# Annex A

## GENERAL REGULATORY FEES AND CHARGES

<table>
<thead>
<tr>
<th>AUTHORIZATION/CERTIFICATION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Issuance of an Electronic Authenticated Copy of the Document</td>
<td>Php2,500.00</td>
</tr>
<tr>
<td>2. Re-issuance of a Lost or Damaged Permit/Certificate</td>
<td>2,500.00</td>
</tr>
<tr>
<td>3. Re-issuance of a Lost or Damaged LTO/CPR</td>
<td>5,000.00</td>
</tr>
<tr>
<td>4. Reconstruction of CPR</td>
<td>10,000</td>
</tr>
<tr>
<td>5. Pre-Market Consultation Fee</td>
<td></td>
</tr>
<tr>
<td>i. Pre-Submission Consultation</td>
<td>10,000/hr.</td>
</tr>
<tr>
<td>ii. Pre-Market Product Development Consultation</td>
<td>15,000/hr.</td>
</tr>
<tr>
<td>6. Legal Consultation Fee</td>
<td>10,000/hr.</td>
</tr>
<tr>
<td>7. Bureau of Customs Clearances</td>
<td></td>
</tr>
<tr>
<td>i. Import Permit for Samples</td>
<td>7,500</td>
</tr>
<tr>
<td>ii. Import Permit for Scientific Research, Education and Development</td>
<td>10,000</td>
</tr>
<tr>
<td>iii. Customs Release for Radiation Device</td>
<td>5,000</td>
</tr>
<tr>
<td>8. Certificate of Donation</td>
<td>5,000</td>
</tr>
<tr>
<td>9. Compassionate Special Permit</td>
<td>5,000</td>
</tr>
<tr>
<td>10. Certificate of Free Sale</td>
<td>2,500</td>
</tr>
<tr>
<td>11. Certificate of No Pending FDA Administrative Case and Unpaid Fees and Penalties</td>
<td>2,500</td>
</tr>
<tr>
<td>12. Permit to Carry/Mail (Personal Use)</td>
<td>500</td>
</tr>
<tr>
<td>13. Permit to Carry/Mail (R&amp; D Use)</td>
<td>10,000</td>
</tr>
<tr>
<td>14. Other Special Permits</td>
<td>10,000</td>
</tr>
</tbody>
</table>
Annex B

FEES AND CHARGES FOR APPLICATIONS FOR LICENSE TO OPERATE

I. VALIDITY PERIOD

<table>
<thead>
<tr>
<th>VALIDITY PERIOD</th>
<th>INITIAL</th>
<th>RENEWAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 YEARS</td>
<td>5 YEARS</td>
<td></td>
</tr>
</tbody>
</table>

* Renewal Fee is equivalent to Seventy Percent (70%) of the Initial License Fee for each application
** Annual Fees apply to both Initial and Renewal LTO

II. CENTER FOR COSMETICS REGULATION AND RESEARCH

A. MANUFACTURERS

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cosmetics Manufacturer</td>
<td>60,000.00</td>
<td>12,000</td>
</tr>
<tr>
<td>2. HUHS/Pesticides Manufacturer</td>
<td>75,000.00</td>
<td>15,000</td>
</tr>
<tr>
<td>3. Toys Manufacturer</td>
<td>30,000.00</td>
<td>7,000</td>
</tr>
<tr>
<td>4. Toys Micro-Scale Manufacturer</td>
<td>TBA</td>
<td>TBA</td>
</tr>
<tr>
<td>6. Cosmetics Micro-Scale Manufacturer</td>
<td>TBA</td>
<td>TBA</td>
</tr>
</tbody>
</table>
## B. DISTRIBUTORS

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. COSMETICS DISTRIBUTORS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importer</td>
<td>50,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>30,000</td>
<td>7,000</td>
</tr>
<tr>
<td>Exporter</td>
<td>15,000</td>
<td>—</td>
</tr>
<tr>
<td>Importer/Wholesaler</td>
<td>75,000</td>
<td>15,000</td>
</tr>
<tr>
<td>Micro-Scale Wholesaler**</td>
<td>TBA</td>
<td>TBA</td>
</tr>
<tr>
<td>On-Line Seller</td>
<td>15,000</td>
<td>3,000</td>
</tr>
</tbody>
</table>

| **2. HUHS/PESTICIDES DISTRIBUTORS** |             |            |
| Importer           | 60,000.00   | 12,000     |
| Wholesaler         | 30,000      | 7,000      |
| Exporter           | 15,000      | 3,000      |
| Importer/Wholesaler | 75,000.00  | 15,000     |
| On-Line Seller     | 25,000      | 5,000      |

| **3. TOYS DISTRIBUTORS** |             |            |
| Importer            | 30,000      | 7,000      |
| Wholesaler          | 30,000      | 7,000      |
| Exporter            | 15,000      | 3,000      |
| Importer/Wholesaler | 75,000.00   | 15,000     |
| Micro-Scale Wholesaler * | TBA | TBA        |
| On-Line Seller      | 15,000      | 3,000      |

* Establishments with <100,000 capitalization
C. VARIATIONS

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>MAJOR VARIATION FEE</th>
<th>MINOR VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. LTO for Cosmetics Manufacturers and Distributors</td>
<td>10,000</td>
<td>5,000</td>
</tr>
<tr>
<td>2. LTO for HUHS/Pesticides Manufacturers and Distributors</td>
<td>20,000</td>
<td>10,000</td>
</tr>
<tr>
<td>3. LTO for Toys Manufacturers and Distributors</td>
<td>10,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>

* Variations do not include change/adding of activities

III. CENTER FOR DRUG REGULATION AND RESEARCH

A. MANUFACTURER, DISTRIBUTOR AND RETAILER

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. DRUG MANUFACTURER</td>
<td>90,000.00</td>
<td>18,000</td>
</tr>
<tr>
<td>B. DRUG DISTRIBUTORS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Importer</td>
<td>60,000</td>
<td>12,000</td>
</tr>
<tr>
<td>2. Wholesaler</td>
<td>30,000</td>
<td>7,000</td>
</tr>
<tr>
<td>3. Exporter</td>
<td>15,000</td>
<td>3,000</td>
</tr>
<tr>
<td>4. Importer/Wholesaler</td>
<td>75,000</td>
<td>15,000</td>
</tr>
<tr>
<td>C. DRUG RETAILERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Retail Pharmacy</td>
<td>20,000.00</td>
<td>5,000</td>
</tr>
<tr>
<td>2. Retail Outlet for Non-Prescription Drugs</td>
<td>10,000.00</td>
<td>2,000</td>
</tr>
<tr>
<td>3. On-Line Pharmacy</td>
<td>15,000.00</td>
<td>3,000</td>
</tr>
<tr>
<td>4. Compounding Pharmacy</td>
<td>25,000.00</td>
<td>5,000</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>-----------</td>
<td>-------</td>
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</table>

### D. OTHER DRUG ESTABLISHMENTS

<table>
<thead>
<tr>
<th>1. Clinical Research Organisation</th>
<th>60,000</th>
<th>12,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Sponsor</td>
<td>60,000</td>
<td>12,000</td>
</tr>
</tbody>
</table>

### B. VARIATIONS

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>MAJOR VARIATION FEE</th>
<th>MINOR VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO for Drug Manufacturers</td>
<td>20,000.00</td>
<td>10,000</td>
</tr>
<tr>
<td>LTO for Drug Distributor</td>
<td>15,000</td>
<td>5,000</td>
</tr>
<tr>
<td>LTO for Drug Retailer</td>
<td>10,000</td>
<td>2,500</td>
</tr>
</tbody>
</table>

* Variations do not include change/adding of activities
IV. CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH

A. MEDICAL DEVICE ESTABLISHMENTS

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Manufacturer</td>
<td>75,000</td>
<td>15,000</td>
</tr>
<tr>
<td>Medical Device Importer</td>
<td>40,000</td>
<td>8,000</td>
</tr>
<tr>
<td>Medical Device Wholesaler</td>
<td>30,000</td>
<td>7,000</td>
</tr>
<tr>
<td>Medical Device Exporter</td>
<td>15,000</td>
<td>3,000</td>
</tr>
<tr>
<td>Medical Device Importer/Wholesaler</td>
<td>60,000</td>
<td>12,000</td>
</tr>
<tr>
<td>Medical Device On-Line Seller</td>
<td>15,000</td>
<td>3,000</td>
</tr>
</tbody>
</table>

B. RADIATION FACILITIES

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE (per device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical X-Ray Facility*</td>
<td>15,000</td>
<td>3,000</td>
</tr>
<tr>
<td>Non-Medical X-Ray Facility**</td>
<td>15,000</td>
<td>3,000</td>
</tr>
<tr>
<td>Specialized Medical Radiation Facility***</td>
<td>25,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Therapeutic Medical Radiation Facility</td>
<td>25,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>

*Medical X-Ray Facility Utilizing X-ray Devices such as: General Radiography and/or Fluoroscopy/Mobile C-Arm, Simulator, Lithotripsy, Bone Densitometry

**Non-Medical X-Ray Facility Utilizing X-Ray Devices for: Industrial, Anti-Crime, Educational and Research, Veterinary, Dental applications

***Specialized Medical Radiation Facility utilizing radiation devices such as: Computed Tomography (CT), Mammography, Interventional Radiology (Cardiac Catheterization), Magnetic Resonance Imaging (MRI)
## C. Variations

<table>
<thead>
<tr>
<th>Type of Authorization</th>
<th>Major Variation Fee</th>
<th>Minor Variation Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO for Medical Device Establishments</td>
<td>20,000</td>
<td>10,000</td>
</tr>
<tr>
<td>LTO for Radiation Facilities (per device)</td>
<td>5,000</td>
<td>2,000</td>
</tr>
</tbody>
</table>

*Variations do not include change/adding of activities*
### V. CENTER FOR FOOD REGULATION AND RESEARCH

#### A. MANUFACTURERS AND DISTRIBUTORS

<table>
<thead>
<tr>
<th>TYPE OF FACILITY</th>
<th>LICENSE FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. FOOD MANUFACTURER (FM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Manufacturer</td>
<td>75,000</td>
<td>15,000</td>
</tr>
<tr>
<td>b. Micro-Scale Manufacturers*</td>
<td>TBA</td>
<td>N/A</td>
</tr>
<tr>
<td>B. FOOD DISTRIBUTOR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Importer</td>
<td>30,000</td>
<td>7,000</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>20,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Exporter</td>
<td>15,000</td>
<td>3,000</td>
</tr>
<tr>
<td>Importer/Wholesaler</td>
<td>50,000</td>
<td>10,000</td>
</tr>
<tr>
<td>On-Line Seller</td>
<td>15,000</td>
<td>3,000</td>
</tr>
</tbody>
</table>

* Establishments with <100,000 capitalization

#### B. VARIATIONS

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>MAJOR VARIATION FEE</th>
<th>MINOR VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTO of Food Manufacturer</td>
<td>10,000</td>
<td>5,000</td>
</tr>
<tr>
<td>LTO of Food Distributor</td>
<td>10,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>

* Variations do not include change/adding of activities
Annex C

FEES AND CHARGES FOR APPLICATIONS FOR

CERTIFICATE OF PRODUCT REGISTRATION

I. VALIDITY PERIOD

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>INITIAL</th>
<th>RENEWAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERTIFICATE FOR PRODUCT REGISTRATION</td>
<td>3 YEARS</td>
<td>5 YEARS</td>
</tr>
<tr>
<td>CERTIFICATE FOR PRODUCT NOTIFICATION</td>
<td>1 YEAR</td>
<td>1 YEAR</td>
</tr>
</tbody>
</table>

* Renewal Fee is equivalent to Seventy Percent (70%) of the Initial Application Fee for each application
** Annual Fees apply to both Initial and Renewal CPR/CPN

II. CENTER FOR COSMETICS REGULATION AND RESEARCH

A. CERTIFICATE OF PRODUCT NOTIFICATION

<table>
<thead>
<tr>
<th>TYPE OF PRODUCT</th>
<th>APPLICATION FEE</th>
<th>ANNUAL FEE (Charged per product)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. COSMETIC PRODUCTS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Product</td>
<td>2,500</td>
<td>2,500</td>
</tr>
<tr>
<td>Per Succeeding Variant</td>
<td>500</td>
<td>N/A</td>
</tr>
<tr>
<td>B. TOYS AND CHILDCARE ARTICLES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per SKU</td>
<td>1,000</td>
<td>N/A</td>
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</table>
### B. CERTIFICATE OF PRODUCT REGISTRATION

<table>
<thead>
<tr>
<th>TYPE OF PRODUCT</th>
<th>APPLICATION FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. HUHS/PESTICIDES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Product</td>
<td>135,000</td>
<td>27,000</td>
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</table>

### C. VARIATION

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>MAJOR VARIATION FEE</th>
<th>MINOR VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPR for HUHS/PESTICIDES</td>
<td>10,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>
## II. CENTER FOR DRUG REGULATION AND RESEARCH

### A. PRODUCT TYPE

<table>
<thead>
<tr>
<th>NEW DRUG APPLICATION</th>
<th>APPLICATION FEE</th>
<th>EVALUATION FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. NEW CHEMICAL ENTITY</strong></td>
<td>100,000</td>
<td>150,000</td>
<td>30,000</td>
</tr>
<tr>
<td><strong>2. VACCINES &amp; BIOLOGICALS</strong></td>
<td>100,000</td>
<td>150,000</td>
<td>30,000</td>
</tr>
<tr>
<td>**3. INNOVATIVE PRODUCTS AND TECHNOLOGIES ***</td>
<td>100,000</td>
<td>150,000</td>
<td>30,000</td>
</tr>
</tbody>
</table>

### 4. GENERICS

#### A. PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10,000</td>
<td>75,000</td>
</tr>
<tr>
<td></td>
<td>5,000</td>
<td>30,000</td>
</tr>
</tbody>
</table>

#### B. NON-PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,500</td>
<td>50,000</td>
</tr>
<tr>
<td></td>
<td>3,500</td>
<td>20,000</td>
</tr>
</tbody>
</table>

### 5. TRADITIONAL and HERBAL MEDICINES

#### A. PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10,000</td>
<td>75,000</td>
</tr>
<tr>
<td></td>
<td>5,000</td>
<td>30,000</td>
</tr>
</tbody>
</table>

#### B. NON-PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,500</td>
<td>50,000</td>
</tr>
<tr>
<td></td>
<td>3,500</td>
<td>20,000</td>
</tr>
</tbody>
</table>
### 6. OTHER DRUG PRODUCTS**

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,500</td>
<td>3,500</td>
</tr>
<tr>
<td>Imported</td>
<td>50,000</td>
<td>20,000</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>10,000</td>
<td>—</td>
</tr>
</tbody>
</table>

### 7. VETERINARY MEDICINES, VACCINES AND BIOLOGICALS

#### A. PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Imported</td>
<td>75,000</td>
<td>30,000</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>15,000</td>
<td>—</td>
</tr>
</tbody>
</table>

#### B. NON-PRESCRIPTION

<table>
<thead>
<tr>
<th></th>
<th>Imported</th>
<th>Locally Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,500</td>
<td>3,500</td>
</tr>
<tr>
<td>Imported</td>
<td>50,000</td>
<td>20,000</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>10,000</td>
<td>—</td>
</tr>
</tbody>
</table>

* e.g. Radio-pharmaceuticals, Blood and Blood Products, Stem Cell, and Human Cell and Tissue-based products

** e.g. Medical Gases

### B. VARIATIONS

<table>
<thead>
<tr>
<th>TYPE OF AUTHORIZATION</th>
<th>MAJOR VARIATION FEE</th>
<th>MINOR VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPR of Imported Drug Products</td>
<td>30,000</td>
<td>10,000</td>
</tr>
<tr>
<td>CPR for a Locally Manufactured</td>
<td>10,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>

### C. OTHER PERMITS

<table>
<thead>
<tr>
<th>PERMIT/CERTIFICATION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Generic Labelling Exemption</td>
<td>5,000</td>
</tr>
<tr>
<td>2. Certificate of Pharmaceutical Product</td>
<td>5,000</td>
</tr>
</tbody>
</table>
### A. Medical Device Products

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>Application Fee (Per Device)</th>
<th>Evaluation Fee (Per Device)</th>
<th>Annual Fee (Per Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>5,000</td>
<td>10,000</td>
<td>2,000</td>
</tr>
<tr>
<td>Class B</td>
<td>10,000</td>
<td>20,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Class C</td>
<td>15,000</td>
<td>45,000</td>
<td>9,000</td>
</tr>
<tr>
<td>Class D (includes devices incorporating medicinal/therapeutic products)</td>
<td>30,000</td>
<td>60,000</td>
<td>12,000</td>
</tr>
</tbody>
</table>

### B. Variations

<table>
<thead>
<tr>
<th>Type of Authorization</th>
<th>Major Variation Fee</th>
<th>Minor Variation Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPR for Class A Devices</td>
<td>2,500</td>
<td>1,000</td>
</tr>
<tr>
<td>CPR for Class B Devices</td>
<td>10,000</td>
<td>5,000</td>
</tr>
<tr>
<td>CPR for Class C Devices</td>
<td>10,000</td>
<td>5,000</td>
</tr>
<tr>
<td>CPR for Class D Devices (includes devices incorporating medicinal/therapeutic products)</td>
<td>20,000</td>
<td>5,000</td>
</tr>
</tbody>
</table>
### C. OTHER PERMITS

<table>
<thead>
<tr>
<th>PERMIT/CERTIFICATION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Quality System Certificate</td>
<td>5,000</td>
</tr>
<tr>
<td>2. Safety Evaluation Report (Per Device)</td>
<td>5,000 per facility/device</td>
</tr>
<tr>
<td>3. Certificate of Radiation Measurement for Extremely Low Frequency (ELF) and Radiofrequency Radiation (RFR) Facilities</td>
<td>14,000 / transmitter site plus transportation cost of the FDA personnel</td>
</tr>
<tr>
<td>4. Pre-Operational Permit for Therapeutic Radiation Facility Utilizing Linear Accelerator (LINAC)</td>
<td>10,000 per LINAC device</td>
</tr>
</tbody>
</table>
# IV. CENTER FOR FOOD REGULATION AND RESEARCH

## A. PRODUCT TYPE

<table>
<thead>
<tr>
<th>PRODUCT TYPE</th>
<th>APPLICATION FEE</th>
<th>ANNUAL FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. FOOD ADDITIVES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imported</td>
<td>3,000</td>
<td>700</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>1,500</td>
<td>—</td>
</tr>
<tr>
<td><strong>2. RAW MATERIALS and OTHER LOW RISK FOOD PRODUCTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imported</td>
<td>3,000</td>
<td>700</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>1,500</td>
<td>—</td>
</tr>
<tr>
<td><strong>3. MEDIUM/HIGH RISK FOOD PRODUCTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imported</td>
<td>5,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>3,000</td>
<td>—</td>
</tr>
<tr>
<td><strong>3. FOOD SUPPLEMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imported</td>
<td>20,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Locally Manufactured</td>
<td>10,000</td>
<td>—</td>
</tr>
</tbody>
</table>

## B. VARIATIONS

<table>
<thead>
<tr>
<th>TYPE OF VARIATION</th>
<th>VARIATION FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amendment</td>
<td>2,500</td>
</tr>
</tbody>
</table>

## C. OTHER PERMITS

<table>
<thead>
<tr>
<th>TYPE OF PERMIT/CERTIFICATION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Analysis Critical Control Point (HACCP) Certification*</td>
<td>10,000/product</td>
</tr>
<tr>
<td>Sangkap Pinoy Seal</td>
<td>8,000</td>
</tr>
</tbody>
</table>

* Validity: Three (3) years
**Annex D**

**GOOD MANUFACTURING PRACTICES (GMP) CONFORMITY ASSESSMENT OF MANUFACTURERS OF DRUG PRODUCTS**

**I. GMP CONFORMITY ASSESSMENT OF OVERSEAS MANUFACTURERS OF DRUG PRODUCT**

<table>
<thead>
<tr>
<th>ASSESSMENT TYPE *</th>
<th>FEE</th>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Verification of GMP Standard (GMP Evidence Evaluation)</td>
<td>50,000</td>
<td>Per manufacturing site</td>
</tr>
<tr>
<td>2. Quality System Dossier (QSD) Evaluation</td>
<td>75,000</td>
<td>Per manufacturing site (one-time payment)</td>
</tr>
<tr>
<td>3. On-site GMP audit of manufacturer located in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. ASEAN country</td>
<td>USD 7,000</td>
<td>Per manufacturing site</td>
</tr>
<tr>
<td>B. Other Asian countries</td>
<td>USD 10,000</td>
<td>Per manufacturing site</td>
</tr>
<tr>
<td>C. Any other country</td>
<td>USD 20,000</td>
<td>Per manufacturing site</td>
</tr>
<tr>
<td>D. Listed Fee **</td>
<td>USD 12,000</td>
<td>Per manufacturing site</td>
</tr>
</tbody>
</table>

* All new overseas manufacturers who intend to register their drug products in the Philippines will be subjected to GMP Conformity Assessment. The service charge varies according to the geographical location of manufacturer. For the purpose of the application of inspection fees, ‘manufacturer’ encompasses all types of manufacturing, including: packaging, re-packaging, labeling and re-labeling. A fee is due only when manufacturer is notified that an inspection is being prepared. Listed fees include travel and accommodation costs of the 2- or 3-member inspection team.

**II. GMP CONFORMITY ASSESSMENT LOCAL/DOMESTIC MANUFACTURERS OF DRUG PRODUCT**

<table>
<thead>
<tr>
<th>ASSESSMENT TYPE</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for GMP Certificate</td>
<td>50,000</td>
</tr>
<tr>
<td>Domestic Manufacturing Inspection</td>
<td>60,000</td>
</tr>
</tbody>
</table>

* All local manufacturing facilities engaged in the manufacture or assembly of drug products must be licensed with the Philippine FDA. The manufacturers are expected to comply with the relevant legislative and regulatory requirements, and GMP standard
### Annex E

LABORATORY FEES FOR CERTIFICATION

<table>
<thead>
<tr>
<th>CERTIFICATION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. GENERAL PERMIT AND/OR APPROVAL</strong></td>
<td></td>
</tr>
<tr>
<td>I. Sustainability Evaluation of Food Contact Materials</td>
<td>2,500</td>
</tr>
<tr>
<td>II. Evaluation of Test Results from Accredited Laboratories</td>
<td>2,500</td>
</tr>
<tr>
<td><strong>B. LOT RELEASE CERTIFICATE</strong></td>
<td></td>
</tr>
<tr>
<td>I. Single Component</td>
<td>3,000</td>
</tr>
<tr>
<td>II. Multiple Component</td>
<td>4,500</td>
</tr>
<tr>
<td><strong>C. BATCH NOTIFICATION CERTIFICATE</strong></td>
<td>6,500</td>
</tr>
</tbody>
</table>