

ADMINISTRATIVE ORDER

No. _____

SUBJECT: New Schedule of Fees and Charges of the Food and Drug Administration for Licensing, Registration, and Other Authorizations and Regulatory Services

I. BACKGROUND AND RATIONALE

Enshrined in Section 12, Article XIII of the 1987 Philippine Constitution, it is the responsibility of the State to establish and maintain an effective food and drug regulatory system. A system that is responsive to the country's current health needs as and capable of providing innovative solutions to unfamiliar problems. Consistent with this national policy, the Congress of the Philippines passed three landmark legislations, namely: Republic Act (RA) No. 9502, (Universally Accessible Cheaper and Quality Medicine Act of 2008), R.A. No. 9711, (Food and Drug Administration Act of 2009) and R.A. No. 10611 (Food Safety Act of 2013), for the promotion and protection of public health and welfare.

Section 31 of R.A. No. 9502 and Section 18 of RA No. 9711, authorize the Food and Drug Administration (FDA) to retain all fees, fines, royalties and other charges under a Special Regulatory Fund. These fees, fines and other charges are dedicated for the following purposes: (a) operations, which includes upgrading of its facilities, equipment outlay, human resource development and expansion; (b) acquisition of the appropriate office space, as well as purchase of laboratory equipment and motor vehicles; (c) upgrading of its current facilities, equipment and maintenance of these facilities; (d) funding for operating expenses of the central office laboratory divisions and satellite laboratories; (e) post market surveillance and other activities or services of the FDA in the performance of its mandate. Furthermore, R.A. No. 9711 supports the self-sufficiency and fiscal sustainability of the FDA.

FDA is rationalizing and streamlining its fee structure to make adjustments in order to: strengthen regulatory enforcement and post-marketing surveillance activities and address rising operational costs. The agency bears costs relating to processing of applications as well as expenses spent for the following: (1) development of qualified personnel with highly specialized skills in the evaluation of health products; (2) improvement and maintenance of electronic systems; (3) upgrade of facilities; (4) development of smart regulation mechanisms; and (5) initiatives to foster public information and services.

The existing schedule of fees was implemented as far back as the year 2001. The FDA has not introduced any increase in fees and charges since. With its upgrade in services and adopting the use of electronic registration, the modification in its current fees and charges is one way of assuring the full implementation of the Agency's Five Year Development plan, sustaining its services and operations, and supporting its continued improvement and growth.

In the interest of 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 heads of bureaus, offices or agencies, upon approval of the concerned department heads are authorized to revise their rates of fees and charges pursuant to Section 54 (1), Chapter 12, Book IV of the Executive Order No. 292 or the Administrative Code of 1987.

As such, FDA is restructuring its fees and charges at a level commensurate with the cost of regulating health products to be able to improve agency performance, sustain its operations, and achieve its legal mandate.

II. OBJECTIVE

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

III. SCOPE

The new schedule of fees and charges shall apply to all establishments and health products under FDA's jurisdiction.

However, the fees and charges for:

1. Authorizations for Pest Control Operators and Applicators (PCOs/PCAs);
2. Authorizations for Household/Urban Hazardous Substances (HUHS) establishments and products; and,
3. laboratory services (except, suitability evaluation of food contact materials, evaluation of test results from accredited laboratories, lot release certification, and batch notification certificates) shall not be covered by this Order.

IV. DEFINITION OF TERMS

- A. "Annual Fee"** refers to a yearly payment made by establishments to retain the validity of a License to Operate (LTO).

- B. “Application Fee”** refers to the amount paid in relation to the screening of applications for LTO and product registration leading to a decision of whether or not the application may be received or accepted for assessment.
- C. Certificate of Free Sale** refers to a Certificate issued by the FDA verifying that the product is legally marketed in the Philippines.
- D. “Electronic Authenticated Copy”** is a valid scanned copy of authorization with a barcode, whether Certificate of Product Registration (CPR) or LTO issued by the FDA for special purposes, e.g. as part of the requirements to be submitted during biddings in government agencies.
- E. “Centers”** shall refer to the Center for Cosmetic Regulation and Research (CCRR), Center for Food Regulation and Research (CFRR), Center for Drug Regulation and Research (CDRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR).
- F. “Evaluation Fee”** refers to the amount paid in relation to the assessment of accepted applications for LTO or product registration to reach a decision to approve or disapprove the said application.
- G. “Initial Application”** is the term used for a first-time application for an LTO or any market authorization from the FDA.
- H. “Legal Consultation Fee”** is the amount charged to avail of legal consultation and guidance services provided by the Legal Services Support Center relating to an interpretation of the law, legal implications of a set of facts and legal remedies.
- I. “License Fee”** refers to the amount paid by establishments for the issuance of the LTO after the evaluation and assessment of the application and upon its approval. It is the fee paid for initial LTO applications. When granted with an LTO, an annual fee is then payable.
- J. “Pre-market Consultation Fee”** is the amount charged prior to submission of an application for license or registration to avail of technical consultation and guidance services on the licensing of an establishment and/or product registration. It also refers to the fee charged to avail of technical, scientific and expert advice valuable for product development.
- K. “Re-issuance of CPR”** is the process of granting a duplicate copy of a valid authorization upon the request of the Marketing Authorization Holder (MAH), due to loss or damage of the original issuance.
- L. “Reconstruction of CPR”** is the process of consolidating all related approved amendments and variations related to a CPR and issuing a new CPR reflecting all the said amendments and variations.
- M. “Variation”** and/or **“Amendment”** refer to post approval changes in the status, condition and other details indicated in the issued authorization by the FDA.

V. GUIDELINES

A. The new schedule of fees and charges is attached as Annexes A to G:

Annex "A" General Regulatory Fees and Charges

Annex "B" Fees and Charges for Applications for License to Operate

Annex "C" Fees and Charges for Applications for Certificate of Product Registration

Annex "D" Good Manufacturing Practices (GMP) Conformity Assessment of Manufacturers of Drug Products

Annex "E" Laboratory Fees for Certification

B. The application fees for granting an authorization prescribed in this issuance shall cover the expenses of the following activities, including post-approval activities, when applicable:

1. Receiving of application documents through manual and online submission systems;
2. Assessment, evaluation, and review of application documents;
3. Inspection of establishments related to the licensing applications;
4. Printing of one (1) original copy and issuance of additional nineteen (19) electronic authenticated copies of the LTO and CPR; and
5. Records management and archiving.

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 RA 3870, as amended by PD 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. Courier services to deliver the authorization;
4. Such other services not listed in the previous section.

D. All fees shall be harmonized with the recent issuance on payments and other related provisions, thus fees either in Cash or Manager's Check payable to Food and Drug Administration shall be collected ONLY through the FDA Cashier and all authorized FDA Satellite Cashiers. Payment of fees shall follow the existing collection policies and procedures.

E. The Annual Fee shall be collected yearly upon issuance of the marketing authorization. Non-payment of the Annual Fee shall lead to the revocation of the marketing authorization.

F. 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, the surcharge or penalty, which shall be imposed only for applications for renewal of LTO or CPR registration received after the date of their expiration, shall be assessed and imposed. This rule applies even in succeeding renewal applications.

An application for renewal of LTO, CPR or other market authorizations received after its date of expiration shall be subject to a surcharge or penalty. The surcharge or penalty shall be equivalent to twice (2x) the renewal licensing or application fee and other market authorization fee/s with an additional payment of 10% of the renewal fee per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days. Any application for renewal of license, registration, and other market authorizations filed thereafter 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 initial filing and evaluation procedure.

For applications for renewal filed within one hundred twenty (120) days from its original expiry, the LTO shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

G. Exemptions. In the interest of public health, selected drug products will be exempted from all product-related fees and charges. The list of such products will be issued in a separate guideline and shall be updated as necessary.

VI. IMPLEMENTATION ARRANGEMENTS

FDA fees and charges shall be reviewed every two (2) years and as may be required by laws, executive orders, regulations and/or other issuances.

VII. REPEALING CLAUSE

Provisions of Administrative Order No. 50 series 2001, FDA Circular No. 2011-004 and other previous issuances inconsistent with this Administrative Order are hereby repealed, rescinded and modified accordingly.

VIII. 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.

IX. EFFECTIVITY DATE

The fees and charges for licensing, GMP inspection/audit, and certain laboratory service fees shall take effect after fifteen (15) days following the completion of publication in two newspapers of general circulation. While, the effectivity date of the

fees and charges for product notification and registration shall be announced in a separate issuance.

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