Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2023- _____

SUBJECT: **Implementing Guidelines on the Schedule of Fees and Charges of the Food and Drug Administration for Licensing, Registration and Other Authorizations and Regulatory Services Repealing Administrative Order No. 50s. 2001, entitled, "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs" and its Amendments**

I. RATIONALE

The Food and Drug Administration (FDA) is mandated by Republic Act 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 that adulterated, unregistered, or misbranded health products are not offered for sale or use.

Pursuant to Article II A. Section 2.s. of the Implementing Rules and Regulations of the Republic Act (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 evidenced by the flourishing volume of industries in health products, 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 the Administrative Order 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 Administrative Order No. 50 s. 2001 is deemed in order.

In the interest of the service and pursuant to the DOF-DBM-NEDA Joint Circular No. 1-2013, also known as the "Implementing Rules and Regulations of Administrative Order 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, the following guidelines are hereby adopted.

II. OBJECTIVE

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

III. SCOPE

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.

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 as amended by EO No. 175 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 as defined by RA No. 9711.

I. **Micro Small Medium Enterprises (MSMEs**) refers to the definition according to Republic Act No. 9501 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. **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.

K. **Renewal** refers to the process of filing an application for the extension of the validity of an authorization.

L. **Risk-based Regulation** refers to the approach on regulating health products, establishments, and facilities by targeting activities that pose the highest risk to the public well-being, and in turn lowers the burden for a variety of lower-risk sectors and firms. Lowering burdens improves compliance and allows firms to benefit from a more level playing field. By directing the government resources towards the highest-risk areas, risk-based approaches also make the most of limited public resources and further improve accountability by enhancing transparency and predictability of requirements in given sectors and as applied to different establishments.

M. **Variation and/or Amendment** refers to post-license changes in the status, circumstances, conditions, claims, or activities of authorized establishments, in accordance with existing guidelines.

V. 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 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 facilities for medical device;
   3. Pre-marketing activities, including but not limited to assessment, technical evaluation and pre-licensing inspection of establishment;
   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;
      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;
   9. Security Seal; and
   10. And all other related activities

C. The application fees 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.
   3. Private/ Special Courier used for the conveyance of the certifications.

D. The FDA shall issue updated guidelines regarding new payment modes and methods as necessary.

1. Through Over-the-Counter at Landbank of the Philippines (LBP) using the LBP Oncoll Payment Slip;
2. Through Online LBP Link.BizPortal; or
3. Through Online Bills payment (Bancnet)
4. Other payment channels as may be determined by the FDA.

E. All payments shall be made not later than the date reflected in the Order of Payment (OP). Payments beyond the validity of the OP shall be automatically forfeited.

F. 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 payment shall be posted after the proof of the full payment is made.

G. Changes and/or additions to the existing FDA payment channels shall be announced through a separate issuance.

H. The size of business operation used by CCHUHSRR and CFRR for licensing purposes (by asset) shall be in accordance with RA No. 9501 and its amendments.

I. Provision of support and assistance to MSMEs may be provided under the coordination of government efforts stipulated in RA No. 9501 Section 5c and its future amendments. Future related provisions will be carried out.

J. Flexibility in payment of fees and charges may be applied by the FDA in lieu of Public Emergency or State of Calamity declaration, provided, however, the following directives may be applied:

1. Upon recommendation of the FDA Director General for local public health emergency to be imposed by the DOH Secretary as declared by the Local Government Unit; or
2. Upon recommendation of the DOH Secretary and the FDA Director General to be imposed by the Office of the President following Republic Act 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"

VI. VALIDITY

The validity period for authorizations, permits, and certificates shall follow existing FDA issuances.

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 are provided below as follows:

A. Pursuant to Section 3, Paragraph (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 CPR received after the date of their expiration. This rule shall apply even in succeeding renewal applications.

B. An application for renewal of an LTO or CPR received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal licensing 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.

C. The LTO or CPR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

D. LTO or CPR applications filed beyond the 120-day period shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the corresponding filing and evaluation procedure.

VIII. MANDATORY REVIEW

The fees and charges shall be subject to mandatory review every three (3) years. The Policy and Planning Service shall undertake periodic review, conduct consultations with stakeholders, and recommend amendments to this Administrative Order to the Office of the Director-General for approval of the Secretary of Health, as may be deemed necessary.

IX. REPEALING CLAUSE

This Administrative Order effectively repeals the following issuances:

A. Administrative Order No. 50 s. 2001 entitled “Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs”;

B. A.O. No. 18-A s. 1993 entitled “Standards of Quality and Requirements for the Processing, Packaging and Labelling of Bottled Drinking Water”;

C. A.O. 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. A.O. 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 A.O. 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";

F. A.O. NO. 82 s. 2003 entitled "Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products";

G. A.O. 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";

H. A.O. No. 2012-0024 entitled "Amendment to A.O. No. 50 s. 2001 Covering Fees and Charges for Accreditation of Bioequivalence Testing Centers and Private Testing Laboratories, as well as, Audits and Inspection";

I. FDA Circular No. 2011-004 entitled "Computation of Surcharge or Penalty Imposable in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products *After* Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes";

J. FDA Circular No. 2013-001- entitled " Revised Notification Template for Cosmetic Products" and its amendment;

K. 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";

L. FDA Circular No. 2015-001 entitled "Clarifications on the Regulations Governing Principal and Identical Drug Products as defined under Administrative Order No. 2005-0031".

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 DATE

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

TEODORO J. HERBOSA, MD
Secretary of Health

Food and Drug Administration	Food and Drug Administration
IRENE F. FLORENTINO-FARIÑAS, RPh, MD, MNSA OIC Director III, Policy and Planning Service	**SAMUEL A. ZACATE, MD** Director General

Keywords	
Related Issuances, laws, directives from other government agencies	Administrative Order No. 50 s. 2001 "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs"