Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

DEC 09 2024

ADMINISTRATIVE ORDER
No. 2024 - 0016

SUBJECT: **Implementing Guidelines on the New Schedule of Fees and Charges of the Food and Drug Administration**

I. RATIONALE

The Food and Drug Administration (FDA) is mandated by Republic Act (RA) No. 9711 also known as the "Food and Drug Administration Act of 2009", to license all the establishments or facilities and issue product market authorization on all health products prior to manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship. Accordingly, to protect public health and uphold consumer safety, the FDA conducts post-market surveillance of health products and establishments or facilities to ensure the safety, efficacy and quality of health products.

Pursuant to Article II A. Section 2.s. of the Implementing Rules and Regulations (IRR) of the RA No. 9711, the FDA is authorized to review its fees periodically and propose any increase and promulgate rules and regulations governing the collection of other related regulatory fees. Accordingly, under Article II B. Section 3 of the said Act, the FDA is authorized to collect, retain, and utilize or apply all fees, fines, royalties, and other charges collected by it under Section 31 of the Republic Act No. 9502 also known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008" which includes upgrading of its facilities, equipment outlay, human resource development, and expansion; acquisition of the appropriate office space, as well as purchases of laboratory equipment and motor vehicles; upgrading of its current facilities and equipment and maintenance; funding for operating expenses of the central office laboratory divisions and satellite laboratories; and other activities or services of the FDA in the performance of its mandate.

With the current innovations in technology and the improvement of the country's economy as evidenced by the flourishing health product industry, a commensurate increase in the fees and charges is considerably needed to be able to meet and sustain the increasing demands of providing the FDA stakeholders quality and efficient services. For more than twenty (20) years, the rate of fees and charges of the Food and Drug Administration has been referred to Administrative Order (AO) No. 50 s. 2001 or the Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs. Thus, in view of the foregoing, a revisit and consequent repeal of AO No. 50 s. 2001 is deemed in order.

In the interest of the service and in compliance with the statutory requirements specified in DOF-DBM-NEDA Joint Circular No. 1-2013, also known as the "IRR of A.O. No. 31 s. 2012 on the Rationalization of Rates of Fees and Charges, Increase in Existing Rates and Imposition of New Fees and Charges", the FDA is restructuring its fees and charges at a level commensurate with the cost of regulating health products, establishments or facilities to protect consumer safety and public health. Thus, this Order is hereby issued.

II. OBJECTIVE

This Administrative Order is issued to prescribe the new schedule of fees and charges for the services rendered by the FDA and provide the guidelines for its implementation.

III. SCOPE

A. The new schedule of fees and charges shall apply to all persons, establishments or facilities and health products under FDA's jurisdiction, whether public or private, including but not limited to national and local government agencies, state colleges and universities, and schools, availing of FDA's services.

B. The following establishments or persons shall be governed by separate rules and regulations and their amendments or revisions:

1. Salt Manufacturers, Distributors, Importers and Traders shall follow RA No. 8172 or the "Asin Law", its revised Implementing Rules and Regulations (IRR) and its future amendments;
2. Certificate of GMP Compliance of Foreign Drug Manufacturers shall follow AO. No. 2013-0022 and FDA Circular (FC) No. 2014-016 or its future amendments or supplements;
3. Fees for Local and Foreign Accreditation of Bioequivalence Testing Center shall follow AO No. 2012-0024 or its amendments and supplements;
4. Fees for Local GMP Certification for drug manufacturers, as specified in Section D Item 2.2 of AO 50 s. 1989 shall be in effect until the regulation on GMP for drug manufacturers with corresponding fees is issued; and
5. Fees for Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers shall follow AO 2019-0010, entitled, "Guidelines on the Regulation of Operators of Pest Control, Certification of Pesticide Handlers, and Accreditation of Their Training Providers and its Amendments".

IV. DEFINITION OF TERMS

For the purpose of implementing this Order, all terms used in this Order that are already defined in RA No. 3720 otherwise known as the "Food, Drugs and Cosmetics Act" as amended by Executive Order (EO) No. 175 entitled "Food, Drugs and Device, and Cosmetics Act" and RA No. 9711 shall have the same meaning as defined therein. For emphasis, the following terms shall be defined as follows:

A. **Accreditation** refers to the attestation conveying a formal demonstration of a laboratory's competence and capability to carry out specific scientific and technical tests or analytical services with respect to health products.

B. **Authorization** refers to the permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and

or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption or any similar document.

C. **Center** refers to any of the following: Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), Center for Food Regulation and Research (CFRR), Center for Drug Regulation and Research (CDRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR) of the FDA.

D. **Establishment** refers to the sole proprietorship, a partnership, a corporation an institution, an association or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

E. **Evaluation** refers to the process of reviewing submitted regulatory documents by applicants based on existing standards, rules, and regulations of the FDA.

F. **Health Products** refers to food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

G. **Health Product Vigilance** refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible problems from Health Products.

H. **Initial application** refers to the term used for a first-time or original application for any authorization.

I. **Micro Small Medium Enterprises (MSMEs)** refers to the definition according to Republic Act No. 9501 entitled "Magna Carta for Micro, Small and Medium Enterprises (MSMEs)" as any business activity or enterprise engaged in industry, agribusiness and/or services, whether single proprietorship, cooperative, partnership or corporation whose total assets, inclusive of those arising from loans but exclusive of the land on which the particular business entity's office, plant and equipment are situated, must have value falling under the following categories: a.) Micro, not more than P3,000,000, b.) Small, P3,000,001 but not more than P15,000,000, and c.) Medium, P15,000,001 but not more than P100,000,000. More than P100,000,000 is considered a large enterprise.

J. **Reapplication** refers to the resubmission of a previously disapproved application and may include additional supporting documents addressing the deficiencies outlined in the letter of disapproval, if deemed necessary.

K. **Request for reconsideration** refers to the process where an applicant formally requests and seeks a review or re-evaluation of a decision disapproving an application for initial authorization, renewal, or variation.

L. **Re-issuance** refers to the process of granting a duplicate copy of a valid authorization due to loss or damage of the original authorization. This is only applicable when the document issued by the FDA is a hard copy and not an electronic copy.

M. **Renewal** refers to the process of filing an application for a new period of validity of an authorization.

N. **Risk Categorization on Food Products** refers to the classification of food products as high risk, medium risk or low risk based on inherent and potential food safety risks in the production/processing system and/or on the possibility of the presence of microbiological and chemical hazards in the food produced; and history of compliance by the establishment with its quality and safety management systems and pertinent regulations.

O. **Risk Categorization on Drug Manufacturer** is a classification system being used to assess and categorize pharmaceutical product manufacturers based on the complexity of the site, the processes involved in the production, and the types of pharmaceutical products manufactured. The classification can be low, medium, or high risk or their equivalence.

P. **Variation and/or Amendment** refers to post-approval changes in the status, circumstances, conditions, claims, or activities of authorized health establishments, facilities and products, in accordance with existing guidelines.

V. GENERAL GUIDELINES

A. The FDA shall implement its new schedule of fees and charges on covered authorizations, accreditations, services and transactions through this Order.

B. The application fees for granting an authorization/accreditation prescribed in this issuance shall cover, but is not limited to, the following activities:

1. Receiving of application documents;
2. Pre- and Post- Licensing Inspection of medical device establishments and radiation facilities
3. Pre-marketing activities, including but not limited to assessment, technical evaluation and pre-licensing inspection of establishment/facilities;
4. Post-marketing surveillance of products and establishments, but not limited to the following:
    a. Collection of samples;
    b. Laboratory testing;
    c. Complaints and reports processing;
    d. Safety monitoring;
    e. Post-licensing inspection;

f. Routine/special inspection;
g. Health Product Vigilance
h. Post evaluation;
i. Product verification and
j. Advertisement monitoring;

5. Printing;
6. Records management, archiving and administrative support;
7. Government Courier services to deliver the authorization, if applicable;
8. IT systems, maintenance, and development; and
9. All other related activities

C. The fees and charges of FDA shall **NOT** cover the following expenses:
   1. UP Law Center's Legal Research Fee (LRF), which is equivalent to P10.00 or 1% of the application fee, whichever is higher, as imposed by Republic Act (RA) No. 3870, as amended by Presidential Decree (PD) No. 200 and further amended by PD 1856, of which FDA is only the collecting agent as per Letter of Instruction No. 1182 dated 16 December 1981;
   2. Other fees incurred from the use of payment collection facilities, such as service fees charged by banks authorized by the FDA to collect its fees; and
   3. Private/ Special Courier used for the conveyance of the authorization.

D. Payment of the fees and charges shall be made through the prescribed FDA payment channels only.

E. Imposition of surcharge and penalty is subject to the conditions provided in Section VII of this Order.

VI. SPECIFIC GUIDELINES

A. The new schedule of fees and charges is attached as Annexes A to F, as follows:
   1. Annex A for Fees on General Certification (Common to all Centers)
   2. Annex B for Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
   3. Annex C for Center for Drug Regulation and Research (CDRR)
   4. Annex D for Center for Device Regulation, Radiation Health, and Research (CDRRHR)
   5. Annex E for Center for Food Regulation and Research (CFRR)
   6. Annex F for Common Services Laboratory (CSL)

B. The validity of the issued License to Operate (LTO) shall follow the rules on the licensing of establishments.

C. The initial and renewal validity of Certificate of Product Registration (CPR) shall be as follows:

Health Products	Initial CPR Validity	Renewal CPR Validity
1. Food	3 years or 6 years*	6 years or 12 years*
2. Device a. Medical Device b. Health Related Device i. Water Purification Device System ii. Equipment or a device used for treating sharps, pathological and infectious waste	6 years	
3. Drugs	6 years	
4. Household/Urban Pesticides (HUP) and Household/Urban Hazardous Substances (HUHS)	6 years or 12 years*	

*The applicant shall have the option to choose the preferred years of CPR validity

The validity of all other certificates shall follow the existing guidelines.

D. The fees for LTO/Facility Registration and CPR/CPN reflected on the Annexes are based on a yearly rate and shall be multiplied by the allowable number of years of validity.

Sample Computation:

Health Product	CPR Validity chosen by the applicant	Application Cost per Year (Annex E)
High Risk Food Product	3 years	P3,500*

*Excluding LRF

Fee for CPR of a High-Risk Food Product = 3 years validity x P3,500 fee per year.

Hence, the fee for CPR of High-Risk Food Product with 3 years validity shall be P10,500.00 + 105.00 (LRF)

E. The following shall be the available FDA payment channels:

1. Through Online LBP Link.BizPortal;
2. Through Online Bills payment (Bancnet) and
3. Through Over the Counter at Landbank of the Philippines (LBP) using the LBP Oncoll Payment Slip;

The FDA shall determine other payment channels and issue a corresponding guideline regarding new payment modes and methods as necessary.

F. All payments beyond the validity of the Order of Payment shall not be accepted.

G. The FDA may grant a request for a refund based on existing policy on refunds and any issuance promulgated pursuant thereto shall apply.

H. Application payments made, including, but not limited to, the following, shall **NOT** be accepted and posted in the system:

1. Application payment with incomplete/insufficient amount paid;
2. Application payment with an incorrect reference number provided;
3. Application payment made through an unauthorized payment channel;
4. Application payment made beyond the validity of the issued FDA Order of Payment; and
5. Such other cases as determined by the FDA.

Applications with deficiency payments shall be posted after proof of the total payment.

I. Authorizations filed within one hundred twenty (120) days from its original expiry shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal. Applications filed beyond the 120-day period shall be considered expired. The said application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and shall undergo the corresponding filing and evaluation procedure.

J. The payment of fees and charges may be modified in case of Public Health Emergency or State of Calamity, subject to compliance of the following:

1. Upon due recommendation of the FDA Director General to the Secretary of Health after the declaration of Public Emergency or State of Calamity by the local authorities; or

2. Upon due recommendation of the Secretary of Health and the FDA Director General following the directives of the President of the Republic of the Philippines issued pursuant to Republic Act No. 11517, entitled "An Act Authorizing the President to Expedite the Processing and Issuance of National and Local Permits, Licenses and Certifications in Times of National Emergency"

K. The size of business operation used by the CFRR for licensing purposes (by asset) shall be in accordance with RA No. 9501, entitled "Magna Carta for Micro, Small and Medium Enterprises (MSMEs)" and its amendments.

L. Provision of support and assistance to MSMEs may be provided through coordination of government efforts as provided for under Republic Act No. 9501 Section 5c and its future amendments.

M. For Drug Manufacturers, fees may vary based on the Risk Categorization:

1. Drug Manufacturer Risk Categorization shall be based on the type of products manufactured:

Low Risk:

i. Manufacturers of External Preparations, Medicinal Gas, and the manufacturer of their starting materials
ii. Repackers of Products

a. **Medium Risk:**
   i. Manufacturers and Packers of Human Non-Sterile Products
   ii. Manufacturers and Packers of Veterinary Sterile and Non-Sterile Products
   iii. Starting materials manufacturers and packers of Human Non-Sterile Products
   iv. Starting materials manufacturers and packers of Veterinary Sterile and Non-Sterile Products

b. **High Risk:**
   i. Manufacturers and Packers of Human Sterile Products, Vaccines, Biologicals, Advanced Therapy Medicinal Products (ATMPs), Blood & Blood Products, Radiopharmaceuticals
   ii. Manufacturers of Veterinary Vaccine Products
   iii. Starting materials manufacturers and packers of Human Sterile Products, Vaccines, Biologicals, Advanced Therapy Medicinal Products (ATMPs), Blood & Blood Products, Radiopharmaceuticals
   iv. Starting materials manufacturers and packers of Veterinary Vaccine Products

2. In the case of more than one product line in a manufacturer with a different identified risk category, the highest risk shall prevail.

N. Changes in the schedule of fees and charges and pertinent provisions, such as penalties, shall be posted on the information billboard and Citizen's Charter in compliance with R.A. No. 11032.

VII. SURCHARGE OR PENALTY

Consistent with R.A. No. 9711 and its IRR and other relevant FDA regulations, the conditions for the imposition of surcharge or penalty shall be provided as follows:

A. Pursuant to Section 3, Paragraphs (A) (2) and (B) (2) of Article 1, Book II on Licensing of Establishments and Registration of Health Products of IRR of RA 9711, applicable surcharge or penalty shall be imposed for applications for renewal of LTO or Authorization/CPR received after the date of their expiration. This rule shall apply even in succeeding renewal applications.

B. An application for renewal of an Authorization received after its expiration date shall be subject to a surcharge or penalty equivalent to twice the renewal fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application within the maximum of one hundred twenty (120) days from its original expiry date.

   This provision shall not apply to non-renewable authorizations.

VIII. PERIODIC REVIEW

The fees and charges shall be subject to periodic review of the FDA's Policy and Planning Service (PPS) pursuant to the pertinent provisions of R.A. 9711 and other applicable laws, rules and regulations. The PPS shall initiate periodic review which may include conducting consultations with stakeholders and recommending amendments to this Administrative Order subject to the approval of the Secretary of Health upon prior recommendation of the FDA Director General."

IX. REPEALING CLAUSE

This Administrative Order effectively repeals the following issuances:

A. DOH AO No. 124 s.1992 entitled "Rules and Regulations Governing the Establishment, Operation, and Maintenance of an X-ray Facility in the Philippines";

B. DOH AO No. 18-A s. 1993 entitled "Standards of Quality and Requirements for the Processing, Packaging and Labelling of Bottled Drinking Water"; (Section IV. Item No. 5 and Section VI. Item No. 3);

C. DOH AO No. 15-A s. 1995 entitled "Guidelines Governing the Implementation of the Sangkap Pinoy Seal (SPS) Program and the Collection and Disbursement of Fees Generated from the Program";

D. DOH AO No. 29, s.2000 entitled "Amendment to AO No. 23 s 1999 and AO No. 50, s.1999 Fees and Charges to be Collected by the Radiation Health Service";

E. DOH AO No. 50 s. 2001 entitled "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs";

F. DOH AO No. 47A s 2001 entitled "Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products";

G. DOH AO No. 134 s. 2002 entitled "Amendment to the Revised 2001 Schedule of Fees and Charges of BFAD for Food Manufacturers";

H. DOH AO NO. 82 s. 2003 entitled "Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products";

I. DOH AO 2005-0003 entitled "Guidelines on the Issuance of Certificate of Product Registration for Water Purification Equipment and Device";

J. DOH AO 2007-014 entitled "Guidelines on the Issuance of Certificate of Product Registration for Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste";

K. DOH AO No. 2007-0023, entitled "Schedule of Fees for the One Stop Shop Licensure System" Table 4 of Section V.A Fees, Surcharges and Discounts;

L. DOH AO No. 2008-0033 entitled "Rules and Conditions in Exempting Antibiotic Drug Products from Batch Certification Requirement Amending for this purpose Item III (C) and (D) of AO No. 103 s. 2002 "Batch Certification of Antibiotics" and for Other Purposes";

M. FDA Circular No. 2013-001- entitled "Revised Notification Template for Cosmetic Products" and its amendment; FDA Circular No. 2013-001-A, specifically the fees for cosmetic variants and

N. FDA Circular No. 2023-003 entitled "Guidelines on the Filing and Submission of Acceptable Variations on Protocols and Non-standard Protocols for the Review and Pre-Approval by the Food and Drug Administration Prior to the Conduct of Bio-efficacy Test Studies of Household Pesticides for the Purposes of Securing a Certificate of Product Registration", Section V. Specific Guidelines E. Fees and Charges

Other issuances or parts thereof, pertaining to specific guidelines for certain establishments which are found to be inconsistent with the provisions of this AO are hereby repealed accordingly.

X. SEPARABILITY CLAUSE

If any provision is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

XI. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in the Official Gazette or in any newspaper of general circulation and the required copies filed with the University of the Philippines Law Center Office of the National Administrative Register.

TEODORO J. HERBOSA, MD
Secretary of Health

ANNEX A

FEES COMMON TO ALL CENTERS

Certification, Other Services or Requests	**Fees per Application (in PhP)***
1. Re-issuance of an Authorization or License (Lost or Damaged Original)	500.00
2. Sales Promotion Permit	
2.1. Discount scheme type of promotion	
NCR only or in several regions, including NCR or nationwide	1,000.00
More than one region but excluding NCR	750.00
Several provinces/cities/municipalities within a single region	500.00
Single province/city/municipality	250.00
2.2. Non-discount scheme type of promotion	
Amount of Prize/s Up to P50,000.00	250.00
P50,001.00 - P150,000.00	500.00
P150,001.00 - P300,000.00	1,000.00
P300,001.00 - P500,000.00	2,000.00
P500,001.00 - P1,000,000.00	3,000.00
Above P1,000,000.00	5,000.00
2.3. Amendment	300.00
3. Pre-assessment	500.00
4. Permit to Carry/Mail (Personal Use)	160.00
5. Permit to Carry/Mail (R& D Use)	160.00
6. Authentication/ CTC	100.00 per page
7. Certificate of Free sale	1650.00
8. Reconsideration	5,000.00
9. Other Certification or Requests	500.00

* All fees are subject to an additional PhP 10.00 or 1% of the application fee, whichever is higher, for Legal Research Fee (LRF)

ANNEX B

CENTER FOR COSMETICS AND HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES REGULATION AND RESEARCH

I. COSMETICS		
A. **License to Operate**		
1. Manufacturer	**Fees per year (in PhP)***	
a. Initial	14,000.00	
b. Renewal	14,000.00	
	Fees per application (in Php)*	
c. Major Variation (w/ Inspection)	7,000.00	
d. Minor Variation	600.00	
2. Distributor/Trader	**Fees per year (in PhP)***	
a. Initial	7,000.00	
b. Renewal	7,000.00	
	Fees per application (in Php)*	
c. Major Variation (w/ Inspection)	N/A	
d. Minor Variation	600.00	
B. **Certificate of Product Notification**		
Basic Notification	**Fees per year (in PhP)***	**Additional fee per variant per year (in PhP)***
a. Initial	1,000.00	100.00
b. Revalidation	1,000.00	100.00

II. HOUSEHOLD/URBAN PESTICIDES (HUPs)		
A. **License to Operate**		
1. Manufacturer	**Fees per year (in PhP)***	
a. Initial	14,000.00	
b. Renewal	14,000.00	
	Fees per application (in PhP)*	
c. Major Variation (w Inspection)	7,000.00	
d. Minor Variation	600.00	
2. Distributor/Trader	**Fees per year (in PhP)***	
a. Initial	7,000.00	
b. Renewal	7,000.00	
	Fees per application (in Php)*	
c. Major Variation (w/ Inspection)	N/A	
d. Minor Variation	600.00	
B. Certificate of Product Registration		
Basic Registration	**Fees per year (in PhP)***	**Fees (in PhP)* Reapplication**
a. Initial	8,000.00	5,600.00
b. Renewal	8,000.00	5,600.00
	Fees per application (in Php)*	**Fees (in PhP)* Reapplication**

c. Variation	5,000.00	3,500.00
d. Emergency Exemption Permi (EEP)	8,000.00	5,600.00

III. TOYS AND CHILDCARE ARTICLES (TCCAs)	
A. License to Operate	
1. Manufacturer	**Fees per year (in PhP)***
a. Initial	9,000.00
b. Renewal	9,000.00
	Fees per application (in Php)*
c. Major Variation (w/ Inspection)	7,000.00
d. Minor Variation	600.00
2. Distributor/Trader	**Fees per year (in PhP)***
a. Initial	7,000.00
b. Renewal	7,000.00
	Fees per application (in Php)*
c. Major Variation (w/ Inspection)	N/A
d. Minor Variation	600.00
B. Certificate of Product Notification	**Fees per year (in PhP)***
Basic Notification	1,000.00 (maximum of 5 SKUs)

IV. HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS)		
A. License to Operate		
1. Manufacturer	**Fees per year (in PhP)***	
a. Initial	14,000.00	
b. Renewal	14,000.00	
	Fees per application (in Php)*	
c. Major Variation (w/ Inspection)	7,000.00	
d. Minor Variation	800.00	
2. Distributor/Trader	**Fees per year (in PhP)***	
a. Initial	7,000.00	
b. Renewal	7,000.00	
	Fees per application (in Php)*	
c. Major Variation (w/ Inspection)	7,000.00	
d. Minor Variation	800.00	
B. Certificate of Product Registration		
Basic Registration	**Fees per year (in PhP)***	**Fees (in PhP)* Reapplication**
a. Initial	5,000.00 (up to 5 variants)	3,500.00
b. Renewal	3,000.00 (up to 5 variants)	2,100.00

	Fees per application (in Php)*	Fees (in PhP)* Reapplication
c. Variation	3,000.00 (up to 5 variants)	2,100.00
d. Emergency Use Permit (EUP)	4,000.00 (per variant)	2,800.00

V. OTHER PERMITS AND CERTIFICATES	Fees per application (in Php)*
1. Certificate of GMP (Local Cosmetics/HUHS Manufacturer)	1,400.00 (per year)
2. Import Permit/Clearance	2,000.00
3. Certificate of Exemption (TCCAs)	2,000.00
4. Pre-Approval of Modified and Non-Standard Bio-Efficacy Test Protocol (HUPs)	14,000.00

*All fees are subject to an additional PhP 10.00 or 1% of the application fee, whichever is higher, for Legal Research Fee (LRF)

ANNEX C

CENTER FOR DRUG REGULATION AND RESEARCH

LICENSE TO OPERATE (LTO)	**Fees (in PhP) per Year*** (Initial/Renewal)	
1. Drug Manufacturer		
a. Low risk	27,500.00	
b. Medium risk	47,500.00	
c. High risk	56,000.00	
2. Drug Trader	8,000.00	
3. Drug Distributor (Importer/Exporter/Wholesaler)	8,000.00	
4. Drugstore / Hospital Pharmacy	3,000.00	
5. Retail Outlet for Non-Prescription Drug	2,000.00	
6. Sponsor/ Contract Research Organization	8,000.00	
Variation	**Fees (in PhP) per Variation***	
1. Drug Manufacturer		
a. Major variation with inspection (transfer of location)	Low risk	27,500.00
	Medium risk	47,500.00
	High risk	56,000.00
b. Other major variation with inspection	Low risk	6,800.00
	Medium risk	11,800.00
	High risk	14,000.00
c. Minor variation	1,170.00	
2. Drug Trader/ Drug Distributor		
a. Major variation with inspection (transfer of location)	8,000.00	
b. Other major variation with inspection	2,000.00	
c. Minor variation	620.00	
3. Drugstore / Hospital Pharmacy		
a. Major variation with inspection (transfer of location)	3,000.00	
b. Other major variation with inspection	1,500.00	
c. Minor variation	620.00	
4. Retail Outlet for Non-prescription		
a. Major variation with inspection (transfer of location)	2,000.00	
b. Other major variation with inspection	1,00.00	
c. Minor variation	620.00	
5. Sponsor/ Contract Research Organization		
a. Major variation with inspection (transfer of location)	8,000.00	
b. Other major variation with inspection	2,000.00	
c. Minor variation	620.00	
Other Permit/ Certificate/Clearance (LTO/Pharmacist Verification request from private individual/law firm, etc.)	1,000.00	

CERTIFICATE OF PRODUCT REGISTRATION	**Fees (in PhP) per Year*** (Initial/Renewal)	**Fees (in PhP)* Reapplication**
New Drug	43,000.00	18,300.00
Biological/ Vaccine	43,000.00	18,300.00
Generic Drug Rx	18,000.00	510.00
Non-prescription Drug / Household Remedy	17,000.00	510.00
Medical Gas	9,000.00	520.00
Traditional Medicine	14,500.00	4,400.00
Herbal Medicine	17,000.00	6,000.00
PCPR Conversion	1,000.00	N/A
CLIDP	10,000.00	200.00
Active Pharmaceutical Ingredient	15,700.00	2,500.00
Foreign Donation	2,000.00	300.00
Export-Only Registration Certificate	11,000.00	1,800.00
Variation	**Fees (in PhP) per Variation***	
Major variation turned initial	18,000.00	12,600.00
Other Major variation	14,000.00	9,800.00
Minor variation	7,000.00	4,900.00
Notification	1,800.00	1,250.00
Brand name	600.00	
Certificate of Pharmaceutical Product Certificate of Free Sale Export Certificate Generic Labeling Exemption	1,650.00	
Clinical Trial	**Fees (in PhP) per Application***	**Fees (in PhP)* Reapplication**
Clinical Trial Approval and Import License (Phase I, II, III)	56,000.00	11,200.00
PMS (Phase IV) CT Approval	34,00.00	23,300.00
Prior Approval CT Protocol Amendment	9,000.00	6,300.00
Other CT Protocol Amendment/Notification	3,000.00	2,100.00
Import License Amendment	3,500.00	2,400.00
Compassionate Special Permit (CSP)		

Other applications	**Fees (in PhP) per Product***
Import/Export Permit (e.g., samples for registration, one-time importation (drug shortage), BE/Biowaiver comparator/sample)	1,200.00
Exhaustion of existing labeling materials/ Relabeling/ Repacking, etc.	1,700.00

*All fees are subject to an additional PhP 10.00 or 1% of the application fee, whichever is higher, for Legal Research Fee (LRF)

ANNEX D

CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH

I. RADIATION FACILITIES

Category	LICENSE TO OPERATE[b]	Fees (in Php)[a] (per machine) per year
Group A	Radiation facilities utilizing radiation emitting devices used for General Radiography/ Fluoroscopy (fixed, mobile or transportable), Mobile C-arm (Radiography/Fluoroscopy), Computed Tomography (CT), Single Photon Emission Computed Tomography/Computed Tomography (SPECT/CT), Positron Emission Tomography/Computed Tomography (PET/CT), Mammography (fixed or transportable), Lithotripsy, Dental Radiology (Panoramic/ Cephalometric), Dental Cone Beam CT, Magnetic Resonance Imaging (MRI) used for but not limited to screening, diagnosis and treatment of diseases, educational, training, and research, and other emerging radiation devices and applications in this category	3,200.00
Group B	Radiation facilities utilizing radiation devices, such as C-arm (Radiography/Fluoroscopy) for Cardiac Catheterization and other emerging radiation technology used in this category for interventional radiology procedures	5,000.00
Group C	Radiation facilities utilizing Linear Accelerator, Tomotherapy or any combination, and other emerging radiation devices in this category used for therapeutic/treatment of diseases	8,900.00
Group D	Radiation facilities utilizing radiation devices used for open-type industrial radiography, non-destructive testing and other emerging technologies in this category used for anti-crime and industrial applications	2,000.00
Group E	Radiation facilities utilizing Linear Accelerator for anti-crime and industrial application and emerging radiation devices in this category used for anti- crime and industrial application	3,100.00
	FACILITY REGISTRATION[b]	
Group F	Radiation facilities utilizing radiation emitting devices used for bone densitometry (DEXA), security and baggage inspection system, closed-type industrial radiography, dental radiography utilizing periapical/intraoral x-ray devices and other emerging radiation devices in this category	1,900.00
AMENDMENT / VARIATION (Facility License/Registration)		

Major Variation	Initial Fee shall apply
Minor Variation	2,400.00

OTHER AUTHORIZATIONS-RADIATION FACILITIES	Fees (in Php)[a]
Certification / Permit/ Clearance Category	
Certificate of Safety Evaluation (CSE) for Non-Ionizing Radiation Facility (Extremely Low Frequency (ELF) and Radiofrequency Radiation (RFR)) Facilities	2,600.00[c]
Certificate of Radiation Measurement for ELF and RFR Facilities	9,200.00 [c]
Pre-Operational Permit	3,000.00[d]
Clearance for Customs Release (CFCR)	900.00[d]

[a] All fees are subject to an additional PhP 10.00 or 1% of the application fee, whichever is higher, for Legal Research Fee (LRF)

[b] For Radiation facilities under the One Stop Shop (OSS) Licensing System of the DOH, the corresponding fee per category mentioned above shall apply

[c] Per application/site

[d] Per machine/unit

II. MEDICAL DEVICES AND HEALTH-RELATED DEVICES

A. **License to Operate**	
Medical Device, Water Purification/Treatment Devices/System, Healthcare Waste Treatment (equipment or devices used for treating sharps, pathological, and infectious waste)	
1. Manufacturer (Low Risk)	**Fees per year (in PhP) ***
Initial	30,900.00
Renewal	30,900.00
Variation (Minor)	1,600.00
Variation (Major)	13,200.00
2. Manufacturer (Medium to High Risk)	
Initial	50,800.00
Renewal	50,800.00
Variation (Minor)	1,600.00
Variation (Major)	13,200.00
3. Distributor (Importers, Exporters and Wholesalers) & Trader	
Initial	8,500.00
Renewal	8,500.00
Variation (Minor)	1,600.00
Variation (Major)	13,200.00
4. Retailer of Medical Device	
Initial	3,000.00
Renewal	3,000.00
Variation (Minor)	620.00
Variation (Major)	3,000.00
Treatment, storage and disposal (TSD) Facility Operator	

TSD Operator	
Initial	5,800.00
Renewal	3,800.00
Variation (Minor)	1,600.00
Variation (Major)	13,200.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Medical Device)	
CIVDR Class A (Registration)	**Fees per year (in PhP) ***
Initial	13,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CIVDR Class B (Registration)	
Initial	18,000.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CIVDR Class C (Registration)	
Initial	18,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CIVDR Class D (Registration)	
Initial	19,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
Certificate of Medical Device Notification/Registration – Class A	
Initial	13,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
Certificate of Medical Device Registration - Class B	
Initial	18,000.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
Certificate of Medical Device Registration - Class C	
Initial	18,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00

Certificate of Medical Device Registration - Class D	
Initial	19,500.00
Renewal	15,300.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

Other Certifications	Fees (in Php)*
CPR Reapplication – CIVDR/CMDN/CMDR Class A (per application)	9,450.00
CPR Reapplication – CIVDR/CMDN/CMDR Class B (per application)	12,600.00
CPR Reapplication – CIVDR/CMDN/CMDR Class C (per application)	12,950.00
CPR Reapplication – CIVDR/CMDN/CMDR Class D (per application)	13,650.00
Medical Device Listing (per product, one-time use)	3,400.00
Compassionate Special Permit (one-time use)	500.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Water Purification/Treatment Device)	
Water Purification System	**Fees per year (in PhP) ***
Initial	9,700.00
Renewal	7,800.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
Water Purification Device	
Initial	9,700.00
Renewal	7,800.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CPR Initial - Healthcare Waste Treatment Equipment (Below 1M)	
Initial	17,500.00
Renewal	15,700.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CPR Initial - Healthcare Waste Treatment Equipment (1M-5M)	
Initial	17,500.00
Renewal	15,700.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CPR Initial - Healthcare Waste Treatment Equipment (5M and above)	

Initial	17,500.00
Renewal	15,700.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
CPR - Healthcare Waste Generators	
Initial	17,500.00
Renewal	15,700.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

In Vitro Diagnostic (IVD) Registration	
IVD Pregnancy Test Kits – Existing Regulations	**Fees per year (in PhP) ***
Initial	18,800.00
Renewal	16,500.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00
IVD – Existing Regulations	
Initial	17,700.00
Renewal	15,400.00
Variation (Minor)	3,000.00
Variation (Major)	4,000.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

ANNEX E

CENTER FOR FOOD REGULATION AND RESEARCH

LICENSE TO OPERATE (LTO)	Fees per year (in Php)*	Fees per Variation (in Php)*	
		w/o inspection	with inspection
1. Manufacturer / Repacker			
a. Micro	2,000.00	700.00	2,000.00
b. Small	5,000.00	700.00	5,000.00
c. Medium	14,000.00	700.00	13,700.00
d. Large	15,000.00	700.00	13,700.00
2. Distributors	6,900.00	700.00	6,700.00
3. Trader			
a. Micro	2,000.00	700.00	2,000.00
b. Small	5,000.00	700.00	5,000.00
c. Medium	6,900.00	700.00	6,700.00
d. Large	6,900.00	700.00	6,700.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

GMP CERTIFICATE	Fees per application (in Php)*	
	Initial Request (with inspection)	Simultaneous with LTO Inspection
Manufacturer		
a. Micro	500.00	500.00
b. Small	500.00	500.00
c. Medium	13,900.00	3,000.00
d. Large	13,900.00	3,000.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

CERTIFICATE OF PRODUCT REGISTRATION (CPR)	Fees per year (in Php)*	Fees per Amendment (in Php)*	Reapplication Fee
1. Bottled Water	4,000.00	225.00	1,000.00
2. Food Supplement	4,000.00	225.00	1,000.00
3. Raw Materials/ Low Risk Food Product	3,000.00	225.00	750.00
4. Medium Risk Food Product	3,500.00	225.00	800.00
5. High Risk Food Product	3,500.00	225.00	900.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

CERTIFICATION	Fees per application (in Php)
1. HACCP Certificate (1 year validity per product)	3,000.00
2. Diamond Sangkap Pinoy Seal	900.00
3. Sangkap Pinoy Seal 3.a. Use of Seal	900.00 8,000.00
4. IAC (Milk Code) Certificate - Ads 4.a. IAC (Milk Code) Certificate - Sponsorship and Donation	2,020.00 500.00
5. Import Permit (per invoice)	650.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

Other Services (Voluntary Application)

Evaluation for Suitability (food-contact) per product type	3,200.00
Export Certification for Woodenwares	3,200.00

ANNEX F
COMMON SERVICES LABORATORY

COST OF LABORATORY ANALYSIS		
CLASSIFICATION		**Fees (in PhP)***
General Tests		
	pH	600.00
	Visual Examination	500.00
	Organoleptic	1,000.00
	Alcohols	8,400.00
1. Physico-chemical Analysis		
	1.1 Drugs and Antibiotics	
	Assay/ Potency	
	Single component	5,300
	Multi- component	8,400
	Two/ Three-component TB Drugs	8,400
	Four-component TB Drugs	12,600
	TB Drugs Kit	15,800
	Dissolution	
	Single component	6,300
	Multiple component (other than TB drugs)	9,500
	Two/ Three-component TB Drugs	9,500
	Four-component TB Drugs	13,700
	TB Drugs Kit	16,800
	Disintegration Test	700
	Hardness Test	700
	Identification Test	
	Single component	3,700
	Multiple component	5,300
	Uniformity of Dosage Units	
	Weight variation	5,000
	Content uniformity	11,000
	Test for Impurities / Related Substances/ Adulterants/	15,800
	Moisture content	1,500
	Loss on Drying	3,000
	Minimum fill	600
	Deliverable volume	600
	1.2 Cosmetics	
	Single analyte	7,900

	Heavy Metal in Cosmetic Products	12,000

	Parabens in Cosmetic Products	8,400
	1.3 Food Products	
	Additives / Preservatives	
	Acesulfame K	5,300
	Aspartame	5,300
	BHA	5,300
	BHT	5,300
	Bromates	500
	Cyclamates	5,300
	Food colors (ID)	2,100
	Nitrate	3,700
	Nitrite	3,700
	Saccharin	5,300
	Sodium Benzoate	5,300
	Sodium metabisulfite	3,700
	Sorbic Acid	5,300
	Two-component preservative	7,900
	Multi -component artificial sweeteners (Maximum of 3 analytes)	8,400
	Multi-component caloric sweeteners (max of 3)	8,400
	Proline	2,600
	Ash	2,600
	Caffeine	5,300
	Contaminants	
	Borax	1,100
	Pesticides Residues	15,800
	Veterinary Drug Residues	15,800
	3-MPCD	15,800
	DEHP	7,900
	Odor	1,100
	Filth	500
	Formalin	2,600
	Histamine	11,000
	Melamine	11,000
	Mycotoxins (per mycotoxin)	11,000
	Trans Fatty Acids	11,000
	Fatty Acid Profile (VCO)	8,400

	Fat	2,600
	Free Fatty Acids	2,600
	% NaCl	2,600
	Calcium	2,600
	Gas Volume	1,100
	Glucose	5,300
	Fructose	5,300
	Lactose	5,300
	Sucrose	5,300
	Heavy Metals	
	Arsenic	5,300
	Cadmium	5,300
	Chromium	5,300
	Lead	5,300
	Mercury	5,300
	Tin	5,300
	Micronutrients	
	Beta Carotene	5,300
	Iodine	2,700
	Iron	3,700
	Moisture	2,600
	Permanganate Oxidation Number (PON)	2,600
	Peroxide Value	2,600
	Protein	3,700
	Soluble Solids	2,600
	Total Acidity	2,600
	Total Solids	2,600
	Total Soluble Solids (Brix)	500
	Water-Insoluble Solids	2,600
	Vitamins	
	Vitamin A	7,900
	Vitamin B1, B6, Niacin	7,900
	Vitamin C	2,600
	Vitamin E	7,900
2. Biological Test		
2.1 Antibiotics		
	Microbiological Assay (Potency of Antibiotics)	6,300
	Sterility Test	6,300

	(Injectables, Medical Devices, and Large Volume Parentals)	
	2.2 Microbiological Tests	
	For food samples a minimum of five (5) samples are analyzed	
	For pharmaceutical, herbal and cosmetic samples, minimum of one sample is analyzed	
	Microbial Enumeration Tests	
	Aerobic Plate Count/ Heterotrophic Plate Count/ Total Aerobic Microbial Count (Food: 5 samples)	4,200
	per sample	1,300
	Coliform Count (Solid Media method) (Food: 5 samples)	4,200
	per sample	1,300
	Coliforms (MPN) (Food: 5 samples)	5,300
	per sample	1,400
	Lactic Acid Bacteria (Food: 5 samples)	5,300
	per sample	1,400
	Osmophilic Yeast (Food: 5 samples)	4,200
	per sample	1,300
	Psychrotrophic Bacteria (Food: 5 samples)	4,200
	per sample	1,300
	Yeast and Mold Count/ Total Yeast and Mold Count (Food: 5 samples)	4,200
	per sample	1,300
	Microbial Identification Tests	
	Bacillus cereus (Food: 5 samples)	5,300
	per sample	1,300
	Bacillus subtilis (Food: 5 samples)	5,300
	per sample	1,300
	Candida albicans per sample	1,300
	Clostridium perfringens (Food: 5 samples)	5,300

	per sample	1,400
	Cronobacter spp. (Food: 5 samples)	5,300
	per sample	1,400
	Enterobacteriaceae (Food: 5 samples)	5,300
	per sample	1,400
	Enterococci *(Food: 5 samples)*	4,200
	per sample	1,400
	Escherichia coli (Solid Media) (Food: 5 samples)	5,300
	per sample	1,500
	Escherichia coli (MPN) (Food: 5 samples)	6,300
	per sample	1,600
	Fecal streptococci (Food: 5 samples)	5,300
	per sample	1,500
	Listeria monocytogenes (Food: 5 samples)	7,400
	per sample	1,900
	Pseudomonas aeruginosa (Food: 5 samples)	5,300
	per sample	1,500
	Salmonella spp. (Food: 5 samples)	7,400
	per sample	1,900
	Staphylococcus aureus (Food: 5 samples)	6,300
	per sample	1,500
	Vibrio parahaemolyticus (Food: 5 samples)	7,400
	per sample	1,600
	Rapid Bacterial Identification Tests	
	Bacillus cereus (Food: 5 samples)	7,400
	Escherichia coli (Food: 5 samples)	7,400
	Listeria monocytogenes (Food: 5 samples)	7,400

	Salmonella (Food: 5 samples)	7,400
	Staphylococcus aureus (Food: 5 samples)	7,400

	Other microbiological tests	
	Commercial sterility (Food)	7,400
	Evaluation of Antimicrobial Protection (Preservative Efficacy Test)	15,800
2.3 Bioassay Tests		
	Bacterial Endotoxin Test (LAL)	7,400
3 Toxicological Tests		
	Bottled Water - Total package	10,500
	Conductivity	800
	Cyanide	1,300
	Heavy Metals (per metal)	4,200
	Nitrate	1,700
	Total Dissolved Solids	800
	Hypochlorite	
	Assay	2,800
	Residual Chlorine	2,800
	Toys / School Supplies	
	Migration of Certain Elements (3 elements)	6,300
	Additional element	2,100
	Phthalates in Toys	16,800
	Test for Packaging Materials	
	Material Testing (Pb and Cd)	4,200
	Migration Testing (package)	6,300
	Medical Devices	
	Efficacy/ Reproducibility	1,100
	Water Leak Test (Condom)	1,600
	Lead in Spray Paint	4,200
	HUP Active Ingredient by HPLC	8,900
4 Other Services		
	Audit of Testing Laboratory (per visit)	
	Within Metro Manila	20,000a
	Outside Metro Manila	20,000b
	Accreditation of Testing Laboratory (per year)	20,000c
	Batch Notification	6,500

	Lot Release Certification	5,300

	Evaluation for Suitability (food-contact) per product type	3,200
	Export Certification for Woodenwares	3,200
	ASEAN REFERENCE SUBSTANCE (ARS)	**50 USD**
	Amendment of Test Report and/or Certificate (per copy)	1,000
	Re-issuance of Test Report and/or Certificate (per copy)	500
5 PHYSICS LABORATORY SUPPORT DIVISION (PLSD)		
	Performance Testing of Radiological Equipment	10,500**
	Output Calibration Measurement / Quality Audit of Radiotherapy Facilities	10,500**
	Calibration of Radiotherapy Dosimeters	9,500 [c]

[a] Plus transportation cost

[b] Plus per diem/ per inspector/auditor plus transportation cost

[c] per year validity of accreditation

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

** Testing and quality audit activities were done in the health care facilities (hospitals/clinics) and all applicable expenses (i.e. plane fare, per diem, etc.) incurred for the travel of at least 2 PLSD personnel were charged to the client