

REVISED 2000 SCHEDULE OF FEES AND CHARGES FOR THE CORRESPONDING SERVICES RENDERED BY THE BUREAU OF LICENSING AND REGULATION, BUREAU OF RESEARCH AND LABORATORIES, BUREAU OF FOOD ...

BFD ADMINISTRATIVE ORDER NO. 104-A, S. 2000, April 17, 2000

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Revised 2000 Schedule of Fees and Charges for the corresponding services rendered by the Bureau of Licensing and Regulation, Bureau of Research and Laboratories, Bureau of Food and Drugs and National Quarantine Office.

The Department of Health pursuant to Executive Order No. 197 Section 1: “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 2000 schedule of fees and charges for compliance.

I. BUREAU OF FOOD AND DRUGS

A. Fee for License to Operate establishments dealing with products regulated by BFAD.

CLASSIFICATION

FEES

Initial

Renewal

(1 year validity)

(2 years validity)

1. Drug Outlets

1.1 Drugstores, Hospital Pharmacy

P2,000.00 P4,000.00

1.2 Chinese Drugstore P1,000.00 P2,000.00

1.3 Retail Outlet for Non-Prescription Drugs only P1,000.00 P2,000.00

2. Drug Distributors: P5,000.00 P10,000.00

(Importer/Wholesaler)

3. Cosmetic Distributor P4,000.00 P8,000.00

(Importer/Wholesaler/Exporter)

4. Medical Devices Distributors P4,000.00 P8,000.00

(Importer/Wholesaler/Exporter)

5. Food Distributors P5,000.00 P10,000.00

(Importer/Wholesaler/Exporter)

6. Household Hazardous Substances Distributors

(Importer/Wholesaler/Exporter) P4,000.00 P8,000.00

7. Drug manufacturer

7.1 P20M and below P10,000.00 P20,000.00

7.2 Over P30M but below P50M P15,000.00 P30,000.00

7.3 P50M and above P20,000.00 P40,000.00

8. Drug Traders

8.1 P20M and below P3,000.00 P6,000.00

8.2 Over P20M but below P50M P5,000.00 P10,000.00

8.3 P50M and above P7,000.00 P14,000.00

9. Cosmetic Laboratory

9.1 P20M and below P5,000.00 P10,000.00

9.2 Over 20M but below P50M P10,000.00 P20,000.00

9.3 P50M and above P15,000.00 P30,000.00

10. Cosmetic Trader

10.1 P20M and below P3,000.00 P6,000.00

10.2 Over P20M but below P50M P5,000.00 P10,000.00

10.3 P50M and above P7,000.00 P14,000.00

11. Medical Device Manufacturer

11.1 P20M and below P5,000.00 P10,000.00

11.2 Over P20M but below P50M P7,000.00 P14,000.00

11.3 P50M and above P10,000.00 P20,000.00

12. Medical Device Trader

12.1 P20M and below P3,000.00 P6,000.00

12.2 Over P20M but below P50M P5,000.00 P10,000.00

12.3 Over P50M P7,000.00 P14,000.00

13. Food Manufacturer

13.1 P10M and below P3,000.00 P6,000.00

13.2 Over P10M but below P20M P5,000.00 P10,000.00

13.3 Over P20M but below P50M P10,000.00 P20,000.00

13.4 P50M and above P15,000.00 P30,000.00

14. Household Hazardous Substances Manufacturers

14.1 P10M and below P3,000.00 P6,000.00

14.2 Over P10M but below P20M P5,000.00 P10,000.00

14.2 Over P20M but below P50M P10,000.00 P20,000.00

14.3 P50M and above P15,000.00 P30,000.00

B. FEES FOR PRODUCT REGISTRATION

FEEES

Initial

Renewal

(5 years validity)

(5 years validity)

1. Drugs

1.1 Monitored release for New Drug P20,000.00 (3 years)

1.2 Unbranded Application P10,000.00 P7,500.00

1.3 Branded Application P15,000.00 P10,000.00

1.4 Re-application Fee for Drug P1,000.00

2. Medical Device P1,500.00 (1 year) P5,000.00

3. Diagnostic Reagents P1,500.00 (1 year) P5,000.00

4. Food

4.1 Category I P1,000.00 (2 years) P3,000.00 (3 years)

4.2 Category II P3,000.00 (2 year) P4,500.00 (3 years)

4.3 Food Supplement P3,000.00 (2 years) P4,500.00 (3 years)

4.4. Bottled Water P2,000.00 (2 years) P3,000.00 (3 years)

5. Household Hazardous Substances P1,500.00 (2 years) P2,250.00 (3 years)

6. Cosmetics

6.1 Listing P1,500.00 (2 years) P2,250.00 (3 years)

6.2 Regular P1,500.00 (2 years) P4,750.00 (5 years)

7. Re-application fee for all products 1,000.00

C. COST OF LABORATORY ANALYSIS

CLASSIFICATION

FEEs

A. Physico-Chemical Analysis

a.1 Drugs and Antibiotics

Visual Examination P 300.00

Assay/Potency (Single Component) P1,500.00

Assay/Potency (Multi Component)
P2,000.00

Dissolution Test P2,000.00

Disintegration Test P 350.00

Hardiness Test P 350.00

Identification Test P 500.00

Purity Test/Related Substances P 500.00

Moisture Content P 300.00

Loss on Drying P 300.00

PH

Vitamins P 300.00

Vitamins A P1,000.00

Vitamin B1, B2, B6 P2,000.00

Vitamin C (Ascorbic Acid) P 500.00

Vitamin E P 500.00

Other Vitamins

P 500.00

Minerals P 800.00

a.2 Diagnostic Reagents P1,000.00

a.3 Medical Devices P1,500.00

a.4 Cosmetic

Assay P1,200.00

Identification Test P 500.00

Volatile/Non-Volatile Matters P 500.00

a.5 Food Products

Moisture P 300.00

Protein P1,000.00

Fat/Oil P 500.00

Starch P 500.00

Glucose P 500.00

Sucrose P 500.00

Lactose P 500.00

Crude Fiber P 500.00

Dietary Fiber P2,000.00

Total Solids P 300.00

Soluble Solids P 300.00

Water Insoluble Solids P 300.00

Ash P 300.00

Acid Insoluble Ash P 500.00

Saponification Number P 500.00

Viscosity P 300.00

Refractive Index P 300.00

Peroxide Value P 500.00

Free Fatty Acids P 500.00

Permanganate Oxidation No (PON)
P 500.00

Total Acidity P 300.00

Water Acidity P 300.00

Vacuum P 300.00

Minerals P1,000.00

Amino Acids (LC) P2,000.00

Proline P 500.00

Additives

Nitrates P 500.00

Nitrite P 500.00

Sodium Benzoate P 500.00

Sorbic Acid P 500.00

Food Color P 300.00/color

Sodium Metabisulfite P 500.00

Bromates P 500.00

BHT P 500.00

BHA P 500.00

Aspartame P 500.00

Saccharin P 500.00

Monosodium Glutamate P 300.00

Micronutrients

Vitamin A P1,000.00

Vitamin E P1,000.00

Beta Carotene P1,000.00

Vitamin C P 500.00

Vitamin B1B6 P1,000.00

Vitamin B2B6 Niacin P1,000.00

Iodine P 500.00

Iron P 500.00

Contaminants

Borax P 300.00

Aflatoxin P2,000.00

Total Heavy Metals P 500.00

Lead P 500.00

Cadmium P 300.00

Chromium P 300.00

Arsenic P 300.00

Mercury P 300.00

Tin P 300.00

Cyanide

P 300.00

Histamine P1,500.00

Filth P 500.00

Formalin P 500.00

Pesticide P2,000.00

Alcohol Content P1,000.00

Gas Volume P 300.00

Total Soluble Solids (Brix) P 300.00

pH P 300.00

Caffeine P 500.00

a.6 Food Supplements P4,000.00

a.7 Beverages

Alcohol content P1,000.00

Gas Volume P 300.00

Total Soluble Solids (Brix) P 300.00

pH P 300.00

Caffeine P 500.00

a.8 Bottled Water P2,000.00

a.9 Food Chemicals/Additives

Direct P1,000.00

Indirect P 500.00

a.10 Containers/Wrappers

Migratable Substances P1,000.00

Plastic Additives P 500.00

Cellulosic Materials for Pesticide Residue P1,500.00

Materials Testing P 500.00

B. Microbiological Assay

(Potency of Antibiotics) P2,500.00

C. Sterility Test

(Injectables, Medical Devices and Large Volume Parenterals P2,500.00

D. Microbial Limit Tests

Aerobic Plate Count P 500.00

Aerobic Halophilic Count P 500.00

Aerobic Psychrophilic Count P 500.00

Aerobic Thermophilic Spore Count P 500.00

Coliform Plate Count P 500.00

Coliform/E Coli (MPN) P 500.00

Fecal Streptococci P 600.00

Yeast and Mold Count P 500.00

Halophilic Yeast Count P 500.00

Staphylococcus Aureus Count P 600.00

Pseudomonas Aeruginosa P 600.00

Identification of Microorganisms

Presumptive Test P 600.00

Confirmatory Test (complete Bio-chemical reaction) P2,000/organism

Commercial Sterility of Thermally Processed Foods in Hermetically Sealed Containers P1,000.00

E. Bioassay Test

Depressor Substances Test P5,500.00

Skin Irritation Test P5,500.00

Eye Irritation Test P5,700.00

Paralytic Shellfish Poisoning Test (red tide) P1,000.00

Safety test P1,500.00

Acute Toxicity Test (rat) P22,000.00

Acute Toxicity Test (mouse) P10,000.00

Pyrogen Test P5,200.00

Bacterial Endotoxin Test (LAL) P4,000.00

F. Others

1. Authentication Fees:

1.1 Express Lane (per copy) P 100.00

1.2 Regular Lane P 50.00

2. Certifications/Re-issuances/Clearances

2.1 Free Sale/CGMP (Certificate of Pharmaceutical Product) P 500.00

2.2 Non Registrable P 500.00

2.3 GMP Certificate P 500.00

2.4 Products/Raw Materials for Exports P 500.00

2.5 Re-issuance of Valid CPR/LTO (for lost CPR or LTO) P 500.00

2.6 Products for Mailing/Hand-carry P50.00/certificate

2.7 Medical Director P 500.00

2.8 Permit to Import/Export P 500.00

2.9 Clearances P 500.00

2.10 All other Certificates P 500.00

3. Amendments:

3.1 Amendments of CPR's/LTO P 500.00

3.2 Extension of Shelf Life P1,000.00

4. Additional source of supplier for LTO (For Importer/wholesaler/Distributor having more than 5 sources per supplier) P 200.00

5. Pre-site inspection P500 + additional cost of transport & per diem

II. BUREAU OF LICENSING AND REGULATION

A. Hospital

Category

License Fees

Initial Renewal

P Primary P750.00 P375.00

Secondary P1,100.00 P500.00

Tertiary P3,000.00 P1,500.00

Fees

Registration Fee (all categories) P200.00

Certification Fee P 50.00

B. PERMIT TO CONSTRUCT

Category

Fees

Primary P300.00

Secondary P500.00

Tertiary P1,000.00

C. DENTAL PROSTHETIC LABORATORIES

Category

License Fees

Initial Renewal

Primary P600.00 P300.00

Secondary P800.00 P400.00

Tertiary P2,000.00 P1,000.00

D. ACCREDITATION AND AUTHENTICATION

Fees

1. Application for accreditation P 1,500.00

2. Accreditation P 1,500.00
3. Cash Bond P50,000.00
4. Authentication per document P 50.00

E. FREE STANDING

Application for LTO P600.00
License P2,000.00

F. AMBULATORY SURGICAL CLINICS

Application P800.00
Accreditation P800.00

G. HEALTH MAINTENANCE ORGANIZATIONS

CLASSIFICATION

CLEARANCE TO OPERATE FEES

Initial Renewal

Stock P50,000.00 P10,000.00

Non-Stock P10,000.00 P2,000.00

III. BUREAU OF RESEARCH AND LABORATORIES

A. Clinical Laboratory

Category

License Fees

Initial

Renewal

Primary P400.00 P200.00

Secondary P600.00 P300.00

Tertiary P1,000.00 P500.00

B. Blood Service Facility (Blood Bank/Blood Center)

A & B P600.00 P400.00

C. Accreditation Fees

HIV Testing Laboratory

CL and BSF P1,000.00 P500.00

Med. Tech. Interns Training Laboratory

CL and BSF P2,000.00 P1,000.00

Water Testing Laboratory

FB and HB P500.00 P250.00

IV. NATIONAL QUARANTINE OFFICE

A. Fees

Category

Fees

1. Immunization

1.1 Yellow Fever P600.00

1.2 Certification of Waiver P 60.00

1.3 Duplicate Certificate of Vaccination P 60.00

1.4 Validation P 40.00

B. Medical Examination Fees of Aliens for Immigration Purposes

Category Fees

1. Physical Examination and Document Fees P200.00

2. Chest X-ray Examination P200.00

3. Serological Test (VDRL/RPR) P150.00

4. Routine Fecalalysis P 50.00

5. Routine Urinalysis P 50.00

6. Certification for Board of Investment P100.00

C. Medical Examination Fees of Stewards and Foodhandlers (Subsidized)

Category

Fees

1. Chest X-ray Examination P100.00

2. Routine Urinalysis P 20.00

3. Routine Fecalalysis P 20.00

4. Serologic Test (VDRL/RPR) P 50.00

D. Derating Certification Fees

1. Deratting Certificate P250.00

2. Deratting Extension Certificate P400.00

E. Derrating Exemption Certificates

1. Vessels 1000 tons or less P400.00

2. Vessels 1001 tons to 2000 tons P600.00

3. Vessels 2001 tons to 3000 tons P1,000.00

4. Vessels 3001 tons to 4000 tons P1,200.00

5. Vessels 4001 tons to 5000 tons P1,500.00

6. Vessels above 5001 tons P1,800.00

F. Miscellaneous Fees

1. Laboratory Examination for Cholera Vibrio P250.00

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

This Order shall take effect on October 16, 2000.

Adopted: 17 April 2000

(SGD.) ALBERTO G. ROMUALDEZ, JR. MD
Secretary of Health

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