



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
San Lazaro Compound, Rizal Avenue, Manila
Telephone No: 743-83-01 to 23 loc. 1125-1126

December 11, 2000

ADMINISTRATIVE ORDER

No. 163-Bs. 2000

SUBJECT: Revised Schedule of Fees and Charges for the services rendered by the Bureau of Food and Drugs.

The Department of Health pursuant to Section 1 of Executive Order No. 197 which provides that "All departments, bureaus, offices, agencies and units, including government owned or controlled corporations are hereby directed to review and upgrade their rates of fees and charges by not less than twenty percent (20%)" hereby prescribes the revised schedule of fees and charges for the services rendered by the Bureau of Food and Drugs.

A. Fees for License to Operate of Establishments dealing with products regulated by BFAD

Classification	Fees	
	Initial (1 year validity)	Renewal (2 years validity)
1. Drug Outlets:		
1.1 Drugstores, Hospital Pharmacy	2,000.00	4,000.00
1.2 Chinese Drugstore	1,000.00	2,000.00
1.3 Retail Outlet for Non-Prescription Drugs Only	1,000.00	2,000.00
2. Drug Distributors: (Importer / Wholesaler / Exporter)	5,000.00	10,000.00
3. Cosmetic Distributors : (Importer / Wholesaler / Exporter)	4,000.00	8,000.00
4. Medical Devices Distributors : (Importer / Wholesaler / Exporter)	4,000.00	8,000.00
5. Food Distributors : (Importer / Wholesaler / Exporter)	5,000.00	10,000.00
6. Household Hazardous Substances Distributors : (Importer / Wholesaler / Exporter)	4,000.00	8,000.00

INS RECORDS SECTION, D.
Signed
Received in the Records
Section on 12/11/00

Classification	Fees	
	Initial (1 year validity)	Renewal (2 years validity)
7. Drug Manufacturer		
7.1 20 Million & below	10,000.00	20,000.00
7.2 over 20 Million but below 50 Million	15,000.00	30,000.00
7.3 50 Million and above	20,000.00	40,000.00
8. Drug Traders		
8.1 20 Million and below	3,000.00	6,000.00
8.2 over 20 Million but below 50 Million	5,000.00	10,000.00
8.3 50 Million and above	7,000.00	14,000.00
9. Cosmetic Manufacturer		
9.1 20 Million and below	5,000.00	10,000.00
9.2 over 20 Million but below 50 Million	10,000.00	20,000.00
9.3 50 Million and above	15,000.00	30,000.00
10. Cosmetic Trader		
10.1 20 Million and below	3,000.00	6,000.00
10.2 over 20 Million but below 50 Million	5,000.00	10,000.00
10.3 50 Million and above	7,000.00	14,000.00
11. Medical Device Manufacturer		
11.1 20 Million and below	5,000.00	10,000.00
11.2 over 20 Million but below 50 Million	7,000.00	14,000.00
11.3 50 Million and above	10,000.00	20,000.00
12. Medical Device Trader		
12.1 20 Million and below	3,000.00	6,000.00
12.2 over 20 Million but below 50 Million	5,000.00	10,000.00
12.3 50 Million and above	7,000.00	14,000.00
13. Food Manufacturer		
13.1 10 Million and below	3,000.00	6,000.00
13.2 over 10 Million but below 20 Million	5,000.00	10,000.00
13.3 20 Million but below 50 Million	10,000.00	20,000.00
13.4 50 Million and above	15,000.00	30,000.00
14. Household Hazardous Substances Manufacturers		
14.1 10 Million and below	3,000.00	6,000.00
14.2 over 10 Million but below 20 Million	5,000.00	10,000.00
14.3 20 Million but below 50 Million	10,000.00	20,000.00
14.4 50 Million and above	15,000.00	30,000.00

B. Fees for Product Registration

<i>Classification</i>	<i>Fees</i>	
	Initial (5 years validity)	Renewal (5 years validity)
1. Drugs		
1.1 Monitored Release for New Drug	20,000.00 (3 years)	
1.2 Unbranded Application	10,000.00	7,500.00
1.3 Branded Application	15,000.00	10,000.00
1.4 Re-application Fee for Drug	1,000.00	
2. Medical Device	1,500.00 (1 year)	5,000.00
3. Diagnostic Reagents	1,500.00 (1 year)	5,000.00
4. Processed Food		
4.1 Category I (Imported)	2,000.00 (2 years)	3,000.00 (3 years)
4.2 Category II (Imported)	3,000.00 (2 years)	4,500.00 (3 years)
4.3 Food Supplement	3,000.00 (2 years)	4,500.00 (3 years)
4.4 Bottled Water	2,000.00 (2 years)	3,000.00 (3 years)
4.5 Locally Manufactured Food Products	2,000.00 (2 years)	3,000.00 (3 years)
5. Household Hazardous Substances	1,500.00 (2 years)	2,250.00 (3 years)
6. Cosmetics Specialties		
6.1 Listing	1,500.00 (2 years)	2,250.00 (3 years)
6.2 Regular	1,500.00 (2 years)	4,750.00 (5 years)
7. Re-application fee for all products	1,000.00	

C. Cost of Laboratory Analysis:

<i>Classification</i>	<i>Fees</i>
A. Physico-chemical Analysis:	
a.1. Drugs and Antibiotics	
Visual examination	300.00
Assay/Potency (Single Component)	1,500.00
Assay/Potency (Multi-Component)	2,000.00
Dissolution Test	2,000.00
Disintegration Test	350.00
Hardness Test	350.00
Identification Test	500.00
Purity Test/Related Substances	500.00
Moisture Content	300.00
Loss on Drying	300.00
pH	300.00
Vitamins –	
Vitamin A	1,000.00
Vitamin B ₁ , B ₂ , B ₆	2,000.00
Vitamin C (Ascorbic Acid)	500.00


<i>Classification</i>	<i>Fees</i>
Vitamin E	500.00
Other Vitamins	500.00
Minerals	800.00
a.2. Diagnostic Reagents	1,000.00
a.3. Medical Devices	1,500.00
a.4. Cosmetic	
Assay	1,200.00
Identification Tests	500.00
Volatile/Non-volatile matters	500.00
a.5. Food Products	
Moisture	300.00
Protein	1,000.00
Fat/Oil	500.00
Starch	500.00
Glucose	500.00
Sucrose	500.00
Lactose	500.00
Crude fiber	500.00
Dietary fiber	2,000.00
Total Solids	300.00
Soluble Solids	300.00
Water Insoluble Solids	300.00
Ash	300.00
Acid Insoluble Ash	500.00
Saponification Number	500.00
Viscosity	300.00
Refractive Index	300.00
Peroxide Value	500.00
Free Fatty Acids	500.00
Permanganate Oxidation Number (PON)	500.00
Total Acidity	300.00
Water Activity	500.00
Vacuum	300.00
Minerals	1,000.00
Amino Acids (LC)	2,000.00
Proline	500.00
<u>Additives:</u>	
Nitrate	500.00
Nitrite	500.00
Sodium Benzoate	500.00
Sorbic Acid	500.00
Food Color	300.00/color
Sodium Metabisulfite	500.00
Bromates	500.00
BHT	500.00
BHA	500.00

<i>Classification</i>	<i>Fees</i>
Aspartame	500.00
Saccharin	500.00
Monosodium Glutamate	500.00
<u>Micronutrients:</u>	
Vitamin A	1,000.00
Vitamin E	1,000.00
Beta Carotene	1,000.00
Vitamin C	500.00
Vitamin B ₁ ,B ₆	1,000.00
Vitamin B ₂ ,B ₆ , Niacin	1,000.00
Iodine	500.00
Iron	500.00
<u>Contaminants:</u>	
Borax	300.00
Aflatoxin	2,000.00
Total Heavy Metals	500.00
Lead	500.00
Cadmium	300.00
Chromium	300.00
Arsenic	300.00
Mercury	300.00
Tin	300.00
Cyanide	300.00
Histamine	1,500.00
Filth	500.00
Formalin	500.00
Pesticide Residue	2,000.00
Alcohol Content	1,000.00
Gas Volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
a.6. Food Supplements	4,000.00
a.7. Beverages	
Alcohol Content	1,000.00
Gas Volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
a.8. Bottled Water	2,000.00
a.9. Food Chemicals/Additives	
Direct	1,000.00
Indirect	500.00
a.10. Containers/Wrappers	
Migratable Substances	1,000.00

<i>Classification</i>	<i>Fees</i>
Plastic Additives	500.00
Cellulosic Materials for Pesticide Residue	1,500.00
Materials Testing	500.00
B. Microbiological Assay (Potency of Antibiotic)	2,500.00
C. Sterility Test (Injectables, Medical Devices and Large Volume Parenterals)	2,500.00
D. Microbial Limit Tests	
Aerobic Plate Count	500.00
Aerobic Halophilic Count	500.00
Aerobic Psychrophilic Count	500.00
Aerobic Thermophilic Spore Count	500.00
Coliform Plate count	500.00
Coliforms/E. Coli (MPN)	500.00
Fecal Streptococci	600.00
Yeast and Mold Count	500.00
Halophilic Yeast Count	500.00
Staphylococcus Aureus Count	600.00
Pseudomonas Aeruginosa	600.00
Identification of Microorganisms	
Presumptive Test	600.00
Confirmatory Test (complete biochemical reaction)	2,000.00/organism
Commercial Sterility of Thermally Processed Foods in Hermetically Sealed Containers	1,000.00
E. Bioassay Test	
Depressor Substances Test	5,500.00
Skin Irritation Test	5,500.00
Eye Irritation Test	5,700.00
Paralytic Shellfish Poisoning Test (Red Tide)	1,000.00
Safety Test	1,500.00
Acute Toxicity Test (Rat)	22,000.00
Acute Toxicity Test (Mouse)	10,000.00
Pyrogen test	5,200.00
Bacterial Endotoxin Test (LAL)	4,000.00
F. Others	
1. Authentication Fees:	
1.1 Express Lane (per page)	100.00
1.2 Regular Lane (per page)	50.00

<i>Classification</i>	<i>Fees</i>
2. Certifications / Relssuances / Clearances	
2.1 Free Sale/CGMP (Certificate of Pharmaceutical Product)	500.00
2.2 Non-Registrable	500.00
2.3 GMP Certificate	500.00
2.4 Products/Raw Materials for Export	500.00
2.5 Re-issuance of Valid CPR/LTO (for lost of CPR or LTO)	500.00
2.6 Products for Mailing/Hand-Carry	50.00 / certificate
2.7 Medical Director	500.00
2.8 Permit to Import	500.00
2.9 Clearances	500.00
2.10 Product Classification, Exemptions and all other Certification	500.00
3. Amendments :	
3.1 Amendment of CPR's / LTO's	500.00
3.2 Extension of Shelf Life	1,000.00
4. Additional Source of Supplier for LTO (For Importer / Wholesaler / Distributor having more than 5 sources per supplier).	200.00
5. Pre-site inspection	1,500.00 + additional cost of transport & per diem

This Administrative Order shall take effect fifteen (15) calendar days after publication in two newspapers of general circulation or in the Official Gazette. All other administrative issuance's inconsistent with the provisions hereof are hereby repealed and/or modified accordingly.


ALBERTO G. ROMUALDEZ, JR., MD
 Secretary of Health