Republic of the Philippines
Department of Health
Food and Drug Administration

# CDRR Public Consultation

## Draft Schedule of Fees and Charges and Rationalization of the Services of FDA

Center for Drug Regulation and Research
Food and Drug Administration
15 July 2015

# Presentation Outline

**Consultation Rules**

**I. Legal Bases**

**II. Background**

**III. Financial Review**

**IV. Proposed Changes**

**V. Considerations for the Proposed Fees**

**VI. Sample Computation**

**VII. Proposed Fees and Charges**

**VIII. Discussion**

# Consultation Rules

Balancing Innovation and Sound Regulation

# Objective

Discuss and solicit comments from stakeholders on the CDRR Fee restructuring.

# Consultation Process

**Review of policies at the Center level**

↓

**Small/Focus Group Discussion**

↓

**Review**

↓

**Public Consultation**

1. Focus on the objective.
2. No single interest shall prevail.
3. All comments and suggestions are based on sound, scientific, technical and unbiased knowledge.
4. Be concise and specific.
5. Treat everyone with dignity, honesty, and respect.

# Ground Rules

Balancing Innovation and Sound Regulation

6. Do not take comments personally.
7. Do not interrupt others.
8. Speak clearly.
9. Actively listen and participate.
10. Turn off your mobile phones or set them to silent mode.

# Ground Rules

# I. Legal Bases

# Article XIII – Social Justice and Human Rights, Health, Section 12

Section 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems.

Balancing Innovation and Sound Regulation

**The 1987 Constitution of the Philippines**

# Chapter III – Creation of Food and Drug Administration, Section 4, f

f. To levy, assess and collect fees for inspection, analysis and testing of products and materials submitted in compliance with the provisions of this Act.

# Chapter XIII – Financing, Section 31

The amount of one million pesos is hereby appropriated from any funds in the National Treasury not otherwise appropriated to augment the funds transferred to this Office under Section eight for the implementation of this Act. All income derived from fees authorized in Section four of this Act shall accrue to the General Fund.

**Republic Act No. 3720**

Balancing Innovation and Sound Regulation

# Section 15

"SECTION 21-C. The Secretary shall promulgate a schedule of fees for the issuance of the certificate of product registration and the license to operate provided for under Section 21, 21-A, and 21-B."

**Executive Order No. 175**

Balancing Innovation and Sound Regulation

# Section 17 – Amending Section 31 of RA 3720

"SEC. 34. *Fees and Other Income.* –

"(a) Upon the sole approval of the Secretary, the authorization and other fees shall annually be determined and reviewed by the FDA and any proposed increase shall be published in two (2) leading newspapers of general circulation.

"(b) There shall be determined and constituted additional fees such as sale of publications and services, assessment fees, fines, penalties, and other fees and charges outside the usual licensing and registration fees, to be known as 'other related regulatory fees'.

**Republic Act No. 9711**

Balancing Innovation and Sound Regulation

# Section 17 – Amending Section 31 of RA 3720

"(c) The Director-General of the FDA, upon approval of the Secretary, shall be authorized to promulgate rules and regulations governing the collection of the 'other related regulatory fees'. Upon approval of the Secretary, these fees shall likewise be reviewed periodically and any proposed increase shall be published in two (2) leading newspapers of general circulation."

**Republic Act No. 9711**

Balancing Innovation and Sound Regulation

# Section 18

SEC. 18. All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a special regulatory fund. Any interest earned by such fund shall form part of the retained income. Such fund shall be used primarily for the acquisition of office and laboratory space, human resource development and expansion, purchase of laboratory equipment and motor

**Republic Act No. 9711**

Balancing Innovation and Sound Regulation

# Chapter 4 – Strengthening of the Bureau of Food and Drugs, Section 31, (a)-(b)

(a) For a more effective and expeditious implementation of this Act, the Director or head of the Bureau of Food and Drugs shall be authorized to retain, without need of a separate approval from any government agency, and subject only to existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected by the Bureau of Food and Drugs under this Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of its facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery of its services to the public. This amount, which shall be in addition to the annual budget of the Bureau of Food and Drugs, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or head.

**Republic Act No. 9502**

Balancing Innovation and Sound Regulation

# Chapter 4 – Strengthening of the Bureau of Food and Drugs, Section 31, (a)-(b)

(b) After five (5) years from the coming into force of this Act, the Director or head of the Bureau of Food and Drugs shall, subject to the approval of the Secretary of the Department of Health, determine if the fees and charges, mentioned in Subsection (a) hereof, are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said Subsection (a) but shall forthwith cease to receive any funds from the annual budget of the National Government; if not, the provisions of Subsection (a) shall continue to apply until such time when the Director or head of the Bureau of Food and Drugs, subject to the approval of the Secretary of the Department of Health, certifies that the above stated fees and charges the Bureau of Food and Drugs shall collect are enough to fund its operations.

Balancing Innovation and Sound Regulation

**Republic Act No. 9502**

# II. Background

Balancing Innovation and Sound Regulation

# Administrative Order No. 50 s. 2001

Republic of the Philippines
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY
San Lazaro Compound, Rizal Avenue,
Sta. Cruz, Manila

September 17, 2001

ADMINISTRATIVE ORDER
No. 50 s. 2001

**Subject:** **REVISED 2001 SCHEDULE OF FEES AND CHARGES FOR THE CORRESPONDING SERVICES RENDERED BY THE BUREAU OF FOOD AND DRUGS**

Pursuant to Executive Order No. 197, s. directing "all departments, bureaus, offices, agencies and units, including government owned or controlled corporations to review and upgrade their rates of fees and charges by not less than twenty percent (20%)", the new fees and charges for the corresponding services rendered by the Bureau of Food and Drugs are hereby prescribed.

Balancing Innovation and Sound Regulation

# Passing of RA 9502

Technical Assistance to the
Health Sector Policy Support Programme

DEVELOPMENT OF REVISED AND UPDATED BFAD
MASTER PLAN FOR 2010 TO 2014

THE BUREAU OF FOOD AND DRUGS (BFAD)
REVIEW OF FEES AND CHARGES

Balancing Innovation and Sound Regulation

# Passing of RA 9502

Financial Management Advisor for Bureau of Food and Drugs (BFAD)

*June 2009*

Technical Assistance to the Health Sector Policy Programme in the Philippines
An EU funded programme managed by the EC Delegation and the DoH

*This was financed by the European Commission and executed by the GTZ-International Service Consortium for the Technical Assistance to the Health Sector Policy Support Programme. The opinions expressed are those of the consultant and do not represent any official view of the European Commission.*

Balancing Innovation and Sound Regulation

# Draft Revised Schedule of Fees 2009

25 August 2009

**ADMINISTRATIVE ORDER**
**No. _____**

**Subject: Revised Schedule of Fees for Services Rendered by the Food and Drug Administration**

**I. RATIONALE:**

The FDA's financial sustainability is anchored on increases in income/revenue, continued cost-effectiveness, enhanced financial management, and an appropriate cost-recovery framework. Full financial sustainability requires full cost recovery. Through all this, FDA is expected to pursue its strengthening objectives and improvements of its services.

# Draft Revised Schedule of Fees 2009

- Consultation conducted 3 December 2009

Balancing Innovation and Sound Regulation

# Draft Revised Schedule of Fees 2013

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

**14 June 2013**

**ADMINISTRATIVE ORDER**
**No. 2013 - _____**

**SUBJECT:** **Revised Schedule of Fees and Rationalization of Services of the Food and Drug Administration**

# Draft Revised Schedule of Fees 2013

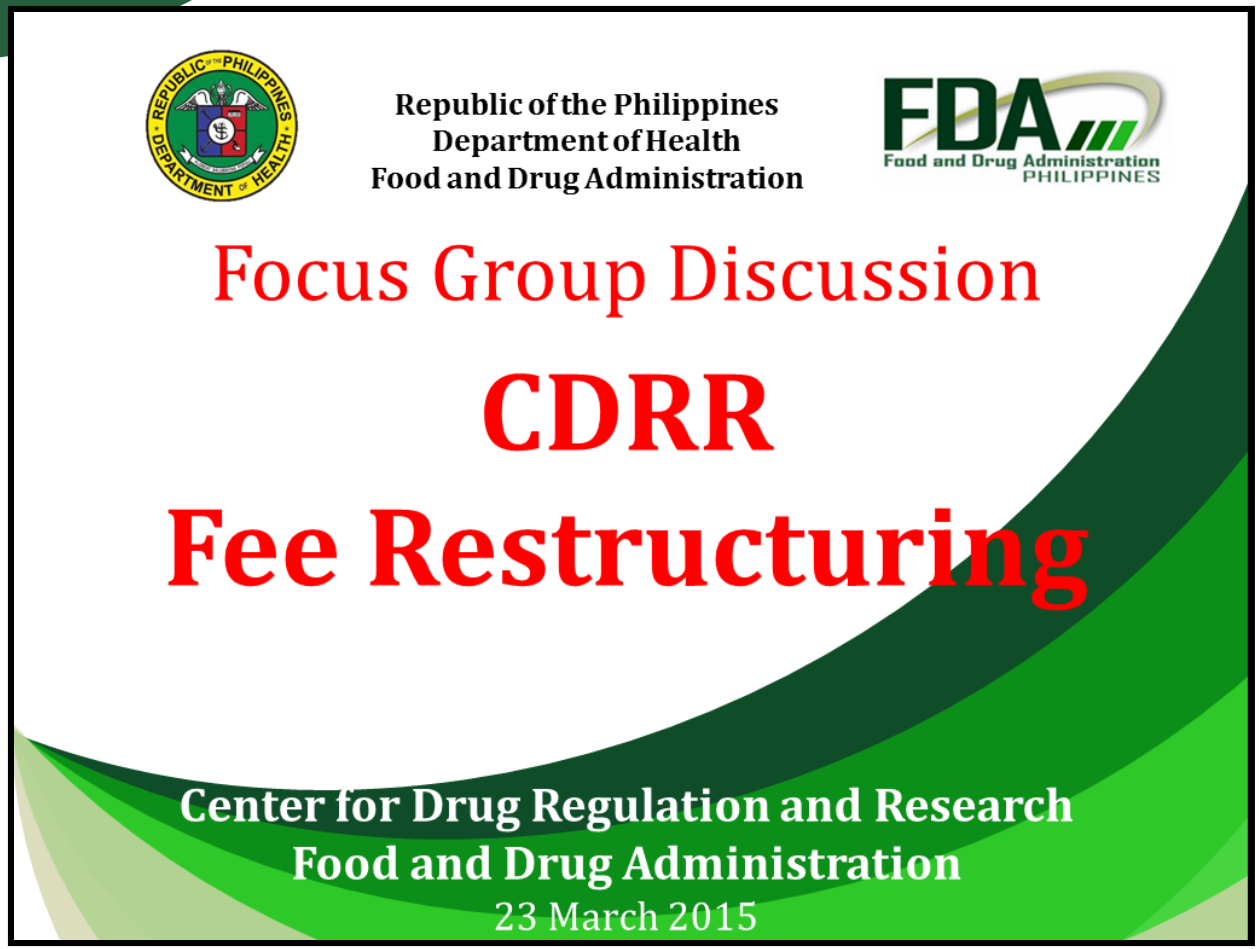
- Consultation conducted last May 2013
- Attendees
  - CHIPI
  - DSAP
  - PAPPI
  - PAPVI
  - PCPI
  - PCRP
  - PPMA
  - PVDA

# Business Plan

- February 2015 - approval of the organogram and 1st year staffing pattern
- Revised schedule of fees is needed

Balancing Innovation and Sound Regulation

# 23 March 2015 FGD



# March – June 2015

- Creation of the FDA TWG for the review of fees and charges
- Financial advisor
- Review of income, applications received

# Summary

- **Income retention**
- **Financial sustainability**
- **Fees and charges as the only source of funding support for operations and capital expenditures**

# III. Financial Review

# Findings

- Last adjustment of fees was in 2001, almost 15 years
- Automation of services/electronic submission was implemented in 2013 to improve operation efficiency but no adjustments in rates
- Replacement of equipment has been very selective
- Last capital outlay approved for FDA was in 2006

# Findings

- Main sources of revenue:
  - Product Registration (49%)
  - License Fees (20%)

- Main expense
  - Personnel costs (45%)

# Findings

- Net income will not be enough to support salary adjustments, inflationary adjustments, capital expenditures
  - FDA Rationalization Plan
  - 5-year prescriptive period for self-sufficiency
- Thus the need to rationalize the FDA rates

# IV. Highlights of the New Schedule of Fees

# Highlights

- Authenticated Copy vs Re-issuance
- Pre-Evaluation
- Legal Research Fee
- Phasing-in

**“Authenticated Copy”**

term used to indicate an issuance of a valid authorization, whether CPR or LTO, which already issued by the FDA for special purposes, e.g. as part of the requirements to be submitted during biddings in government agencies. The client shall be issued a scanned copy of the authorization

# Definition of Terms

**“Re-issuance”**

term used is a term used to indicate an issuance of a lost or damaged but still with valid authorization or LTO. The client has to present an affidavit of loss or the damaged document as a requirement for re-issuance. The client shall be issued an original copy of the authorization but will have the same number.

# Definition of Terms

1. Schedule for submission
2. Payment of filing fee
   - LTO: P500.00
   - CPR: P500.00 or 1% of the total CPR application fee, whichever is higher
3. Pre-evaluation at PAIR/Regional Office for the completeness of documents based on the Checklist of Requirements

# Pre-Evaluation

Balancing Innovation and Sound Regulation

4. If complete, full payment and submission of document
5. If found to be incomplete, client may re-apply → re-payment of filing fee

# Pre-Evaluation

Balancing Innovation and Sound Regulation

# Legal Research Fee

- Republic Act No. 3870
- Proposed fees are inclusive of LRF that is equivalent to 1% of the particular application fee

# Phasing-in

no phasing-in of fees, and payments shall be according to the schedule of fees as shown in the Annexes

# V. Considerations for the Proposed Fees

- Drug Establishments – no SME classification
- Cover inspection fees once a year for every valid year
- Validity changes:
  - Initial: from 1 year to 2 years
  - Renewal: from 2 years to 3 years
- From amendment to variations:
  - Major, Minor-Prior Approval, Minor-Notification

# Licensing Fees

- Evaluation costs
- Supply costs
- Inspection costs
- TEV
- Indirect Costs*
- Mark-up margins

# Licensing Fees: Inclusions

- New drug classification:
  - New Chemical Entities
  - Generic Products
  - Biotechnological Products
  - Other class: OTC, Veterinary, TM, HR, Medical Gas
- One-step submission – quality and clinical/non-clinical review (streamlined process)

# Registration Fees

Balancing Innovation and Sound Regulation

- Cover PMS fees (sampling and lab testing**) throughout the validity
- From amendment to variations:
  - Major, Minor-Prior Approval, Minor-Notification
- Removal of the distinction between branded and unbranded registration fees

# Registration Fees

Balancing Innovation and Sound Regulation

- Evaluation costs
- NDAC evaluation costs
- PMS costs***
- Sampling costs
- Laboratory testing costs
- Supply costs
- Indirect Costs*

# Registration Fees

Balancing Innovation and Sound Regulation

# Indirect Costs*

- salaries and wages
- advertisement costs
- communication costs
- consultancy costs
- Fuel, oil, and lubricants
- General services
- Legal fees
- Other professional expense

# Indirect Costs*

- Other supplies and materials
- Printing and publication
- Subscription
- Training
- Transportation
- Utilities (lights and water)
- Repairs and maintenance
- Taxes and licenses

# Indirect Costs*

- Representation
- Extraordinary and miscellaneous expense
- Other maintenance and Operating expenses
- Depreciation

# Laboratory Testing**

| Dosage Form | Tests Considered |
|---|---|
| Tablets | Visual Examination, Assay, Dissolution, Disintegration, ID Test, Purity Test, Moisture Content |
| Capsules | Visual Examination, Assay, Dissolution, ID Test, Purity Test, Moisture Content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Emulsion | Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product

# Laboratory Testing**

| Dosage Form | Tests Considered |
|---|---|
| Oral Solutions/ Suspensions | Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Oral Powders for Reconstitution | Visual Examination, Assay, ID Test, Purity Test, Moisture content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Metered Dose Inhalation/Nasal Aerosols | Visual Examination, Assay, ID Test, Purity Test, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product

# Laboratory Testing**

| Dosage Form | Tests Considered |
|---|---|
| Nasal Sprays | Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Tropical Preparation | Visual Examination, Assay, ID Test, Purity Test, Moisture content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Ophthalmic/Otic Solution | Visual Examination, Assay, ID Test, Purity Test, Sterility |

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product

# Laboratory Testing**

| Dosage Form | Tests Considered |
|---|---|
| Suppositories | Visual Examination, Assay, Dissolution, ID Test, Purity Test, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate |
| Small Volume Parenterals | Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL |
| Large Volume Parenterals | Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL |
| Drug Admixture | Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL |

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product

# Laboratory Testing**

| Dosage Form | Tests Considered |
|---|---|
| Freeze Dried Products | Visual Examination, Assay, ID Test, Purity Test, Moisture Content, pH |

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product

# PMS costs***

- Complaints processing
- Product Verification
- ADR Report processing
- RMP Evaluation and Post-marketing Commitments

# VI. Sample Computation

# Sample Computation

- Initial Licensing Fee - Distributor
- New Chemical Entity Registration

# Initial Licensing Fee - Distributor

Evaluation costs

\+ Supply costs

\+ Inspection costs

\+ TEV

\+ Indirect Costs*

\+ Mark-up margins

---

Initial Licensing Fee - Distributor

# Evaluation costs

Step 1(SG x processing time)

+ Step 2(SG x processing time)

+ Step 3(SG x processing time)..

+ Step n(SG x processing time)

---

**3470.48 (12.6 hours)**

# Supply Costs

**50.00**

# Inspection Cost

SG per day of inspector
x average length of inspection (3 days)
x number of inspectors (1)
x year validity (2)

**16,714.08**

# TEV

Reasonable TEV per day (400)
x average length of inspection (3 days)
x number of inspectors (1)
x year validity (2)

**2,400.00**

# Indirect Costs

Total processing time (12.6 hours)

x indirect costs per hour (410.5)

**5,172.30**

# Mark-up Margin

**5%**

# Initial Licensing Fee - Distributor

Evaluation costs

\+ Supply costs

\+ Inspection costs

\+ TEV

\+ Indirect Costs*

\+ Mark-up margins

---

Initial Licensing Fee - Distributor

# Initial Licensing Fee - Distributor

| | |
|---|---|
| | 3470.48 |
| + | 50.00 |
| + | 16,714.08 |
| + | 2,400.00 |
| + | 5,172.30 |
| + | 5% |
| | **29,270.38** |

# NCE Registration Fee

Evaluation costs
+ NDAC evaluation costs
+ PMS costs
+ Sampling costs
+ Laboratory testing costs
+ Supply costs
+ Indirect Costs*
+ Mark-up Margins

NCE Registration Fee

# Evaluation Costs

Step 1(SG x processing time)

+ Step 2(SG x processing time)

+ Step 3(SG x processing time)..

+ Step n(SG x processing time)

---

**36,618.84 (97.85 hours)**

# NDAC Evaluation Costs

SG per day of NDAC

x average length of evaluation (3 days)

x number of NDAC experts (2)

**12,000.00**

# PMS costs

[Step 1(SG x processing time)

+ Step 2(SG x processing time)

+ Step 3(SG x processing time)..

+ Step n(SG x processing time)]

**68,413.76**

# Sampling Costs

Sampling allotment (400)

x sampling frequency (4 times)

---

**1600.00**

# Laboratory Testing Costs

Laboratory testing fees
x testing frequency (4 times)

**42,219.55**

# Supply Costs

**50.00**

# Indirect Costs

Total processing time (97.85 hours)

x indirect costs per hour (410.5)

---

**40,167.43**

# Mark-up Margin

**5%**

# NCE Registration Fee

Evaluation costs
+ NDAC evaluation costs
+ PMS costs
+ Sampling costs
+ Laboratory testing costs
+ Supply costs
+ Indirect Costs
+ Mark-up Margins

NCE Registration Fee

# NCE Registration Fee

| | |
|---|---|
| | 36,618.84 |
| + | 12,000.00 |
| + | 68,413.76 |
| + | 1,600.00 |
| + | 42,219.55 |
| + | 50.00 |
| + | 40,167.43 |
| + | 5% |
| | 211,652.19 |

# VII. Proposed Fees

# License to Operate

| Category | Fee (in PhP) | | | | |
|---|---|---|---|---|---|
| | Initial (2-year validity) | Renewal (3-year validity) | Variation | | |
| | | | MaV | MiV-PA | MiV-N |
| Drug Manufacturer (Repacker, Packer) | 110,000.00 | 157,000 | 9,500.00 | 1,500.00 | 1,500.00 |
| Drug Trader/ Distributor (Exporter, Importer, Wholesaler) | 30,000.00 | 36,500.00 | 6,500.00 | 1,500.00 | 1,500.00 |
| Drugstore/Pharmacy/ Botica and similar outlets | 6,500.00 | 9,500.00 | 3,500.00 | 1,500.00 | 1,500.00 |
| Retail Outlet for Non-Prescription Drugs (RONPD) | 6,500.00 | 9,500.00 | 3,500.00 | 1,500.00 | 1,500.00 |
| Sponsor/Contract Research Organization | 30,000.00 | 36,500.00 | 6,500.00 | 1,500.00 | 1,500.00 |

# Product Registration

| Category | Fee (in PhP) | | | | |
|---|---|---|---|---|---|
| | Initial (5-year validity) | Renewal (5-year validity) | Variation | | |
| | | | MaV | MiV-PA | MiV-N |
| New Chemical Entity (NCE) | 215,000.00 | 74,000.00 | 64,500.00 | 6,500.00 | 1,500.00 |
| Generic Drugs | 105,500.00 | 74,000.00 | 64,500.00 | 6,500.00 | 1,500.00 |
| Biotechnological Products | 235,000.00 | 94,000.00 | 64,500.00 | 6,500.00 | 1,500.00 |
| Other Drug Product Classification | 105,500.00 | 74,000.00 | 64,500.00 | 6,500.00 | 1,500.00 |

# Other Licensing/ Authorization Fees

| Category | Fee (in PhP) |
|---|---|
| **Permits and Clearances** | |
| GLE Permit/year | 1,500.00 |
| Conversion to PCPR | 1,500.00 |
| Donation | 1,500.00 |
| Export Certificate | 1,500.00 |
| BOC Clearances<br>Permit for Samples for Regn<br>Permit for CT Use | 1,000.00 |
| CoPP | 1,500.00 |
| Other Permits and Clearances | 1,000.00 |
| Product Classification | 1,500.00 |

# Other Licensing/ Authorization Fees

| Category | Fee (in PhP) |
|---|---|
| **Foreign GMP Application Fees** | |
| **Initial Application** | 10,000.00 |
| **Renewal Application** | 6,000.00 |
| **Foreign GMP Inspection App** | 6,000.00 |

# General Certification Fees

| Category | Fee (in PhP) |
|---|---|
| Authenticated Copy | 1,000.00 |
| Re-issuance | 2,000.00 |
| Other BOC Certification | 1,000.00 |
| CFS | 1,000.00 |
| Verification Certificate | 1,000.00 |
| Certification for Exhibit/Demo | 1,000.00 |
| Permit to Carry/Mail | 500.00/transaction |
| Promo Permit (across all prizes) | 6,000.00 |

# VIII. Discussion

# Discussion

- Comparison of Proposed Fees
- Position Papers/Comments

| Category | 2001 Fees | 2009 Proposed | 2013 Proposed | 2015 Proposed |
|---|---|---|---|---|
| **Drug Manufacturer - Initial** | | | | |
| **<20M below**** | 20,000 | 74,000 | 108,000 | 110,000 |
| **20-50 M** | 30,000 | 108,000 | 108,000 | 110,000 |
| **>50 M** | 40,000 | 141,000 | 108,000 | 110,000 |
| **Drug Manufacturer - Renewal** | | | | |
| **<20M below** | 30,000 | 111,000 | 162,000 | 157,000 |
| **20-50 M** | 45,000 | 162,000 | 162,000 | 157,000 |
| **>50 M** | 60,000 | 211,500 | 162,000 | 157,000 |
| **Drug Trader - Initial***** | | | | |
| **<20M below** | 6,000 | 23,000 | 108,000 | 30,000 |
| **20-50 M** | 10,000 | 38,000 | 108,000 | 30,000 |
| **>50 M** | 14,000 | 52,000 | 108,000 | 30,000 |
| **Drug Trader - Renewal** | | | | |
| **<20M below** | 9,000 | 34,500 | 162,000 | 36,500 |
| **20-50 M** | 15,000 | 57,000 | 162,000 | 36,500 |
| **>50 M** | 21,000 | 78,000 | 162,000 | 36,500 |
| **Drug Distributor - Initial** | 10,000 | 35,000 | 32,400 | 30,000 |
| **Drug Distributor - Renewal** | 15,000 | 52,500 | 48,600 | 36,500 |
| **Drugstore/RONPD – Initial** | 2,000 | 7,000 | 14,400 | 6,500 |
| **Drugstore/RONPD - Renewal** | 3,000 | 10,500 | 21,600 | 9,500 |

| Category | 2001 Fees | 2009 Proposed | 2013 Proposed | 2015 Proposed |
|---|---|---|---|---|
| NCEs | 40,000 | 350,000 | 350,000 | 215,000 |
| Generic - Initial | | | | |
| Unbranded | 10,000 | 142,500 | 142,500 | 105,500 |
| Branded | 15,000 | 180,000 | 180,000 | 105,500 |
| Generic - Renewal | | | | |
| Unbranded | 7,500 | 142,500 | 142,500 | 74,000 |
| Branded | 10,000 | 180,000 | 180,000 | 74,000 |
| Biotech products – Initial | | | | |
| Unbranded | 7,500 | 142,500 | 142,500 | 235,500 |
| Branded | 10,000 | 180,000 | 180,000 | 235,500 |
| Biotech products – Renewal | | | | |
| Unbranded | 7,500 | 142,500 | 142,500 | 94,000 |
| Branded | 10,000 | 180,000 | 180,000 | 94,000 |
| Other Products – Initial | | | | |
| Unbranded | 7,500 | 142,500 | 142,500 | 105,500 |
| Branded | 10,000 | 180,000 | 180,000 | 105,500 |
| Other Products – Renewal | | | | |
| Unbranded | 7,500 | 142,500 | 142,500 | 74,000 |
| Branded | 10,000 | 180,000 | 180,000 | 74,000 |
| Major Variation | 15,000 | 180,000 | 100,000 | 64,500 |
| Minor Variation-PA | 3,000 | 4,500 | 24,000 | 6,500 |
| Minor Variation-N | 500 | 4,500 | 2,000 | 1,500 |

# Position papers, Comments

- Position papers
- FGD Inquiries - 23 March 2015
- Email inquiries

# (1) Query

- What are the expected improvements in the delivery of FDA's services? Shortened processing timeline?

- Expect change will happen however do not expect it to be immediate. Please understand that changes will be implemented on a stepwise approach, starting with additional personnel to address the existing backlogs, followed by expansion, and automation that will redound to reduction in the processing time
- FDA addresses other issues on several fronts, including policy changes all in the direction of a more responsive regulatory agency

# (2) Query

- What will FDA do with the expected influx of licensing and registration applications?

- As early as now, FDA is informing the public of the implementation of new fees.
- Appropriate scheduling by PAIR will be implemented.
- Additional manpower

# (3) Query

- Classification of veterinary drugs lumped as “other classes”. How about new veterinary drug products, will it fall under NCE fee?

- Veterinary drugs also refer to new veterinary drug products.

# (4) Query

- Why is the distinction for unbranded and branded fees removed?

- The evaluation process for safety, efficacy, and quality, is the same

# (5) Query

- Why is the SME classification removed?

- Drug products are higher risk products.

# (6) Query

- Early renewal applications be considered prior to the implementation of the new fees.

- As much as we want to assist stakeholders, the existing policies clearly state that the earliest submission of renewal applications:
  - LTO: within 6 months (AO 34)
  - CPR: within 3 months (MC 7)

# (7) Query

- When will the fees be implemented?

- The draft provides 15 days following publication in two newspaper of general circulation

# (8) Query

- Can the pre-evaluation be brought back? We have several applications that are denied because we have failed to comply with some of the requirements. The pre-evaluation will help us in ensuring we are compliant

- Already included in the Draft AO

# (9) Query

- Will the new fees have implication on the variations following turned initial fees?

- If a variation falls under turned initial, the corresponding variation fee shall apply

# (10) Query

- For products with multiple variations, will the fees be per variation?

- If a major variation is included, the fee for major variation will only be collected