

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SAN LAZARO COMPOUND
RIZAL AVENUE, STA. CRUZ
MANILA, PHILIPPINES
TEL. NO. 711-80-80

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, dated January 13, 2000, 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.

A. Fees for Licensing of Establishments regulated by BFAD (LTO)

Classification	Fees (Pesos)	
	Initial (1 year validity)	Renewal (2 years validity)
1. Drug Outlets 1.1. Drugstore, Hospital Pharmacy 1.2. Chinese Drugstore 1.3. Retail outlet for non-prescription drugs only	1,000.00	2,000.00
2. Drug Distributors Importer, Exporter, Wholesaler	5,000.00	10,000.00
3. Medical Devices Distributors Importer, Exporter, Wholesaler	4,000.00	8,000.00
4. Food Distributors Importer, Exporter, Wholesaler	4,000.00	8,000.00
5. Iodized Salt Importer	1,000.00	2,000.00
6. Cosmetics Distributors Importer, Exporter, Wholesaler	3,000.00	6,000.00
7. Household Hazardous Substances Importer, Exporter, Wholesaler	3,000.00	6,000.00

Signed AO
Received in the Records
Section on 9/24/01

8. Drug Manufacturer		
8.1 20 Million and below	10,000.00	20,000.00
8.2 over 20 Million but below 50 Million	15,000.00	30,000.00
8.3 50 Million and above	20,000.00	40,000.00
9. Drug Trader		
9.1 20 Million and below	3,000.00	6,000.00
9.2 over 20 Million but below 50 Million	5,000.00	10,000.00
9.3 50 Million and above	7,000.00	14,000.00
10. Cosmetics Manufacturer		
10.1 20 Million and below	5,000.00	10,000.00
10.2 over 20 Million but below 50 Million	10,000.00	20,000.00
10.3 50 Million and above	15,000.00	15,000.00
11. Cosmetics Trader		
11.1 20 Million and below	3,000.00	6,000.00
11.2 over 20 Million but below 50 Million	5,000.00	10,000.00
11.3 50 Million and above	7,000.00	14,000.00
12. Medical Device Manufacturer		
12.1 20 Million and below	5,000.00	10,000.00
12.2 over 20 Million but below 50 Million	7,000.00	14,000.00
12.3 50 Million and above	10,000.00	20,000.00
13. Medical Device Trader		
13.1 20 Million and below	3,000.00	6,000.00
13.2 over 20 Million but below 50 Million	5,000.00	10,000.00
13.3 50 Million and above	7,000.00	14,000.00
14. Food Manufacturer		
14.1 1 Million and below	1,000.00	2,000.00
14.2 over 1 Million but below 5 Million	2,000.00	4,000.00
14.3 5 Million but below 10 Million	3,000.00	6,000.00
14.4 10 Million but below 20 Million	5,000.00	10,000.00
14.5 20 Million but below 50 Million	10,000.00	20,000.00
14.6 50 Million and above	15,000.00	30,000.00
15. Household Hazardous Substance Manufacturer		
15.1 1 Million and below	1,000.00	2,000.00
15.2 over 1 Million but below 5 Million	2,000.00	4,000.00
15.3 5 Million but below 10 Million	3,000.00	6,000.00
15.4 10 Million but below 20 Million	5,000.00	10,000.00
15.5 20 Million but below 50 Million	10,000.00	20,000.00
15.6 50 Million and above	15,000.00	30,000.00

16. Others	
16.1 Pre-Site Inspection of Establishments	- 500.00 +cost of transportation & accommodation if outside M.Mla.
16.2 Clearance to Import Antibiotics	- 300.00
16.3 Amendment of LTO or Re-issuance (if lost)	- 500.00
16.4 Addition or deletion of sources	- 50.00 / source; 300 if > 5 sources
16.5 Certification/Clearance for BOC purpose and Donation	- 300.00
16.6 Change of business name/address of supplier	- 300.00

Note:

1. The fees charged for manufacturers and traders of products regulated by BFAD are based on the capital invested.
2. Renewal of LTO shall be on the anniversary of its issuance and shall be valid for two years.
3. A surcharge of 25% of annual fee shall be charged per quarter (every three months) of delay in filing an application for renewal of the LTO .

B. Fees for Registration of Products Regulated by BFAD

Classification	Fees (Pesos)	
	Initial (for one year)	Renewal (for 5 years)
1. Drugs		
1.1 New Drug / Monitored Release	20,000.00 / 3 yrs	
1.2 Unbranded	2,000.00	7,500.00
1.3 Branded	3,000.00	10,000.00
2. Medical Device	1,500.00	5,000.00
3. Diagnostic Reagent	1,500.00	5,000.00
4. Food		
4.1 Category 1	200.00	1,000.00
4.2 Category 2	250.00	1,250.00
4.3 Food Supplement	1,000.00	5,000.00
4.4 Bottled Water	1,000.00	5,000.00
5. Cosmetics		
5.1 Listing	500.00	2,500.00
5.2 Registration	750.00	3,750.00
	+ 100.00 per variant or 50.00 per variant if more than 6	
6. Household Hazardous Substances (HHS)	500.00	2,500.00

7. Others:	(per product)
7.1 Product Classification (by ACB)	500.00
7.2 Certificate of Exemption from registration (<i>non-registrable product</i>)	500.00
7.3 Re-application	
7.3.1 Drug, Device, Reagent	1,000.00
7.3.2 Food	200.00
7.3.3 Cosmetics	250.00
7.3.4 HHS	250.00
7.4 Amendment of CPR	
7.4.1 Food	200.00
7.4.2 Drug, Devices, Reagent (<i>Change of business name/address; change of importer or distributor; or additional package size</i>)	500.00
7.4.3 Cosmetics / HHS	300.00
7.5 Re-issuance of CPR (for lost CPR)	500.00
7.6 Extension of Shelf-life	1,000.00
7.7 Food: Provisional Permit to Market (locally manufactured)	200.00 / document
7.8 Drug	
7.8.1 Accreditation of Bioequivalence Testing Center (3-year validity)	10,000.00 / year
7.8.2 Periodic inspection of Bioequivalence Testing Center	5,000.00 / audit
7.8.3 Review by ACB	
a. New Chemical Entity	5,000.00
b. New Dosage Form / Strength	2,500.00
c. New Formulation (SUPAC Guidelines)	2,500.00
d. New / Additional Indication	2,500.00
e. Protocol for MR / Post Marketing Surveillance	2,500.00
f. Protocol for Clinical Study (Phases I, II, III)	2500.00 / phase
g. Amendment of Protocol	1,000.00 / phase
h. Monitored Release Extension	6,000.00 / year
i. Compassionate Special Permit (<i>except drugs for cancer, HIV / AIDS, and other life threatening diseases</i>)	500.00

j. Re-classification: Rx to OTC, OTC to HHR	3,000.00
k. Rationale for Fixed-Dose-Combination (FDC)	3,000.00
7.8.4 Approval for change in packaging materials / revision of packaging design (ex.for mergers)	500.00
7.8.5 Change or addition of brand name	2,500.00
7.8.6 Importation Clearance for Clinical Study	500.00/ product / year
7.9 Cosmetics	
7.9.1 Approval for product / label claim (by ACB)	500.00

Note:

1. Initial registration for the different categories of products may be valid for 2, 3, 4 or 5 years with payment of corresponding fees, except food supplement for which maximum is 2 years.
2. Renewal of registration is for a five-year duration starting on the date of expiration of the CPR.
3. A surcharge of 50% of renewal fee is collected if renewal registration is submitted within 3 months after the expiration of the Certificate of Product Registration (CPR). Application for renewal filed beyond the third month after expiration of CPR shall be considered as initial application.
4. Local or imported food products shall be classified according to Category 1 and Category 2 of Bureau Order No. 163, s.1997

C. Cost of Laboratory Analysis

CLASSIFICATION	FEES
1. Physico-chemical Analysis	
1.1 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 B1, B2, B6	2,000.00
Vitamin C (Ascorbic Acid)	500.00
Vitamin E	500.00
Other Vitamins	500.00
Minerals	800.00
1.2 <i>In Vitro</i> Diagnostic Reagents	1,000.00
1.3 Medical Devices	1,500.00
1.4 Cosmetics	
Assay	1,200.00
Identification Test	500.00
Volatile / Non-volatile Matters	500.00
1.5 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 Fibers	500.00
Dietary Fibers	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
Additives –	
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
Aspartame	500.00
Saccharin	500.00
Monosodium Glutamate	500.00
Micronutrients:	
Vitamin A	1,000.00
Vitamin E	1,000.00
Beta Carotene	1,000.00
Vitamin C	500.00

Vitamin B1, B6	1,000.00
Vitamin B1, B6, Niacin	1,000.00
Iodine	500.00
Iron	500.00
Contaminants:	
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
1.6 Food Supplements	4,000.00
1.7 Beverages	
Alcohol Content	1,000.00
Gas Volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00

1.8 Bottled Water	2,000.00
1.9 Food Chemicals / Additives	
Direct	1,000.00
Indirect	500.00
1.10 Containers / Wrappers	
Migratable Substances	1,000.00
Plastic Additives	500.00
Cellulosic Materials for Pesticide Residue	1,500.00
Materials Testing	500.00
2. Microbiological Assay (Potency of Antibiotics)	2,500.00
3. Sterility Test (Injectables, Medical Devices and Large Volume Parenterals)	2,500.00
4. Microbial Limit Tests	
Aerobic Plate Count	500.00
Aerobic Halophilic Count	500.00
Aerobic Thermophilic Count	500.00
Coliform Plate Count	500.00
Coliform / <i>E.coli</i> (MPN)	500.00
Fecal Streptococci	600.00
Yeast and Mold Count	500.00
Halophilic Yeast Count	500.00
<i>Staphylococcus aureus</i> Count	600.00
<i>Pseudomonas aeruginosa</i>	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
5. Bioassay Tests	
Depressor Substance 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

D. Other Fees and Charges

1. Authentication Fees	(per page)
1.1 Express Lane	100.00
1.2 Regular Lane	50.00
2. Certification / Re-issuance / Clearance	(per certificate)
2.1 Medical Director	500.00
2.2 Free Sale / CGMP / Certificate of Pharmaceutical Product	500.00
2.3 Permit to Export: Product / Raw Material	500.00
2.4 Permit to hand carry / mail of drug product	50.00
2.5 Permit to release drug product for personal use from BOC	50.00
2.6 All other certificates / clearances	500.00
3. Copy of laws, rules, regulations, & standards	1.00 / page

Existing issuance and orders related to the subject which are inconsistent with this Administrative Order are hereby rescinded or revoked.

This Order shall take effect fifteen (15) days after publication in a newspaper of general circulation.


MANUEL M. DAYRIT, M.D., MSc.
 Secretary of Health