affect or modify the structure or any function of the body of humans or animals



16 September 2004

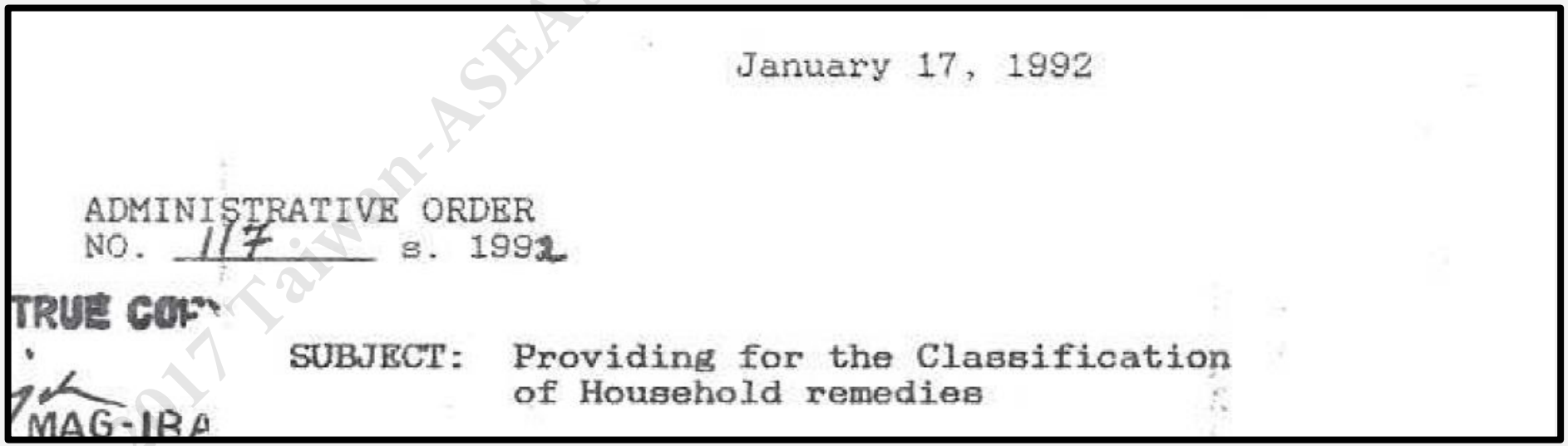
ADMINISTRATIVE ORDER
No. 172 s. 2004

SUBJECT: Guidelines on the Registration of Herbal Medicines

Drug Class

6. Household Remedies

containing pharmaceutical substances of common or ordinary use to relieve common physical ailments which may be dispensed without a medical prescription in original packages, bottles or containers, the nomenclature of which has been duly approved by FDA in the process of registration. A household remedy preparation should have **no history of or recognized adverse reaction** after being marketed and used **for at least twenty (20) years** according to its indication



January 17, 1992

ADMINISTRATIVE ORDER
NO. 117 s. 1992

TRUE COPY

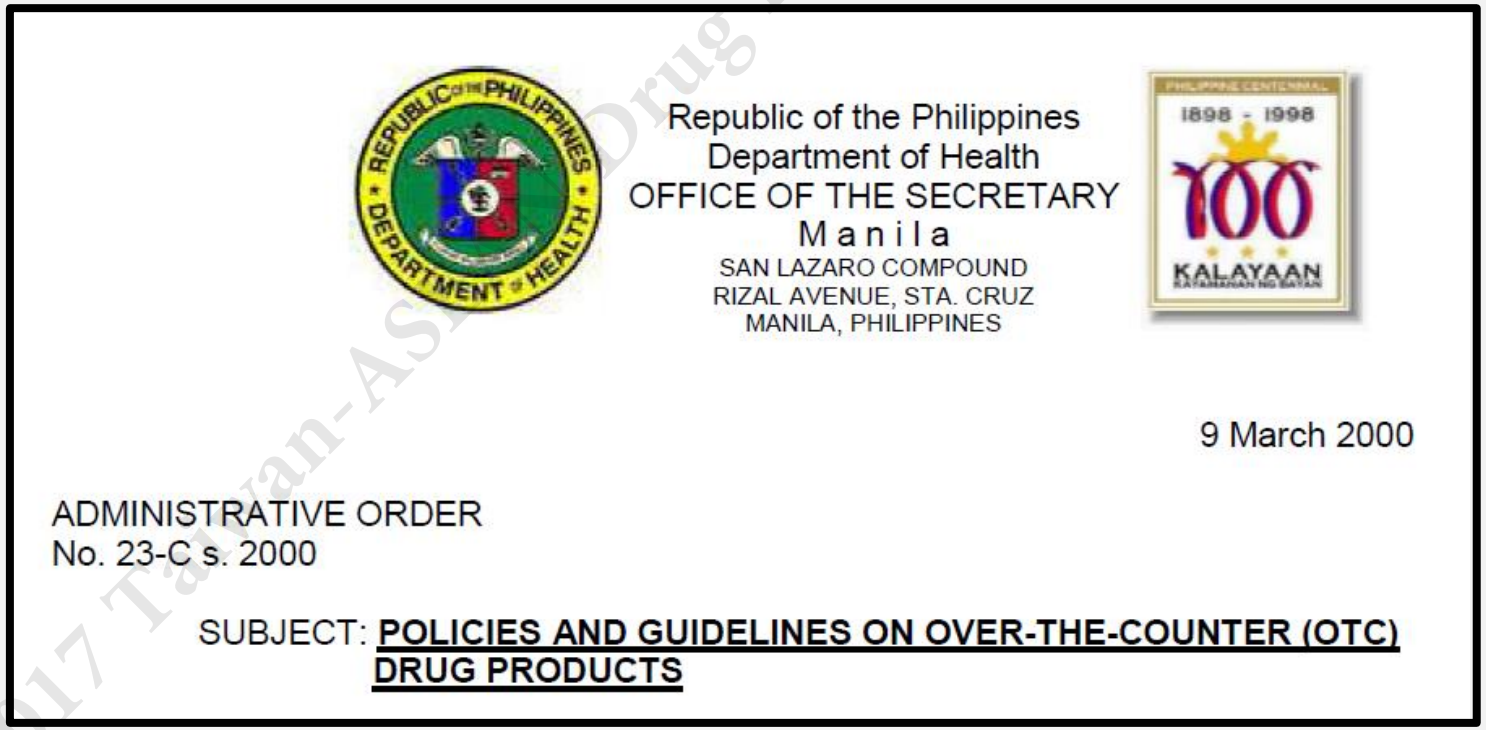
SUBJECT: Providing for the Classification of Household remedies

MAG-IBA

Drug Class

7. Over-the-Counter Preparations

drug products or preparations that can be dispensed even **without the written order of a licensed physician or dentist**



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila
SAN LAZARO COMPOUND
RIZAL AVENUE, STA. CRUZ
MANILA, PHILIPPINES

9 March 2000

ADMINISTRATIVE ORDER
No. 23-C s. 2000

SUBJECT: **POLICIES AND GUIDELINES ON OVER-THE-COUNTER (OTC) DRUG PRODUCTS**

Drug Class

8. Medical Gases

Any gas or mixture of gases intended for administration to patients for anesthetic, therapeutic, diagnostic, or prophylactic purposes, which may be manufactured in a liquefied, non-liquefied, or cryogenic state and administered as a gas

September 3, 2002 Memo : PSD02-12

To : ALL CONCERNED COMPANIES

From : NAZARITA T. LANUZA
OIC, Product Services Division

Subject : UPDATED CHECKLIST OF REQUIREMENTS FOR REGISTRATION

Drug Class

9. Veterinary Drugs

any substance, including biological products, applied or administered to food producing, companion, aquatic, laboratory and exotic animals, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviors

DEPARTMENT OF AGRICULTURE
Administrative Order No. 33
Series of 1991

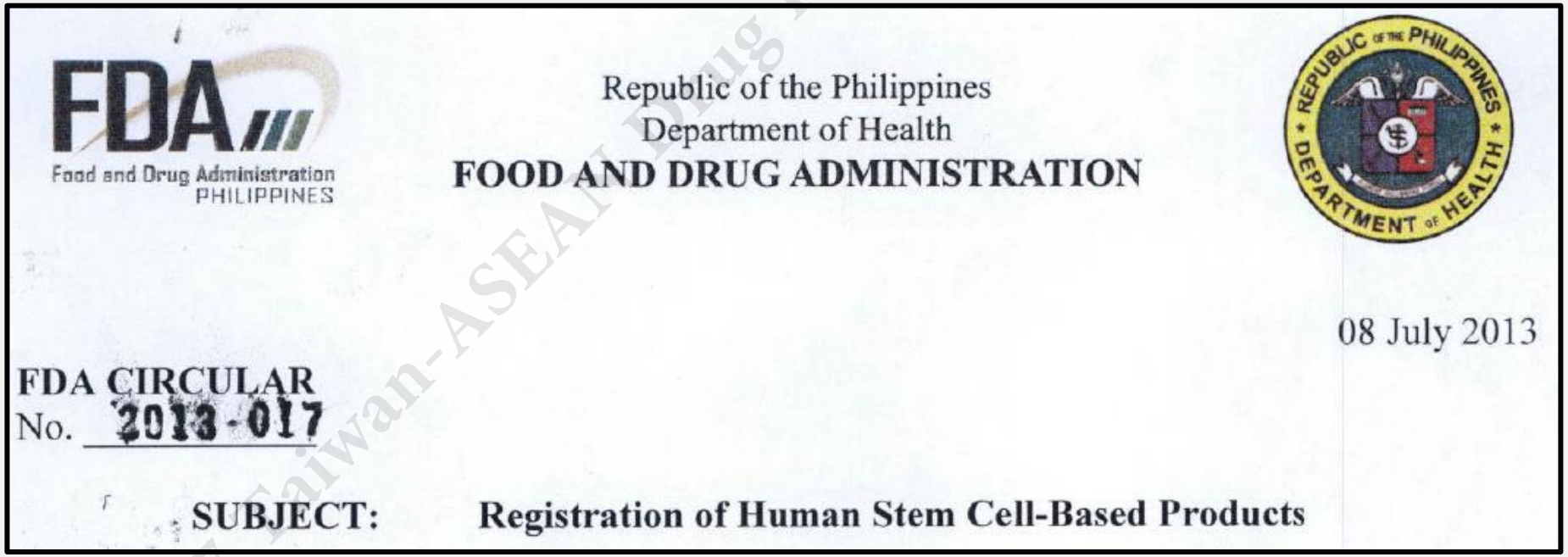
DEPARTMENT OF HEALTH
Administrative Order No. 114
Series of 1991

SUBJECT: RULES AND REGULATIONS ON REGISTRATION OF VETERINARY DRUGS AND PRODUCTS

Drug Class

10.Stem Cell-Based Products

Comprised of human cells, tissues, and cellular and tissue-based products (HCT/Ps) that are subject to Philippine FDA regulations



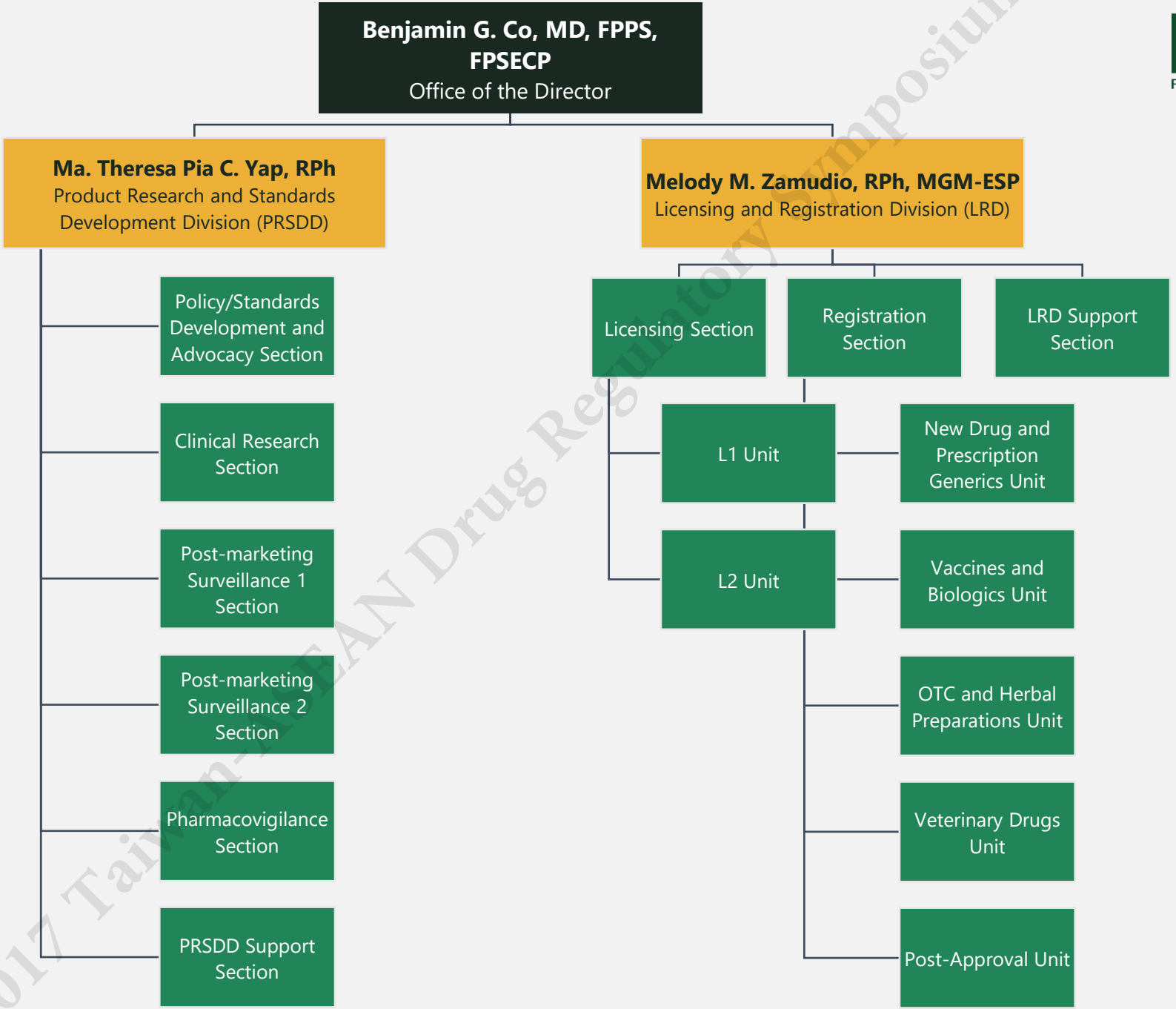
FDA
Food and Drug Administration
PHILIPPINES

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

08 July 2013

FDA CIRCULAR
No. 2013-017

SUBJECT: Registration of Human Stem Cell-Based Products

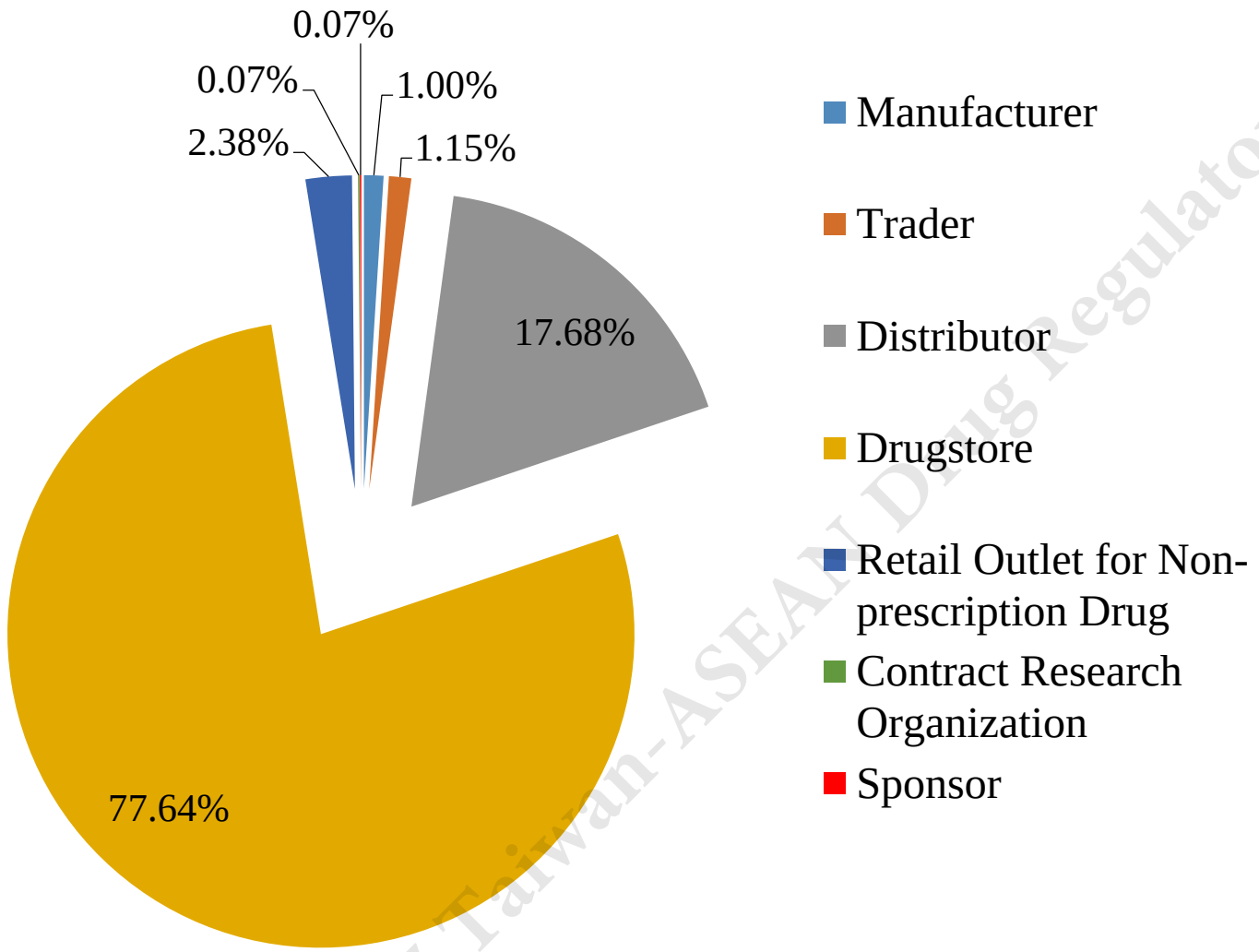


Citizen's Charter

Type of Application	Duration of Activity
Licensing of drug establishment	30 calendar days
Initial application	254 calendar days
Renewal application	68 calendar days
Automatic Renewal application	33 calendar days
CLIDP application	31 calendar days
Variation application	52 calendar days
Certificate of Pharmaceutical Products (CoPP)	14 calendar days
Certificate of Free Sale	14 calendar days
Export Certificate	14 calendar days

Type of Application	Duration of Activity
Product Variation Notification	72-hours (3-working days)
LTO Variation on the Addition/ Deletion of Source(s) through Notification	72-hours (3-working days)
Extension of CPR Validity for Renewal Applications	72-hours (3-working days)
Import Permit for Samples for Product Registration and Development	72-hours (3-working days)
Export Permit for Drug Samples Used for Bioequivalence Studies	72-hours (3-working days)
Certification for Animal Feeds and Feed Products	72-hours (3-working days)
Sales Promotion Permit	72-hours (3-working days)

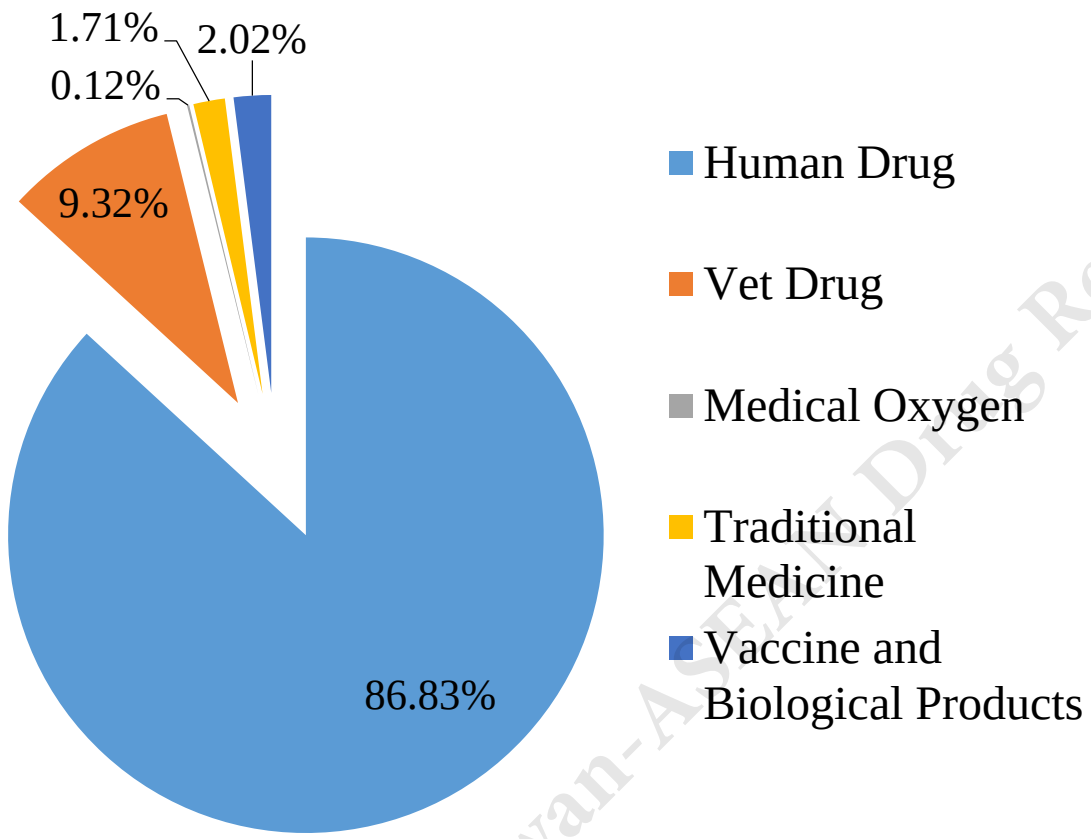
Licensed Drug Establishments



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

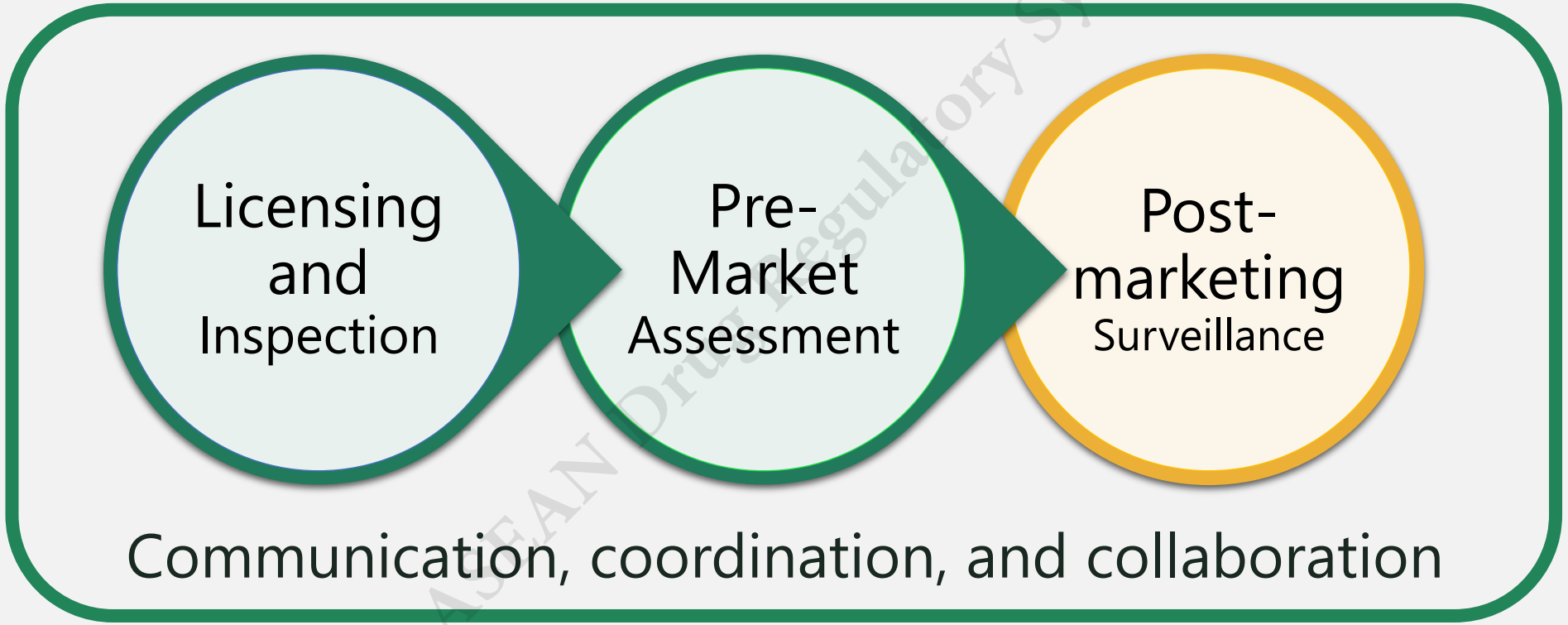
Registered Drug Products



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

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

Licensing and Inspection:
at par with international standards

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

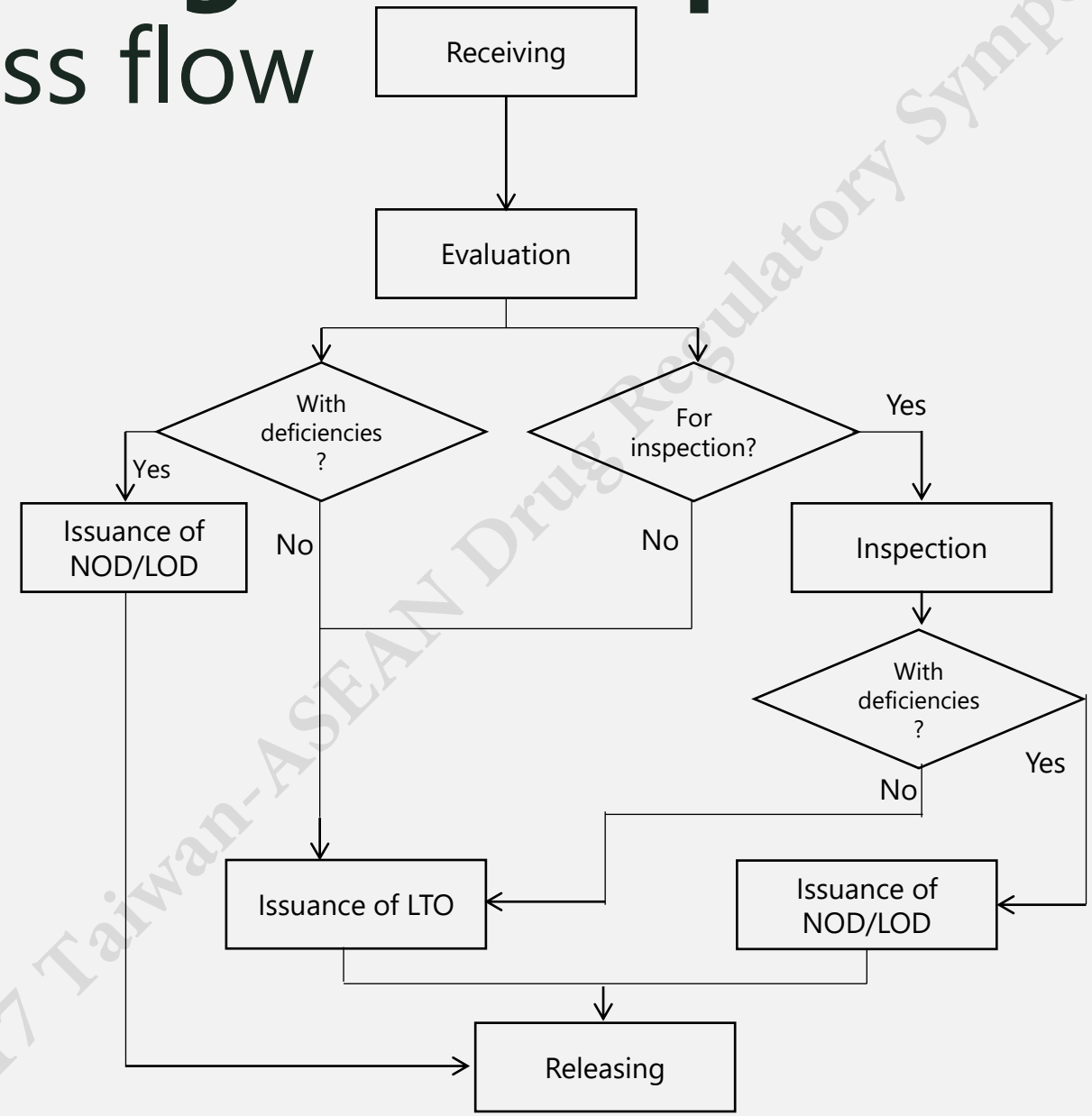
FEB 15 2016

ADMINISTRATIVE ORDER
No. 2016-0003

SUBJECT: Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)

B. All establishments covered in this AO shall first secure the appropriate LTO or authorization from FDA prior to engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertisement and/or sponsorship of any activity that involves health product.

Licensing and Inspection: process flow



Licensing and Inspection: process flow

Licensing and Inspection: Requirements

1. LTO Application form
2. Proof of Business Name Registration
3. Site Master file
4. Risk Management Plan
5. Proof of Payment

Pre-Market Assessment:
at par with international standards

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

Guidance for Industry

E6 Good Clinical Practice:
Consolidated Guidance

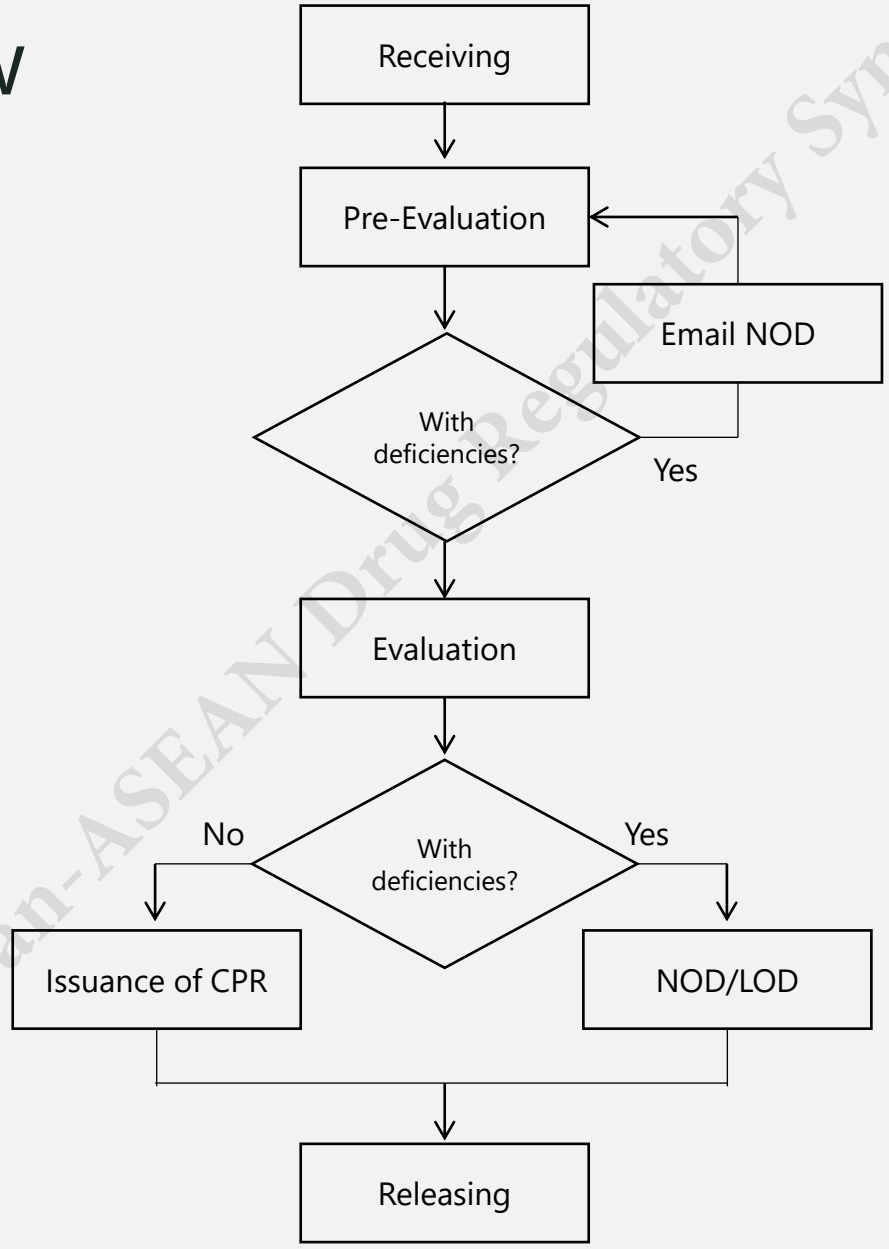
Pre-Market Assessment:
at par with international standards

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 interchangeability	→ FC 2016-019

Pre-Market Assessment:
process flow



Pre-Market Assessment:
Requirements

Part I: Administrative Data and Product Information

- Application Form
- GMP Certificate/LTO
- Supply Agreements
- Labeling
- Product Information

Pre-Market Assessment:
Requirements

Part II: Quality

Drug Substance

S1 General Information: general properties of the API

S2 Manufacture: description of the API manufacturing process

S3 Characterization: confirmation of the structure of the API

S4 Control of Drug Substance: tests and specification for API

S5 Reference Standard: standard for testing of API

S7 Stability: stability of the API

Pre-Market Assessment:
Requirements

Part II: Quality

Drug Product

P1 Description and Composition: description of product

P2 Pharmaceutical Development: dev't of formulation

P3 Manufacture: manufacturing process of product

P4 Control of Excipients: tests and specification for excipients

P5 Control of Finished Product: tests and specification of product

P6 Reference Standards or Materials: standard for testing

P7 Container Closure System: storage system of product

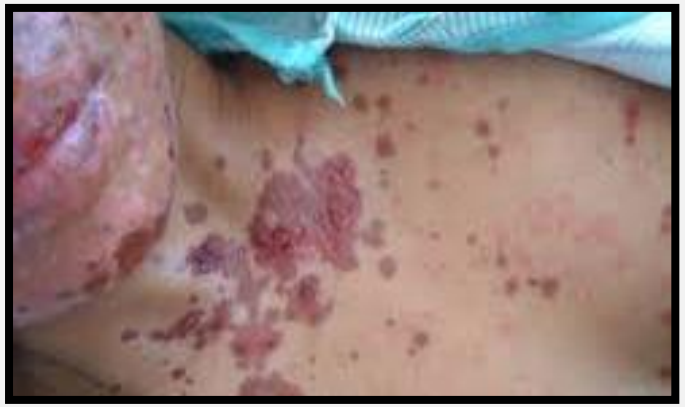
P8 Stability: stability of the API

P9 Proof of Interchangeability: BA/BE, biowaiver

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

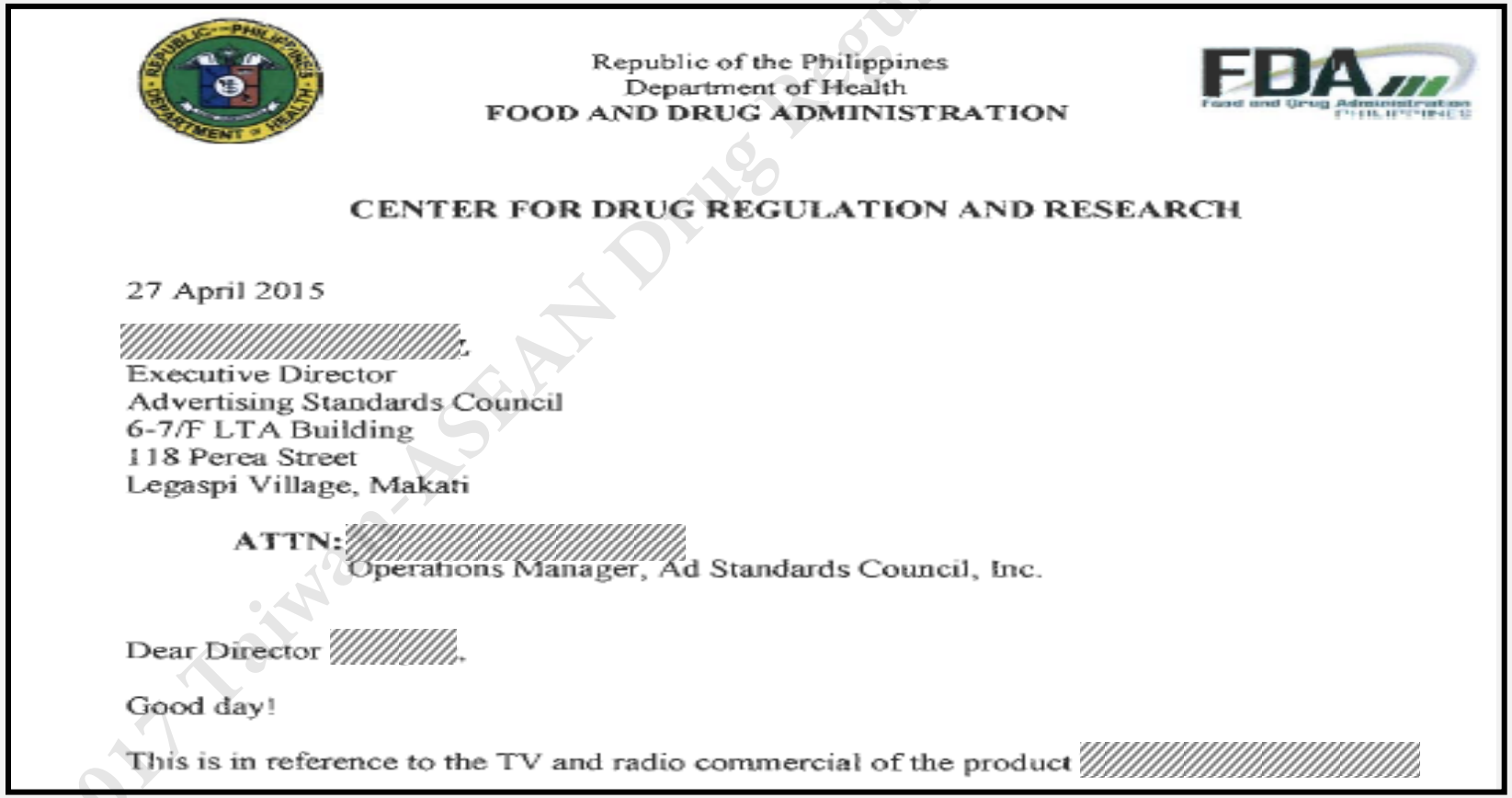


Postmarketing Surveillance
strengthened enforcement

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.

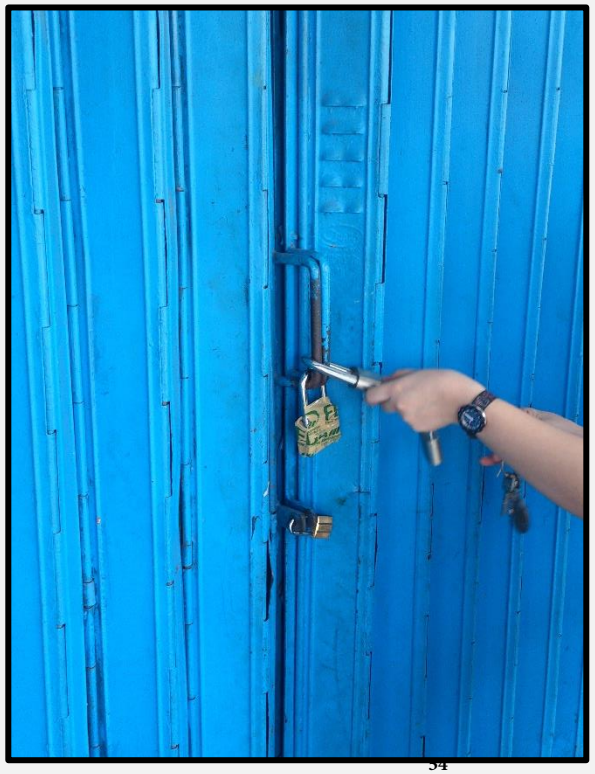
12 May 2011

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

USAID FROM THE AMERICAN PEOPLE | USP PROMOTING THE QUALITY OF MEDICINES

ICH harmonisation for better health

FDA 食品藥物管理署 Food and Drug Administration

APEC

MFDS KOREA

asean

pmda

Communication, Coordination, and Collaboration

2. Alignment with other government agencies

Communication, Coordination, and Collaboration

3. Partnerships with professional associations and private institutions

Way Forward

1. International and Local Collaboration

- ✓ Regulatory alignment

2. Reduce regulatory burden

- ✓ Risk-based approach
- ✓ Increase manpower complement
- ✓ Upgrading of facilities