

24 June 2011

FDA Circular
No. 2011- 003

SUBJECT: Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856.

I. Background/Rationale:

Republic Act No. 3870 (as amended by PD 200 and further amended by PD 1856) otherwise known as “An Act Defining the Functions of the U.P. Law Center, Providing for its Financing and for other Purposes” expressly mandates that:

Section 4. In order to provide for the support of the U.P. Law Center and the University of the Philippines Law Complex, the additional amount of one percent (1%) of the filing fee imposed, but in no case lower than Twenty Pesos, in the case of the appellate courts and the additional amount of one percent (1%) of the filing fee imposed, but in no case lower than Ten Pesos in the case of all other courts, including all administrative or special courts, as well as agencies or tribunals exercising quasi-judicial functions and those enumerated in Letter of Instructions No. 1182, issued on December 16, 1981, shall be collected by their respective clerks of court, or equivalent functionary, for each action or special proceeding filed therewith and for which the fees prescribed in the Rules of Court or in any statute or regulation as due and payable. For this purpose, “special proceeding” shall include any petition or application, paper or document seeking official action to establish a status, a right, privilege or particular fact or command the performance of a duty. Such additional amounts shall be receipted for as part of a special fund to be known as the “Legal Research Fund,” and shall, upon collection, be immediately remitted to the University of the Philippines and deposited in a separate account in any authorized government depository bank in the name of the National Treasurer as Ex-Officio Treasurer of the U.P. under this Charter.

Letter of Instructions No. 1182, issued on December 16, 1981 identified the Food and Drug Administration as one of those agencies covered by Republic Act No.

3870 (as amended by PD 200 and further amended by PD 1856). A copy of LOI No. 1182 is attached to this Circular as Annex "A". In compliance with the above provision, this Order is hereby issued concerning the collection of Legal Research Fee (LRF) for adherence of all concerned.

II. Details:

1. In line with the implementation of the above laws, the computation of the Legal Research Fee for the University of the Philippines Law Center (UPLR Fee) shall be based on the schedule of fees and charges implemented by the FDA and assessed only and exclusively against the following applications/ transactions:

1. Fees for Licensing of Establishments regulated by FDA or any amendment thereto.
2. Fees for Registration and Notification of, or other Authorization for Products Regulated by FDA or any amendment thereto.
3. Cost of Laboratory Analysis.
4. Accreditation of Testing Laboratories including Bioequivalence testing center.
5. Fees for appropriate Advertisements, Promotions, Sponsorships and/or other marketing activities.
6. Fees as may be imposed for Other Special proceedings.

2. From the date of effectivity of this Circular, the Cashier Section of the Administrative Division of this Office, including the Bureau of Health Devices and Technology, is directed to immediately collect the LRF corresponding for each services enumerated in the list below and thereafter remit such fees without delay to the University of the Philippines (UP) following the procedure of remitting LRF established by UP. The said list may be revised from time to time.

3. Schedule of Fees

A. Licensing of Establishment

Fees for Licensing of Establishments	AO 50 s. 2001					
	Initial			Renewal		
	Fee	LRF	Total	Fee	LRF	Total
1. Drug Outlets:	1,000.00	10.00	1,010.00	2,000.00	20.00	2,020.00
1.1 Drugstores, Hospital Pharmacies						
1.2 Chinese Drugstores						
1.3 Retail Outlet for Non-Prescription Drugs						
2. Drug Distributors:	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
Importers, Exporters, Wholesalers						
3. Medical Device Distributors:	4,000.00	40.00	4,040.00	8,000.00	80.00	8,080.00
Importers, Exporters, Wholesalers						

Fees for Licensing of Establishments	AO 50 s. 2001					
	Initial			Renewal		
	Fee	LRF	Total	Fee	LRF	Total
4. Food Distributors:	4,000.00	40.00	4,040.00	8,000.00	80.00	8,080.00
Importers, Exporters, Wholesalers						
5. Iodized Salt Importers	1,000.00	10.00	1,010.00	2,000.00	20.00	2,020.00
6. Cosmetic Distributors:	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
Importers, Exporters, Wholesalers						
7. Household Hazardous Substance Distributors:	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
Importers, Exporters, Wholesalers						
8. Drug Manufacturers:						
8.1 20 Million and below	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
8.2 over 20 Million but below 50 Million	15,000.00	150.00	15,150.00	30,000.00	300.00	30,300.00
8.3 50 Million and above	20,000.00	200.00	20,200.00	40,000.00	400.00	40,400.00
9. Drug Traders:						
9.1 20 Million and below	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
9.2 over 20 Million but below 50 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
9.3 50 Million and above	7,000.00	70.00	7,070.00	14,000.00	140.00	14,140.00
10. Cosmetic Manufacturers:						
10.1 20 Million and below	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
10.2 over 20 Million but below 50 Million	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
10.3 50 Million and above	15,000.00	150.00	15,150.00	30,000.00	300.00	30,300.00
11. Cosmetic Traders:						
11.1 20 Million and below	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
11.2 over 20 Million but below 50 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
11.3 50 Million and above	7,000.00	70.00	7,070.00	14,000.00	140.00	14,140.00
12. Medical Device Manufacturers:						
12.1 20 Million and below	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
12.2 over 20 Million but below 50 Million	7,000.00	70.00	7,070.00	14,000.00	140.00	14,140.00

	AO 50 s. 2001					
	Initial			Renewal		
12.3 50 Million and above	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
13. Medical Device Traders:						
13.1 20 Million and below	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
13.2 over 20 Million but below 50 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
13.3 50 Million and above	7,000.00	70.00	7,070.00	14,000.00	140.00	14,140.00
14. Food Manufacturers:						
14.1 1 Million and below	1,000.00	10.00	1,010.00	2,000.00	20.00	2,020.00
14.2 over 1 Million but below 5 Million	2,000.00	20.00	2,020.00	4,000.00	40.00	4,040.00
14.3 5 Million but below 10 Million	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
14.4 10 Million but below 20 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
14.5 20 Million but below 50 Million	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
14.6 50 Million and above	15,000.00	150.00	15,150.00	30,000.00	300.00	30,300.00
15. Household Hazardous Substance Manufacturers:						
15.1 1 Million and below	1,000.00	10.00	1,010.00	2,000.00	20.00	2,020.00
15.2 over 1 Million but below 5 Million	2,000.00	20.00	2,020.00	4,000.00	40.00	4,040.00
15.3 5 Million but below 10 Million	3,000.00	30.00	3,030.00	6,000.00	60.00	6,060.00
15.4 10 Million but below 20 Million	5,000.00	50.00	5,050.00	10,000.00	100.00	10,100.00
15.5 20 Million but below 50 Million	10,000.00	100.00	10,100.00	20,000.00	200.00	20,200.00
15.6 50 Million and above	15,000.00	150.00	15,150.00	30,000.00	300.00	30,300.00
16. Others:						
16.1 Pre-site Inspection of Establishments						
16.2 Clearance to Import Antibiotics	200.00	10.00	210.00			
16.3 Amendment of LTO or Re-Issuance	3,000.00	30.00	3,030.00			

	AO 50 s. 2001					
	Initial			Renewal		
16.4 Addition or Deletion of Sources	50.00	10.00	60.00			
16.5 Certification/Clearance for BOC purpose and Donation	300.00	10.00	310.00			
16.6 Change of Business Name/ Address of Supplier	300.00	10.00	310.00			

B. PRODUCT REGISTRATION

1. Drugs:						
1.1 New Drug/Monitored Release	25,000.00	250.00	25,250.00			
1.2 Unbranded	2,000.00	20.00	2,020.00	7,500.00	75.00	7,575.00
1.3 Branded	3,000.00	30.00	3,030.00	10,000.00	100.00	10,100.00
2. Medical Device	1,500.00	15.00	1,515.00	5,000.00	50.00	5,050.00
3. Diagnostic Reagents	1,500.00	15.00	1,515.00	5,000.00	50.00	5,050.00
4. Food:						
4.1 Category 1	200.00	10.00	210.00	1,000.00	10.00	1,010.00
4.2 Category 2	250.00	10.00	260.00	1,250.00	12.50	1,262.50
4.3 Food Supplement	1,000.00	10.00	1,010.00	5,000.00	50.00	5,050.00
4.4 Bottled Water	1,000.00	10.00	1,010.00	5,000.00	50.00	5,050.00
5. Cosmetics:						
5.1 Listing	500.00	10.00	510.00	2,500.00	25.00	2,525.00
5.2 Registration	750.00	10.00	760.00	3,750.00	37.50	3,787.50
6. Household Hazardous Substances	500.00	10.00	510.00	2,500.00	25.00	2,525.00
7. Other Fees and Charges:						
7.1 Product Classification (by ACB)	500.00	10.00	510.00			
7.2 Certificate of Exemption from registration (non-registrable product)	500.00	10.00	510.00			
7.3 Re-Application:						
7.3.1 Drug, Device, Reagent	1,000.00	10.00	1,010.00			
7.3.2 Food	200.00	10.00	210.00			
7.3.3 Cosmetics	250.00	10.00	260.00			
7.3.4 HHS	250.00	10.00	260.00			

				AO 50			
7.4 Amendment of CPR							
7.4.1 Food	200.00	10.00	210.00				
7.4.2 Drugs, Devices, Reagent (change of business name/address, change of importer/distributor, additional package size) per product/per change	500.00	10.00	510.00				
7.4.3 Cosmetics/HHS (change of business name/address, change of manufacturer/importer/distributor, additional package size, change of brand name) per product/per change	300.00	10.00	310.00				
7.5 Re-Issuance of CPR (Lost/Reconstruction)	300.00	10.00	310.00				
7.6 Extension of Shelf-Life	1,000.00	10.00	1,010.00				
7.7 Food: Provisional Permit to Market (locally manufactured)	200.00	10.00	210.00				
7.8 Drug:							
7.8.1 Accreditation of Bioequivalence Testing Center (3-year validity)	10,000.00	100.00	10,100.00				
7.8.2 Periodic inspection of Bioequivalence Testing Center	5,000.00	50.00	5,050.00				
7.8.3 Review by ACB							
a. New Chemical Entity/New Drug	5,000.00	50.00	5,050.00				
b. New Dosage/Strength/Line Extension	2,500.00	25.00	2,525.00				
c. New Formulation/ Reformulation (SUPAC Guidelines)	2,500.00	25.00	2,525.00				
d. New/Additional Indication	2,500.00	25.00	2,525.00				
e. Protocol for Monitored Release/ Post-Marketing Surveillance Study	2,500.00	25.00	2,525.00				
f. Protocol for Clinical Trial/Study (Phases I, II, III)	2,500.00	25.00	2,525.00				
g. Protocol Amendment	2,500.00	25.00	2,525.00				
h. Extension of Monitored Release	1,000.00	10.00	1,010.00				
i. Compassionate Special Permit (except drugs for cancer, HIV/AIDS, and other life threatening diseases)	6,000.00	60.00	6,060.00				
j. Reclassification (Rx to OTC, OTC to DRHR, etc.)	3,000.00	30.00	3,030.00				
k. Rationale for Fixed-Dose Combination	3,000.00	30.00	3,030.00				
7.8.4 Approval for change in packaging materials/revision of packaging design (ex for mergers)/labeling design/layout	500.00	10.00	510.00				
7.8.5 Change/addition of brand name	2,500.00	25.00	2,525.00				
7.8.6 Importation Clearance for Clinical Trial/Study	500.00	10.00	510.00				
7.9 Cosmetics							
7.9.1 Approval for product / label claim (by ACB)	500.00	10.00	510.00				

C. LABORATORY ANALYSIS

CLASSIFICATION							
1.1 Drugs and Antibiotics							
Visual Examination	300.00	10.00	310.00				

	AO 50 s.2001					
Assay/Potency (Single Component)	1,500.00	15.00	1,515.00			
Assay/Potency (Multi Component)	2,000.00	20.00	2,020.00			
Dissolution Test	2,000.00	20.00	2,020.00			
Disintegration Test	350.00	10.00	360.00			
Hardness Test	350.00	10.00	360.00			
Identification Test	500.00	10.00	510.00			
Purity Test / Related Substances	500.00	10.00	510.00			
Moisture content	300.00	10.00	310.00			
Loss on Drying	300.00	10.00	310.00			
pH	300.00	10.00	310.00			
Vitamins						
Vitamin A	1,000.00	10.00	1,010.00			
Vitamin B1, B2, B6	2,000.00	20.00	2,020.00			
Vitamin C (Ascorbic Acid)	1,400.00	14.00	1,414.00			
Vitamin E	500.00	10.00	510.00			
Other Vitamins	500.00	10.00	510.00			
Minerals	800.00	10.00	810.00			
1.2 In Vitro Diagnostic Reagents	1,000.00	10.00	1,010.00			
1.3 Medical Devices	1,500.00	15.00	1,515.00			
1.4 Cosmetics						
Assay	1,200.00	12.00	1,212.00			
Identification Test	500.00	10.00	510.00			
Volatile / Non-Volatile Matters	500.00	10.00	510.00			
1.5 Food Products						
Moisture	300.00	10.00	310.00			
Protein	1,000.00	10.00	1,010.00			
Fat / Oil	500.00	10.00	510.00			
Starch	500.00	10.00	510.00			
Glucose	500.00	10.00	510.00			
Sucrose	500.00	10.00	510.00			
Lactose	500.00	10.00	510.00			
Crude Fibers	500.00	10.00	510.00			
Dietary Fibers	2,000.00	20.00	2,020.00			
Total Solids	300.00	10.00	310.00			
Soluble Solids	300.00	10.00	310.00			
Water-Insoluble Solids	300.00	10.00	310.00			

