CDRR Public Consultation
New Schedule of Fees and Charges of the Food and Drug Administration for Licensing, Registration, and Other Certifications

Center for Drug Regulation and Research
Food and Drug Administration
14 June 2016
Presentation Outline
Consultation Rules
I. Legal Bases
II. Background
III. Salient Points of the Proposed AO
IV. Considerations for the Proposed Fees and Sample Computation
V. Proposed Fees and Charges
VI. Discussion
Consultation Rules
Objective

Discuss and solicit comments from stakeholders on the fee restructuring affecting drug establishments and products.
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
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.
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
"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."
“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’.
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.”
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
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
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.
SECTION 54. Charges for Property Sold or Services Rendered; Refunds. — (1) For services required by law to be rendered for a fee, for supplies furnished, or articles of any kind sold to other divisions of the government or to any person, the head of bureau, office or agency may, upon approval of the Secretary charge and collect the cost of the service, supplies, or articles or other rate in excess of cost prescribed by law or approved by the same authority. For local governments, the rate, except where otherwise prescribed by law, shall be affixed at cost or at such other reasonable rate in excess of cost by the boards or councils concerned;
In summary, FDA may

- assess its fees and charges
- collect these fees and charges for the services rendered
- retain these collected fees and charges
II. Background
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.
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
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.
ADMINISTRATIVE ORDER

No.

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

1. 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.
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
Business Plan

• February 2015 - approval of the organogram and 1st year staffing pattern
• Revised schedule of fees is needed for the 2nd year staffing pattern
23 March 2015

FGD

Focus Group Discussion

CDRR

Fee Restructuring

Center for Drug Regulation and Research
Food and Drug Administration
23 March 2015
23 March 2015

FGD

• Attendees:
  – CHIPI
  – DSSAP
  – PAPPI
  – PAPVI
  – PCPI
  – PCRP
  – PPMA
  – PPMA
  – PVDA
March – June 2015

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

- 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 of Financial Review

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

- Main expense
  - Personnel costs (45%)
Findings of Financial Review

• Existing net income will not be enough to support salary adjustments, inflationary adjustments, capital expenditures
  – FDA Rationalization Plan
  – 5-year prescriptive period for withdrawal of subsidy support
• Thus the need to rationalize the FDA rates
ADMINISTRATIVE ORDER
No. 2015 - _______

SUBJECT: New Schedule of Fees and Charges and Rationalization of the Services of the Food and Drug Administration (FDA)

I. BACKGROUND AND RATIONALE

Enshrined in Section 12, Article XIII on Health of the 1987 Philippine Constitution is the responsibility of the State to establish and maintain an effective food and drug regulatory system and to undertake research responsive to the country's health needs and problems. Consistent with the national policy, the Congress of the Philippines passed three landmark legislations, namely Republic Act (RA) No. 9502, (Universally Accessible Cheaper and Quality Medicine Act of 2008), Republic Act No. 9711, (Food and Drug Administration Act of 2009) and Republic Act 10611 (Food Safety Act of 2013), to ensure protection of public health and welfare.
CDRR Public Consultation
Draft Schedule of Fees and Charges and Rationalization of the Services of FDA
9 December 2015
Expanded TWG Consultation

Expanded TWG Consultation
Draft Schedule of Fees and Charges of FDA

Center for Drug Regulation and Research
Food and Drug Administration
09 December 2015
III. Salient Points of the Proposed AO
Salient Points

1) Assessment and assessment fee
2) Electronic authenticated copies
3) Activities covered by fees
4) Exclusive fees
5) Early renewal
6) Re-application fee
(1) Assessment and Fee

• process of initial review on the completeness of the documents submitted upon payment of assessment fee
• Applicable for CPR applications
• P500 or 1% of the total product registration fee, whichever is higher shall be collected
(2) Electronic authenticated copies

• a valid scanned copy of authorization with barcode, whether CPR or LTO, issued by the FDA for special purposes (e.g. as part of the requirements for bidding).

• 1 original copy

• 19 e-copies
(3) Activities covered by fees

1. Receiving
2. Pre-market (assessment, technical evaluation and pre-licensing inspection)
3. PMS of products and establishments, but not limited to the following:
   a) Collection of sample
   b) Laboratory testing
   c) Complaints and reports processing
   d) Safety monitoring
   e) Post-licensing inspection
   f) Routine inspection
(3) Activities covered by fees

4. Printing of original copy and electronic authenticated copies of LTO and CPR;
5. Records management and archiving; and
6. Courier services to deliver the authorization.
(4) Exclusive fees

Exclusive:
1. LRF

UP Law Center’s Legal Research Fee (LRF) which is equivalent to ₱10.00 or 1% of the application fee, whichever is higher, as imposed by RA 3870, as amended by PD 200 and further amended by PD 1856, of which FDA is only the collecting agent
(4) Exclusive fees

Exclusive:

2. Other Fees

Other fees incurred from the use of payment collection facilities, such as service fees charged by banks authorized by the FDA to collect its fees.
(5) Early Renewal

• Applications made 6-3 months prior to expiration of LTO/CPR
• 10% discount, provided compliant with the renewal requirements
(6) Re-application Fees

- P500.00 or 1% of the current application fee for product registration, whichever is higher,
- resetting of timelines for applications that failed to meet the prescribed timeline to comply with a Notice of Deficiency/Letter of Denial
IV. Considerations for the Proposed Fees and Sample Computation
Republic of the Philippines
Department of Health
Food and Drug Administration

Licensing 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 and Minor Variations

Licensing Fees
# Initial Licensing Fee - Distributor

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation Costs</td>
<td>SG of Evaluator x Evaluation Period x Validity</td>
</tr>
<tr>
<td>Supply Costs</td>
<td>Papers, printing, security paper, e-copies</td>
</tr>
<tr>
<td>Inspection Costs</td>
<td>SG of Inspector x inspection period x # of Inspectors</td>
</tr>
<tr>
<td>TEV</td>
<td>Transportation expenses per inspection</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>As discussed*</td>
</tr>
<tr>
<td>Mark-up</td>
<td>To adjust for inflationary changes</td>
</tr>
</tbody>
</table>

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**Initial Licensing Fee**
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
## Initial Licensing Fee - Distributor

<table>
<thead>
<tr>
<th>Costs</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation Costs</td>
<td>P3,470.48</td>
</tr>
<tr>
<td>Supply Costs</td>
<td>P50.00</td>
</tr>
<tr>
<td>Inspection Costs</td>
<td>P16,714.08</td>
</tr>
<tr>
<td>TEV</td>
<td>P2,400</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>P5,172.30</td>
</tr>
<tr>
<td>Mark-up</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Total:** P29,270.38
Registration Fees
• 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)
• 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
NCE Registration Fee

Evaluation Costs → SG of Evaluator x Evaluation Period x Validity
Supply Costs → Papers, printing, security paper, e-copies
Indirect Costs → As discussed*
Laboratory Costs → As discussed
Consultancy Costs → Consultation fees of advisory council
PMS Costs → Complaints processing, product verification
PV Report processing, RMP Evaluation
Mark-up → To adjust for inflationary changes

NCE Registration Fee
## Laboratory Testing

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tests Considered</th>
<th>Computed Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>Visual Examination, Assay, Dissolution, Disintegration, ID Test, Purity Test, Moisture Content</td>
<td>P9,070.61</td>
</tr>
<tr>
<td>Capsules</td>
<td>Visual Examination, Assay, Dissolution, ID Test, Purity Test, Moisture Content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P12,349.83</td>
</tr>
<tr>
<td>Emulsion</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P8,380.24</td>
</tr>
</tbody>
</table>

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

Computation based on AO 50
## Laboratory Testing

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tests Considered</th>
<th>Computed Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Solutions/ Suspensions</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P8,380.24</td>
</tr>
<tr>
<td>Oral Powders for Reconstitution</td>
<td>Visual Examination, Assay, ID Test, Purity Test, Moisture content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P8,898.02</td>
</tr>
<tr>
<td>MDI/Nasal Aerosols</td>
<td>Visual Examination, Assay, ID Test, Purity Test, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P7,862.47</td>
</tr>
</tbody>
</table>
## Laboratory Testing

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tests Considered</th>
<th>Computed Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Sprays</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P8,380.24</td>
</tr>
<tr>
<td>Tropical Preparation</td>
<td>Visual Examination, Assay, ID Test, Purity Test, Moisture content, pH, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P8,898.02</td>
</tr>
<tr>
<td>Ophthalmic / Otic Solution</td>
<td>Visual Examination, Assay, ID Test, Purity Test, Sterility</td>
<td>P8,725.42</td>
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</tbody>
</table>

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product. Computation based on AO 50.
# Laboratory Testing

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tests Considered</th>
<th>Computed Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suppositories</td>
<td>Visual Examination, Assay, Dissolution, ID Test, Purity Test, Aerobic Plate, Aerobic Halophilic, Aerobic Thermophilic, Coliform Plate</td>
<td>P11,314.29</td>
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<tr>
<td>Small Volume Parenterals</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL</td>
<td>P16,146.83</td>
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<tr>
<td>Large Volume Parenterals</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL</td>
<td>P16,146.83</td>
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<tr>
<td>Drug Admixture</td>
<td>Visual Examination, Assay, ID Test, Purity Test, pH, Sterility, LAL</td>
<td>P16,146.83</td>
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</tbody>
</table>

Dosage forms and the corresponding tests were derived from the ASEAN Guideline on Stability of Drug Product. Computation based on AO 50.
## Laboratory Testing

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Tests Considered</th>
<th>Computed Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze Dried Products</td>
<td>Visual Examination, Assay, ID Test, Purity Test, Moisture Content, pH</td>
<td>P5,446.20</td>
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</tbody>
</table>

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

Computation based on AO 50
NCE Registration Fee

<table>
<thead>
<tr>
<th>Cost Type</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Evaluation Costs</td>
<td>P36,618.84</td>
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<tr>
<td>Supply Costs</td>
<td>P50.00</td>
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<tr>
<td>Indirect Costs</td>
<td>P40,167.43</td>
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<tr>
<td>Laboratory Costs</td>
<td>P42,219.55</td>
</tr>
<tr>
<td>Consultancy Costs</td>
<td>P12,000.00</td>
</tr>
<tr>
<td>PMS Costs</td>
<td>68,413.76</td>
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<tr>
<td>Mark-up</td>
<td>5%</td>
</tr>
</tbody>
</table>

P211,652.19
Reduction in the Computed Fees

• DBM will continue to provide financial support that is allotted to personnel services
V. Proposed Fees
## License to Operate

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial (2-year validity)</th>
<th>Renewal (3-year validity)</th>
<th>Variation</th>
<th>MaV</th>
<th>MiV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Manufacturer (Repacker, Packer)</td>
<td>75,000.00</td>
<td>114,000.00</td>
<td>8,500.00</td>
<td>1,500.00</td>
<td></td>
</tr>
<tr>
<td>Drug Trader/Distributor (Exporter, Importer, Wholesaler)</td>
<td>30,000.00</td>
<td>36,500.00</td>
<td>6,500.00</td>
<td>1,500.00</td>
<td></td>
</tr>
<tr>
<td>Drugstore/Pharmacy/Botica and similar outlets</td>
<td>4,500.00</td>
<td>6,500.00</td>
<td>3,500.00</td>
<td>1,500.00</td>
<td></td>
</tr>
<tr>
<td>Retail Outlet for Non-Prescription Drugs (RONPD)</td>
<td>4,500.00</td>
<td>6,500.00</td>
<td>3,500.00</td>
<td>1,500.00</td>
<td></td>
</tr>
<tr>
<td>Sponsor/Contract Research Organization</td>
<td>30,000.00</td>
<td>36,500.00</td>
<td>6,500.00</td>
<td>1,500.00</td>
<td></td>
</tr>
</tbody>
</table>
# Product Registration

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial (5-year validity)</th>
<th>Renewal (5-year validity)</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>MaV-A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MaV-B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MiV-PA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MiV-N</td>
</tr>
<tr>
<td>New Chemical Entity (NCE)</td>
<td>155,000.00</td>
<td>35,000.00</td>
<td>25,000.00</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>6,500.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,500.00</td>
</tr>
<tr>
<td>Generic Drugs</td>
<td>76,000.00</td>
<td>35,000.00</td>
<td>25,000.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6,500.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,500.00</td>
</tr>
<tr>
<td>Biological Products</td>
<td>170,000.00</td>
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<td>25,000.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6,500.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,500.00</td>
</tr>
<tr>
<td>Other Drug Product Classification</td>
<td>76,000.00</td>
<td>35,000.00</td>
<td>25,000.00</td>
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<tr>
<td></td>
<td></td>
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<td>6,500.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,500.00</td>
</tr>
</tbody>
</table>

*Major Variation 1, 4, 5, 9, 10, 11, 12, 13 and Country Specific Major Variations as provided in FDA Circular No. 2014-008. For multiple variations on product registration with any major variation enumerated herein, only the major variation fee will be collected.*
## Other Fees

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee (in PhP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permits and Clearances</td>
<td></td>
</tr>
<tr>
<td>GLE Permit/year</td>
<td>1,500.00</td>
</tr>
<tr>
<td>Conversion to PCPR</td>
<td>1,500.00</td>
</tr>
<tr>
<td>CSP Institutional Use</td>
<td>6,000.00</td>
</tr>
<tr>
<td>Donation</td>
<td>1,500.00</td>
</tr>
<tr>
<td>Export Certificate</td>
<td>1,500.00</td>
</tr>
<tr>
<td>CoPP</td>
<td>1,500.00</td>
</tr>
<tr>
<td>Product Classification</td>
<td>1,500.00</td>
</tr>
</tbody>
</table>
# Other Fees

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee (in PhP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permits and Clearances</strong></td>
<td></td>
</tr>
<tr>
<td>Authenticated copy (first 5; for succeeding, P50.00/copy)</td>
<td>500.00</td>
</tr>
<tr>
<td>Reissuance</td>
<td>2,000.00</td>
</tr>
<tr>
<td>Certification / Clearance / Verification/Special Permit*</td>
<td>500.00</td>
</tr>
<tr>
<td><strong>BOC Clearances</strong></td>
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</tr>
<tr>
<td>Permit for Samples for Regn</td>
<td>1,000.00</td>
</tr>
<tr>
<td>Permit for CT Use</td>
<td></td>
</tr>
<tr>
<td><strong>CFS</strong></td>
<td>1,000.00</td>
</tr>
<tr>
<td>Permit to Carry-Mail (Personal)</td>
<td>50.00/transaction</td>
</tr>
</tbody>
</table>
VI. Discussion
Discussion

• Comparison of Proposed Fees
• Position Papers/Comments
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Manufacturer - Initial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20M below****</td>
<td>20,000</td>
<td>74,000</td>
<td>108,000</td>
<td>110,000</td>
<td>75,000</td>
</tr>
<tr>
<td>20-50 M</td>
<td>30,000</td>
<td>108,000</td>
<td>108,000</td>
<td>110,000</td>
<td>75,000</td>
</tr>
<tr>
<td>&gt;50 M</td>
<td>40,000</td>
<td>141,000</td>
<td>108,000</td>
<td>110,000</td>
<td>75,000</td>
</tr>
<tr>
<td>Drug Manufacturer - Renewal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20M below</td>
<td>30,000</td>
<td>111,000</td>
<td>162,000</td>
<td>157,000</td>
<td>114,000</td>
</tr>
<tr>
<td>20-50 M</td>
<td>45,000</td>
<td>162,000</td>
<td>162,000</td>
<td>157,000</td>
<td>114,000</td>
</tr>
<tr>
<td>&gt;50 M</td>
<td>60,000</td>
<td>211,500</td>
<td>162,000</td>
<td>157,000</td>
<td>114,000</td>
</tr>
<tr>
<td>Drug Trader - Initial*****</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20M below</td>
<td>6,000</td>
<td>23,000</td>
<td>108,000</td>
<td>30,000</td>
<td>30,000</td>
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<tr>
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<td>108,000</td>
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<td>30,000</td>
</tr>
<tr>
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<td>52,000</td>
<td>108,000</td>
<td>30,000</td>
<td>30,000</td>
</tr>
<tr>
<td>Drug Trader - Renewal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20M below</td>
<td>9,000</td>
<td>34,500</td>
<td>162,000</td>
<td>36,500</td>
<td>36,500</td>
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<tr>
<td>20-50 M</td>
<td>15,000</td>
<td>57,000</td>
<td>162,000</td>
<td>36,500</td>
<td>36,500</td>
</tr>
<tr>
<td>&gt;50 M</td>
<td>21,000</td>
<td>78,000</td>
<td>162,000</td>
<td>36,500</td>
<td>36,500</td>
</tr>
<tr>
<td>Drug Distributor - Initial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10,000</td>
<td>35,000</td>
<td>32,400</td>
<td>30,000</td>
<td>30,000</td>
<td></td>
</tr>
<tr>
<td>Drug Distributor - Renewal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15,000</td>
<td>52,500</td>
<td>48,600</td>
<td>36,500</td>
<td>36,500</td>
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<tr>
<td>Drugstore/RONPD - Initial</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2,000</td>
<td>7,000</td>
<td>14,400</td>
<td>6,500</td>
<td>4,500</td>
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<tr>
<td>Drugstore/RONPD - Renewal</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3,000</td>
<td>10,500</td>
<td>21,600</td>
<td>9,500</td>
<td>6,500</td>
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</tbody>
</table>
Proposed Fee In(de)crease

Manufacturer

- Manufacturer - Initial
- Manufacturer - Renewal

46% decrease from 2016 to 2015
Proposed Fee In(de)crease

![Graph showing proposed fee decrease for distributors over years. The graph indicates a significant decrease from 2009 to 2016.]
Proposed Fee In(de)crease

Drugstore/RONPD

<table>
<thead>
<tr>
<th>Year</th>
<th>DS/RONPD - Initial</th>
<th>DS/RONPD - Renewal</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>7000</td>
<td>6500</td>
</tr>
<tr>
<td>2013</td>
<td>21600</td>
<td>9500</td>
</tr>
<tr>
<td>2015</td>
<td>14400</td>
<td>6500</td>
</tr>
<tr>
<td>2016</td>
<td>7000</td>
<td>6500</td>
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</tbody>
</table>

- DS/RONPD - Initial
- DS/RONPD - Renewal

- 38% decrease
- 36% decrease
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>NCEs</td>
<td>40,000</td>
<td>350,000</td>
<td>350,000</td>
<td>215,000</td>
<td>155,000</td>
</tr>
<tr>
<td><strong>Generic - Initial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>10,000</td>
<td>142,500</td>
<td>142,500</td>
<td>105,500</td>
<td>76,000</td>
</tr>
<tr>
<td>Branded</td>
<td>15,000</td>
<td>180,000</td>
<td>180,000</td>
<td>105,500</td>
<td>76,000</td>
</tr>
<tr>
<td><strong>Generic - Renewal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>7,500</td>
<td>142,500</td>
<td>142,500</td>
<td>74,000</td>
<td>53,500</td>
</tr>
<tr>
<td>Branded</td>
<td>10,000</td>
<td>180,000</td>
<td>180,000</td>
<td>74,000</td>
<td>53,500</td>
</tr>
<tr>
<td><strong>Biotech products - Initial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>7,500</td>
<td>142,500</td>
<td>142,500</td>
<td>235,500</td>
<td>170,000</td>
</tr>
<tr>
<td>Branded</td>
<td>10,000</td>
<td>180,000</td>
<td>180,000</td>
<td>235,500</td>
<td>170,000</td>
</tr>
<tr>
<td><strong>Biotech products - Renewal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>7,500</td>
<td>142,500</td>
<td>142,500</td>
<td>94,000</td>
<td>68,000</td>
</tr>
<tr>
<td>Branded</td>
<td>10,000</td>
<td>180,000</td>
<td>180,000</td>
<td>94,000</td>
<td>68,000</td>
</tr>
<tr>
<td><strong>Other Products - Initial</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>7,500</td>
<td>142,500</td>
<td>142,500</td>
<td>105,500</td>
<td>76,000</td>
</tr>
<tr>
<td>Branded</td>
<td>10,000</td>
<td>180,000</td>
<td>180,000</td>
<td>105,500</td>
<td>76,000</td>
</tr>
<tr>
<td><strong>Other Products - Renewal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unbranded</td>
<td>7,500</td>
<td>142,500</td>
<td>142,500</td>
<td>74,000</td>
<td>53,500</td>
</tr>
<tr>
<td>Branded</td>
<td>10,000</td>
<td>180,000</td>
<td>180,000</td>
<td>74,000</td>
<td>53,500</td>
</tr>
<tr>
<td><strong>Major Variation</strong></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15,000</td>
<td>180,000</td>
<td>100,000</td>
<td>64,500</td>
<td>35,000</td>
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<tr>
<td><strong>Minor Variation-PA</strong></td>
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<td>4,500</td>
<td>24,000</td>
<td>6,500</td>
<td>6,500</td>
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<tr>
<td><strong>Minor Variation-N</strong></td>
<td>500</td>
<td>4,500</td>
<td>2,000</td>
<td>1,500</td>
<td>1,500</td>
</tr>
</tbody>
</table>
Proposed Fee In(de)crease

NCEs and Biotechnological Products

- New Chemical Entities
- Biotechnological Products - Initial
- Biotechnological Products - Renewal

- 2009: 180000
- 2013: 180000
- 2015: 94000
- 2016: 68000

- 2009: 350000
- 2013: 350000
- 2015: 235000
- 2016: 170000

51% 56% 62%
Proposed Fee In(de)crease

Generic and Other Products

Generic and Other Products - Initial

Generic and Other Products - Renewal

180000

180000

105500

76000

53500

50000

70000

90000

110000

130000

150000

170000

190000

2009 2013 2015 2016

58%

70%
### Daily Regulatory Fee: License to Operate

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial (2-year validity)</th>
<th>Daily Fee (730 working days)</th>
<th>Renewal (3-year validity)</th>
<th>Daily Fee (1095 working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Manufacturer (Repacker, Packer)</td>
<td>75,000.00</td>
<td>102.74</td>
<td>114,000.00</td>
<td>104.11</td>
</tr>
<tr>
<td>Drug Trader/ Distributor (Exporter, Importer, Wholesaler)</td>
<td>30,000.00</td>
<td>41.10</td>
<td>36,500.00</td>
<td>33.33</td>
</tr>
<tr>
<td>Drugstore/Pharmacy/ Botica and similar outlets</td>
<td>4,500.00</td>
<td>6.16</td>
<td>6,500.00</td>
<td>5.94</td>
</tr>
<tr>
<td>Retail Outlet for Non-Prescription Drugs (RONPD)</td>
<td>4,500.00</td>
<td>6.16</td>
<td>6,500.00</td>
<td>5.94</td>
</tr>
<tr>
<td>Sponsor/Contract Research Organization</td>
<td>30,000.00</td>
<td>41.10</td>
<td>36,500.00</td>
<td>33.33</td>
</tr>
</tbody>
</table>
# Daily Regulatory Fee: Product Registration

<table>
<thead>
<tr>
<th>Category</th>
<th>Initial (5-year validity)</th>
<th>Daily Fee (1825 working days)</th>
<th>Renewal (5-year validity)</th>
<th>Daily Fee (1825 working days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Chemical Entity (NCE)</td>
<td>155,000.00</td>
<td><strong>84.93</strong></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Generic Drugs</td>
<td>76,000.00</td>
<td><strong>41.64</strong></td>
<td>53,500.00</td>
<td><strong>29.32</strong></td>
</tr>
<tr>
<td>Biological Products</td>
<td>170,000.00</td>
<td><strong>93.15</strong></td>
<td>68,000.00</td>
<td><strong>37.26</strong></td>
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<tr>
<td>Other Drug Product Classification</td>
<td>76,000.00</td>
<td><strong>41.64</strong></td>
<td>53,500.00</td>
<td><strong>29.32</strong></td>
</tr>
</tbody>
</table>
(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. 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 (e.g. pre-evaluation, risk-based evaluation), including policy changes (e.g. unified licensing, e-LTO) all in the direction of a more responsive regulatory agency.
Policies for 2016

• Streamlined Foreign GMP Application
• Notification of Variations
• One step LTO-CPR variation application
• Electronic Registration Process
• Collaborative Review Process
(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

- Will there be a fee for additional sources in the LTO?

- Only those variations identified in the existing policies that will be charged. Add source is not an identified variation in AO 2016-0003
(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 establishments $\rightarrow$ drug products $\rightarrow$ higher risk products $\rightarrow$ more extensive inspection compared to other establishments
(6) Query

• When will the fees be implemented?

• The draft provides 15 days following publication in two newspapers of general circulation
(7) 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
(8) Query

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

- If a variation falls under turned initial, the corresponding variation fee will be followed
(9) 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
(10) Query

• Is the P1,500 fee for CLIDP mean P1,500 per year, or for the registration of the whole product for full validity?

• The P1,500 fee is only for conversion of the CPR to PCPR. The provided fees for generic will be divided to determine the per year fee of the CLIDP
(11) Query

• Will pre-evaluation cover renewal and variation applications?

• Yes, all product applications
(12) Query

- The default validity of CPR is 5 years. Will establishments be given a choice to select the validity.

- No, application submitted, if approved shall be granted 5 years
(13) Query

- When will the fees be reviewed again? The previous fees took 15 years before being reviewed again.

- The draft provides for the creation of a TWG that is responsible for the periodic review of the fees.
(14) Query

• Why are there no fees for promotion?

• The policy for promotion is a joint issuance with DTI. A separate policy will be issued to address this.