Annex A

GENERAL REGULATORY FEES AND CHARGES

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

Annex B

FEES AND CHARGES FOR APPLICATIONS FOR

LICENSE TO OPERATE

I. VALIDITY PERIOD

	INITIAL	RENEWAL
VALIDITY PERIOD	**3 YEARS**	**5 YEARS**

* 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

TYPE OF FACILITY	LICENSE FEE	ANNUAL FEE
1. Cosmetics Manufacturer	60,000.00	12,000
2. HUHS/Pesticides Manufacturer	75,000.00	15,000
3. Toys Manufacturer	30,000.00	7,000
4. Toys Micro-Scale Manufacturer	TBA	TBA
6. Cosmetics Micro-Scale Manufacturer	TBA	TBA

B. DISTRIBUTORS

TYPE OF FACILITY	LICENSE FEE	ANNUAL FEE
1. COSMETICS DISTRIBUTORS		
Importer	50,000	10,000
Wholesaler	30,000	7,000
Exporter	15,000	—
Importer/Wholesaler	75,000	15,000
Micro-Scale Wholesaler**	TBA	TBA
On-Line Seller	15,000	3,000
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

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
1. LTO for Cosmetics Manufacturers and Distributors	10,000	5,000
2. LTO for HUHS/Pesticides Manufacturers and Distributors	20,000	10,000
3. LTO for Toys Manufacturers and Distributors	10,000	5,000

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

III. CENTER FOR DRUG REGULATION AND RESEARCH

A.MANUFACTURER, DISTRIBUTOR AND RETAILER

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

4. Compounding Pharmacy	25,000.00	5,000
D. OTHER DRUG ESTABLISHMENTS		
1. Clinical Research Organisation	60,000	12,000
2. Sponsor	60,000	12,000

B. VARIATIONS

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
LTO for Drug Manufacturers	20,000.00	10,000
LTO for Drug Distributor	15,000	5,000
LTO for Drug Retailer	10,000	2,500

* Variations do not include change/adding of activities

IV. CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH

A. MEDICAL DEVICE ESTABLISHMENTS

TYPE OF FACILITY	LICENSE FEE	ANNUAL FEE
Medical Device Manufacturer	75,000	15,000
Medical Device Importer	40,000	8,000
Medical Device Wholesaler	30,000	7,000
Medical Device Exporter	15,000	3,000
Medical Device Importer/Wholesaler	60,000	12,000
Medical Device On-Line Seller	15,000	3,000

B. RADIATION FACILITIES

TYPE OF FACILITY	LICENSE FEE	ANNUAL FEE (per device)
Medical X-Ray Facility*	15,000	3,000
Non-Medical X-Ray Facility**	15,000	3,000
Specialized Medical Radiation Facility***	25,000	5,000
Therapeutic Medical Radiation Facility	25,000	5,000

*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

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
LTO for Medical Device Establishments	20,000	10,000
LTO for Radiation Facilities (per device)	5,000	2,000

* Variations do not include change/adding of activities

V. CENTER FOR FOOD REGULATION AND RESEARCH

A.MANUFACTURERS AND DISTRIBUTORS

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

* Establishments with <100,000 capitalization

B. VARIATIONS

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
LTO of Food Manufacturer	10,000	5,000
LTO of Food Distributor	10,000	5,000

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

Annex C

FEES AND CHARGES FOR APPLICATIONS FOR

CERTIFICATE OF PRODUCT REGISTRATION

I. VALIDITY PERIOD

TYPE OF AUTHORIZA-TION	INITIAL	RENEWAL
CERTIFICATE FOR PRODUCT REGISTRATION	**3 YEARS**	**5 YEARS**
CERTIFICATE FOR PRODUCT NOTIFICATION	**1 YEAR**	**1 YEAR**

* 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

TYPE OF PRODUCT	APPLICATION FEE	ANNUAL FEE (Charged per product)
A. COSMETIC PRODUCTS		
Single Product	2,500	2,500
Per Succeeding Variant	500	N/A
B. TOYS AND CHILDCARE ARTICLES		
Per SKU	1,000	N/A

B. CERTIFICATE OF PRODUCT REGISTRATION

TYPE OF PRODUCT	APPLICATION FEE	ANNUAL FEE
A. HUHS/PESTICIDES		
Per Product	135,000	27,000

C. VARIATION

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
CPR for HUHS/PESTICIDES	10,000	5,000

II. CENTER FOR DRUG REGULATION AND RESEARCH

A.PRODUCT TYPE

NEW DRUG APPLICATION	APPLICATION FEE	EVALUATION FEE	ANNUAL FEE
1. NEW CHEMICAL ENTITY	100,000	150,000	30,000
2. VACCINES & BIOLOGICALS	100,000	150,000	30,000
3. INNOVATIVE PRODUCTS AND TECHNOLOGIES *	100,000	150,000	30,000
4. GENERICS			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—
5. TRADITIONAL and HERBAL MEDICINES			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—

6. OTHER DRUG PRODUCTS**			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—
7. VETERINARY MEDICINES, VACCINES AND BIOLOGICALS			
A. PRESCRIPTION			
Imported	10,000	75,000	15,000
Locally Manufactured	5,000	30,000	—
B. NON- PRESCRIPTION			
Imported	7,500	50,000	10,000
Locally Manufactured	3,500	20,000	—

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

B. VARIATIONS

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
CPR of Imported Drug Products	30,000	10,000
CPR for a Locally Manufactured	10,000	5,000

C. OTHER PERMITS

PERMIT/CERTIFICATION	FEE
1. Generic Labelling Exemption	5,000
2. Certificate of Pharmaceutical Product	5,000

III. CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH

A.MEDICAL DEVICE PRODUCTS

RISK CLASS	APPLICATION FEE (PER DEVICE)	EVALUATION FEE (PER DEVICE)	ANNUAL FEE (Per Device)
CLASS A	5,000	10,000	2,000
CLASS B	10,000	20,000	5,000
CLASS C	15,000	45,000	9,000
CLASS D (includes devices incorporating medicinal/therapeutic products)	30,000	60,000	12,000

B.VARIATIONS

TYPE OF AUTHORIZATION	MAJOR VARIATION FEE	MINOR VARIATION FEE
CPR for CLASS A Devices	2,500	1,000
CPR for CLASS B Devices	10,000	5,000
CPR for CLASS C Devices	10,000	5,000
CPR for CLASS D Devices (includes devices incorporating medicinal/therapeutic products)	20,000	5,000

C.OTHER PERMITS

PERMIT/CERTIFICATION	FEE
1. Quality System Certificate	5,000
2. Safety Evaluation Report (Per Device)	5,000 per facility/device
3. Certificate of Radiation Measurement for Extremely Low Frequency (ELF) and Radiofrequency Radiation (RFR) Facilities	14,000 / transmitter site plus transportation cost of the FDA personnel
4. Pre-Operational Permit for Therapeutic Radiation Facility Utilizing Linear Accelerator (LINAC)	10,000 per LINAC device

IV. CENTER FOR FOOD REGULATION AND RESEARCH

A.PRODUCT TYPE

PRODUCT TYPE	APPLICATION FEE	ANNUAL FEE
1. FOOD ADDITIVES		
Imported	3,000	700
Locally Manufactured	1,500	—
2**. RAW MATERIALS and OTHER LOW RISK FOOD PRODUCTS**		
Imported	3,000	700
Locally Manufactured	1,500	—
3**. MEDIUM/HIGH RISK FOOD PRODUCTS**		
Imported	5,000	1,000
Locally Manufactured	3,000	—
3**. FOOD SUPPLEMENT**		
Imported	20,000	5,000
Locally Manufactured	10,000	—

B.VARIATIONS

TYPE OF VARIATION	VARIATION FEE
Amendment	2,500

C. OTHER PERMITS

TYPE OF PERMIT/CERTIFICATION	FEE
Hazard Analysis Critical Control Point (HACCP) Certification*	10,000/product
Sangkap Pinoy Seal	8,000

* 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

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

* 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.

** To cover costs and reasonable expenses by each inspector, including costs for travel/transportation fare, accommodation, and per diem/allowance.

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

ASSESSMENT TYPE	FEE
Application for GMP Certificate	50,000
Domestic Manufacturing Inspection	60,000

* 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

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