Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

NOV 2 2 2012

ADMINISTRATIVE ORDER
No. 2012 - 0024

Subject: 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. RATIONALE:

Executive Order No. 197 series of 2000 was issued reiterating the importance of revising the rates of fees and charges and directing all departments, bureaus, commissions, agencies, offices and instrumentalities of the National Government, including government-owned controlled corporations, to increase their fees and charges by not less than 20 percent (20%).

Pursuant to the above authority, Administrative Order No. 50 s. 2001 and Administrative Order No. 134 s. 2002 (Amendment to the Revised 2001 Schedule of Fees and Charges of BFAD for Food Manufacturers) were issued and are still the bases for the Food and Drug Administration in charging fees for services rendered. Eleven years have passed since the time of the promulgation of such schedule of fees and charges applicable to FDA and the same has not been adjusted or amended to cover new regulated activities. In contrast and with the passage and adoption of new laws and policies for FDA to implement, among others, Republic Act No. 9502 or the Cheaper Medicines Act of 2008 and the more recent Republic Act No. 9711 or the FDA Act of 2009, the establishments, health products and activities being regulated by the FDA have more than doubled thereby immensely expanding the regulatory function or control of the FDA over such establishments, products and activities. As such, the aforesaid Administrative Order do not reflect the charges for new regulated activities such as the Accreditation of Private Testing Laboratories and the Audit and Inspection. On the other hand, the existing rates of fees for the accreditation of Bioequivalence Testing Centers and Inspection are too low and are not commensurate to fulfill the regulatory function over these very technical and highly scientific activities. Indisputably, the fees and charges of the FDA that have been in place since 2001 is deemed no longer commensurate for FDA to undertake services and other operational requirement to perform such very technical and scientific evaluations.

Thus, for FDA to effectively implement the laws it is tasked to enforce and to fulfill its regulatory function or coverage and control over establishments and products under its jurisdiction and pursuant to Republic Act No. 9711 expressly authorizing the

FDA to initiate the annual determination and review of authorization and other fees, as well as determination and constitution of additional fees such as sale of publication and services, assessment fees, fines, penalties and other fees and charges outside the usual licensing and registration fees, to be known as "other regulated fees", the FDA undertook the review of its existing schedule of fees and charges.

Now therefore, pursuant to the above express powers provided by law, the imperativeness to update the existing fees and charges implemented by the FDA, and after complying with the requirements of public consultation, this Order is hereby issued to cover the fees and charges for the accreditation of bioequivalence testing centers and private testing laboratories, as well as, audits and inspection and to further amend Administrative Order No. 50 s. 2001.

II. OBJECTIVE

This Administrative Order is issued to prescribe the corresponding schedule of fees for the services rendered by the FDA on matters pertaining to accreditation of bioequivalence testing centers and private testing laboratories, as well as, audits and inspections in order for the persons or establishments receiving the services for which the fees are imposed to be made to share the burden of the expenses incurred by the government in relation to the regulation of products and establishments within its jurisdiction.

III. SCOPE AND COVERAGE

This issuance shall apply to all person and/or establishments applying for accreditation of bioequivalence testing centers and private laboratories as well as audit or inspection.

This schedule of fees shall also apply to the concerned unit or divisions in the FDA tasked to implement this Order.

IV. SCHEDULE OF FEES

A. Accreditation of Bioequivalence Testing Centers and Private Testing Laboratory

ITEMS	FEES
1. Accreditation of BioequivalenceTestingCenter (3-year validity)	20,000 (per year)
2. Accreditation of Testing Laboratories	20,000 (per year)

B. Audits and Inspections

ITEMS	FEES
I. GCP/GLP audit of clinical trial sites/ Bioavailability/Bioequivalence Testing Centers *(minimum of 2 auditors)*	
A.Local	
1. Within Metro Manila	Php 15,000 + Transportation Cost
2. Outside Metro Manila	Php 15,000 + Per Diem/Per Inspector + Transportation Cost
B. Overseas	
1. ASEAN Countries	US$3,500 + UNDP Per Diem Rate* + Transportation Cost
2.Asia Pacific Countries (other than ASEAN)	US$7,000 + UNDP Per Diem + Transportation Cost
3. All countries outside of Asia Pacific	US$10,500 + UNDP Per Diem+ Transportation Cost
II. GLP Audit of Testing Laboratories	
A. Local	
1. Within Metro Manila	Php10,000 + Transportation Cost
2. Outside Metro Manila	Php10,000 + Per Diem/Per Inspector + Transportation Cost
B. Overseas	
1. ASEAN Countries	US$3,500 + UNDP Per Diem* + Transportation Cost
2. Asia Pacific Countries (other than ASEAN)	US$7,000 + UNDP Per Diem + Transportation Cost
3. All countries outside of Asia Pacific	US$10,500 + UNDP Per Diem+ Transportation Cost

*Overseas Per Diem shall be computed based on the current UNDP-United Nations Development Program rate

V. MONITORING OF COLLECTIONS AND REPORTING

The Administrative Division of the FDA, in coordination with its concerned Division, shall closely monitor the assessment of the above fees and charges and ensure that they are properly collected and accounted. It shall prepare a monthly report of collections based on the daily report of deposited collections to be submitted to the appropriate Department or Office pursuant to RA 9711.

The application, assessment and payment for each type of activity identified above shall follow the existing procedure implemented by FDA. The FDA shall likewise ensure that the affected stakeholders shall be informed of the above schedule of rates by any means allowed by law.

VI. SEPARABILITY/REPEALING CLAUSE

In the event that any section, paragraph, sentence, clause or word of this Administrative Order is declared invalid, other provisions not affected thereby shall remain in effect.

Any provisions of existing and other related issuances which are inconsistent or contrary with the provisions of this Administrative Order are hereby revised, modified or rescinded accordingly.

VII. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days after its publication in two (2) leading newspapers of general circulation.

ENRIQUE T. ONA, MD, FPCS, FACS
Secretary of Health

CERTIFIED TRUE COPY
NOV 22 2012
MAYLEEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health