Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE / DEPARTMENT ORDER
No. _____

SUBJECT: **Addendum to 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."**

I. RATIONALE

On 18 August 2009, Republic Act (RA) No. 9711 also known as "Food and Drug Administration (FDA) Act of 2009", is issued to empower the Food and Drug Administration (FDA) in regulating establishments and health products under its jurisdiction. Paragraph (o) of Section 2, Article II (A) of "The Rules and Regulations Implementing Republic Act No. 9711 or The Food and Drug Administration (FDA) Act of 2009" has mandated the FDA to develop and issue appropriate authorizations that would cover establishments, facilities and health products. One of the authorizations being issued by the FDA is the License to Operate (LTO).

On 08 May 2020, Administrative Order (AO) No. 2020-0017 entitled, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003", is issued to simplify the requirements and processes for initial, renewal, and variation applications for LTO. The AO also requires manufacturers, traders and distributors (importers, exporters, and wholesalers) of health-related devices such as equipment or devices used for treating sharps, pathological and infectious wastes, and water treatment devices/systems, to secure an LTO from the FDA. Payment of licensing fees and other charges for these health-related device establishments, according to the AO, shall be based on the latest FDA issuance.

AO No. 50 series 2001 entitled, "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs" is issued on 17 September 2001 to provide the basis for fees for FDA Marketing Authorizations including the LTO. The fees in the AO cover all types of health products and establishments under the FDA's jurisdiction excluding the fees and charges for health-related devices and establishments. Hence, the need for the issuance of this AO supplementing AO No. 50 s. 2001 to provide guidelines for the licensing fees for the said health-related device establishments.

In line with the mandate of the FDA to implement the licensing of health-related device establishments, this Order is hereby being issued.

II. OBJECTIVES

This Order aims to provide reference for the licensing fees of manufacturers, traders and distributors (importers, exporters, and wholesalers) of health-related devices.

III. SCOPE OF APPLICATION

This Order shall cover manufacturers, traders and distributors (importers, exporters, and wholesalers) of health-related devices such as:

A. Equipment or devices used for treating sharps, pathological and infectious wastes
B. Water treatment devices/systems
C. Other health-related devices as determined by the FDA

IV. GUIDELINES

Fees and charges for licensing of manufacturers, traders and distributors (importers, exporters, and wholesalers) of health-related devices shall be as follows:

Classification	Fees (in Peso)	
	Initial (1 year validity)	Renewal (2 year validity)
Distributors, Importers, Exporters Wholesalers	4,000.00	8,000.00
Manufacturers		
a. 20 Million and below	5,000.00	10,000.00
b. Over 20 Million but below 50 Million	7,000.00	14,000.00
c. 50 Million and above	10,000.00	20,000.00
Traders		
a. 20 Million and below	3,000.00	6,000.00
b. Over 20 Million but below 50 Million	5,000.00	10,000.00
c. 50 Million and above	7,000.00	14,000.00

V. SEPARABILITY CLAUSE

If any part or provision of this Order is rendered invalid by any court of law or competent authority, the remaining parts or provisions not affected shall remain valid and effective.

VI. EFFECTIVITY

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.

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO II
Secretary of Health

ANNEX A: REFERENCES

Congress of the Philippines. 18 August, 2009. R.A. No. 9711. The Food and Drug Administration Act of 2009.

Department of Health, DOH. September 17, 2001. Administrative Order (A.O.) No. 50 s. 2001, "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs.

Department of Health, DOH. May 8, 2022. A.O. No. 2020-0017. Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003.