Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

6 May 2013

ADMINISTRATIVE ORDER
No. 2013 - _____

SUBJECT: 2013-2014 Schedule of Fees and Rationalization of Services of the Food and Drug Administration

I. RATIONALE

It is the responsibility of the State to establish and maintain an effective health product regulatory system and undertake research responsive to the country's health needs and problems. This declaration of policy is enshrined in Section 12, Article XIII on Health of the 1987 Philippine Constitution. Further enshrining this duty, the Fourteenth Congress passed two landmark bills, namely Republic Act (RA) No. 9502, (Universally Accessible Cheaper and Quality Medicine Act of 2008), and Republic Act No. 9711, (Food and Drug Administration Act of 2009), which ensured protection of the health and welfare of consumers as well as access to affordable and safe medicine.

Section 31of RA No. 9502 authorizes the Food and Drug Administration (FDA) to retain all fees, fines, royalties and other charges and to use them as follows: operations, including upgrading of its facilities, equipment outlay, human resource development and expansion; acquisition of the appropriate office space, purchase of laboratory equipment and motor vehicles; upgrading of its current facilities and equipment and maintenance; to fund operating expenses of the central office laboratory divisions and satellite laboratories, as well as other activities or services of the FDA in the performance of its mandate. Consistent with Section 31 of RA No. 9502, Section 18 of RA No. 9711 authorizes the FDA to retain its income as a Special Regulatory Fund. The FDA shall cease to be allotted in the General Appropriations Act after it has established itself to be fiscally sustainable. Thus, a fee increase is necessary given that the current income does not breakeven. For the agency to pursue any of the aforementioned purposes of the retained income, income has to first exist and sufficiently accumulate.

The setting of fees is a reflection of the agency's policies. As part of the Philippine government, the agency is fully supportive of local industries that are

striving to be competitive in the global market. The nature of the FDA as a regulator of trade becomes apparent – high fees, stiff competition and high technological requirement would challenge the entry of new establishments. Raising fees too high will stifle growth and innovation. But the FDA is first and fundamentally a public health agency. It is to the quality, efficacy and safety of health products and transparency of processes that the agency is dedicated. It is the intention of this agency that setting higher fees will not only provide the necessary funds to fully implement the provisions of Republic Acts No. 9502 and 9711, but also establish a reasonable barrier to entry that will help select against establishments that don't have the capacity to comply with complex health regulations. Ultimately, risky products and irresponsible business practices are minimized from affecting adversely the health of the public.

II. OBJECTIVE

This Administrative Order is being issued to prescribe the schedule of fees and charges for the services, as well as other regulated fees, rendered to establishments and their products that the FDA regulates and, as appropriate, to consumers and the general public.

III. SCOPE AND COVERAGE

This schedule of fees shall apply to all establishments and products regulated by the FDA or under its jurisdiction, and to all private citizens who want to avail any of the services offered by the FDA. Other government agencies, state colleges and universities, public schools, and non-governmental organizations are also covered by this Administrative Order.

Fees and charges of advertisement and promotion permits, laboratory analyses, bioequivalence centre accreditation, clinical research officers and clinical trials are not covered by this Administrative Order and will continue to charge the fees indicated in the Department of Health Administrative Order no. 2001-0050, and/or other relevant issuances.

IV. FEE RESTRUCTURING

A. The fees charged by the FDA are amended as indicated in Annex I..
B. The fees for granting an authorization cover the expense of the following activities:
    1 Submission of application dossier either through hardcopy or electronically;

2 Forwarding of application to respective Center of Product Regulation and Research;
3 Initial inspection of facility indicated in the application;
4 Audit(s) of the facility indicated in the application, to be done at a
5 frequency and interval decided by the appropriate Center considering risk classification of product(s) involved, and location of the facility;
5 Technical evaluation of application dossier by the appropriate Center;
6 At least three application status updates:
i. Upon forwarding to appropriate Center,
10 ii. Notice of inspection or audit, or evaluation status, and
iii. Upon approval or denial of application;
7 Printing and authentication of ten (10) copies of the official authorization;
8 Forwarding the letter of disapproval or authorization to the Administrative and Finance Office for releasing,
15 9 Records management and archiving, and
10 Legal research fund.

C. Fees for the use of payment collection facilities authorized by the FDA are not included in the fees set in this administrative order
D. Parcel service delivering the authorization or letter of disapproval are not
20 included in the fees, but can be availed at the discretion of the applicant.
E. The market capitalization stratification of licenses to operate is into two categories: 1) micro-, small- and medium-scale establishments, and 2) large-scale establishments. The classification of establishment based on asset size shall overrule that based on number of employees.[1]

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[1] *As defined under Small and Medium Enterprise Development (SMED) Council Resolution No. 01 Series of 2003 dated 16 January 2003- Micro, small, and medium enterprises (MSMEs) are defined as any business activity/enterprise engaged in industry, agri-business/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:

By Asset Size*

Micro:	Up to P3,000,000
Small:	P3,000,001 - P15,000,000
Medium:	P15,000,001 - P100,000,000
Large:	above P100,000,000

Alternatively, MSMEs may also be categorized based on the number of employees:

Micro:	1 - 9 employees
Small:	10 -- 99 employees
Medium:	100 -- 199 employees
Large:	More than 200 employees

F. The fee stratification of Botika ng Barangay and Retail Outlet for Non-Prescription Drugs as distinct from Drugstores is discontinued.

G. Drug registration fees do not discriminate between ASEAN Common Technical Document standards, and otherwise.

H. Drug manufacturing establishments are EXEMPTED from the provision creating two fee brackets for a license to operate. Given the high-risk nature of the products involved, it is consistent with ensuring the quality, safety and efficacy of drugs and related products that a barrier be set up against the entry of less than capable establishments into the industry of drug manufacturing.

I. The following products of the Centre for Drug Regulation and Research are discontinued:

1 Generic labelling exemption, which will be included in the activities covered by product registration, and

2 Application for exhaustion of labels, which is implied and covered for in every amendment.

J. The phasing-in of fees is as follows: 30% of the new fees on 1 July 2013, 60% of the new fees on 1 January 2014; and 100% of the new fees on 1 July 2014.

K. Fees and charges are subject for review by the FDA as appropriate.

V. VALIDITY OF AUTHORIZATIONS

Extending the validity of authorizations is an enactment of the agency's policy of promoting establishment maturity and accountability.

I. All licenses to operate and certificates of product registration to be issued by the FDA shall, regardless of initial or renewal status, be valid for FIVE (5) YEARS, until revoked.

II. Cosmetic notifications are exempted from the preceding provision and shall be valid for ONE (1) YEAR until revoked.

III. Food establishments have the option to secure a TWO (2) YEAR authorization to market food products. This exemption is in consideration of food products that vary on an annual or shorter basis.

IV. New drugs on monitored release are granted FIVE (5) YEARS authorization with no provision for extension. At the end of the five years, the drug establishment must file an application for authorization under regular registration.

V. No surcharges shall be levied against establishments for delay in renewing expired authorizations. However, the renewed authorization shall have gained validity on the day of expiry of the preceding authorization.

VI. Establishments that continue to pursue activities allowed only with a valid authorization, but have not received confirmation of their application for renewal from the appropriate Centre for Product Regulation and Research, are considered in violation of Republic Act No. 9711 and shall have their authorization revoked.

VII. Establishments that have expired licenses but have received confirmation of their application for renewal of authorization from the appropriate Centre for Product Regulation and Research, are considered duly authorized by the FDA.

VI. RE-APPLICATIONS

A. Applications that have been denied are granted one opportunity to re-apply.

B. A corresponding re-application fee equivalent to Php 5,000 or 20% of the current fee for the authorization concerned, whichever is higher, shall be imposed along with the resetting of timelines.

C. Full fees of the appropriate authorization shall again be charged after disapproval of a re-application.

D. Re-application privileges do not apply to renewal of expired authorizations.

VII. CUSTOMS CLEARANCE

The FDA will no longer issue clearance certificates for release of imported products from the Bureau of Customs starting 1 July 2014. Until then, all clearances shall be charged Php 1,500 for every shipment of a single product, regardless of volume.

VIII. REPEALING CLAUSE

Provisions of Administrative Order No. 2001-0050 and other previous issuances, inconsistent with this Order are hereby rescinded and modified accordingly.

IX. SEPARABILITY CLAUSE

If any provision of this Order is declared invalid by any court of law or any competent authority, those provisions not affected shall remain valid and effective.

X. EFFECTIVITY

This order shall take effect fifteen (15) days after publication on the FDA website (www.fda.gov.ph), and the Official Gazette or two (2) newspapers of general circulation.

ANNEX I

Fee Schedule for Center for Food Regulation and Research

Table 1

License to Operate	New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
Food Manufacturers				
1 Micro, Small and Medium-scale Enterprises	Php 30,000	Php 9,000	Php 18,000	Php 30,000
2 Large Scale Enterprises	Php 162,000	Php 48,600	Php 97,200	Php 162,000
Food Distributor (Importer/ Exporter or Wholesaler)	Php 100,000	Php 30,000	Php 60,000	Php 100,000

Table 2

Product Registration	New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
Food Category I				
2-year validity	Php 4,000	Php 1,200	Php 2,400	Php 4,000
5-year validity	Php 10,000	Php 3,000	Php 6,000	Php 10,000
Food Category II				
2-year validity	Php 10,000	Php 3,000	Php 6,000	Php 10,000
5-year validity	Php 25,000	Php 7,500	Php 15,000	Php 25,000

Table 3

Other CFRR Products	New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
1 HACCP[2] Certificate	Php 25,000	Php 7,500	Php 15,000	Php 25,000
2 Additional Copies of Authorization	Php 2,500	Php 2,500	Php 2,500	Php 2,500
3 Amendment[3]	Php 1,000	Php 1,000	Php 1,000	Php 1,000

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[2]Hazard Analysis and Critical Control Points – granted per product, valid for ONE (1) YEAR

[3]Amendment – as per issuance from the Centre for Food Regulation and Research

Fee Schedule for Center for Cosmetic Regulation and Research

Table 4

License to Operate	New Fees	1 July 2013	Date Effective: 1 January 2014	1 July 2014
Laboratory/ Manufacturer/ Trader				
1 Micro, Small and Medium-scale Enterprises	Php 30,000	Php 9,000	Php 18,000	Php 30,000
2 Large Scale Enterprises	Php 162,000	Php 48,600	Php 97,200	Php 162,000
Distributor (Importers, Exporters and Wholesalers)	Php 52,500	Php 15,750	Php 31,500	Php 52,500

Table 5

Product Registration	New Fees	1 July 2013	Date Effective: 1 January 2014	1 July 2014
Cosmetic Notification[4]				
First, second and third	Php 1,000	Php 1,000	Php 1,000	Php 1,000
Fourth and so on	Php 200	Php 200	Php 200	Php 200
Household Hazardous Substances	Php 25,000	Php 7,5000	Php 15,000	Php 25,000
Household Urban Pesticides	Php 50,000	Php 15,000	Php 30,000	Php 50,000

Table 6

Other CCRR Products	New Fees	1 July 2013	Date Effective: 1 January 2014	1 July 2014
1 **Additional Copies of Authorization**	Php 2,500	Php 2,500	Php 2,500	Php 2,500
2 **Amendment**[5]	Php 2,500	Php 2,500	Php 2,500	Php 2,500
3 **Certificate of Free Sale/ Export Certificate**	Php 2,500	Php 2,500	Php 2,500	Php 2,500

[4] Cosmetic Notification – Authorizations are granted per variant, and are valid for ONE YEAR

[5] Amendment - as per issuance from the Centre for Cosmetic Regulation and Research

Fee Schedule for Center for Drug Regulation and Research

Table 7

License to Operate	New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
Drug Retail Outlet[6]	Php 40,000	Php 12,000	Php 24,000	Php 40,000
Drug Distributors (Importers, Exporters, Wholesalers)	Php 90,000	Php 27,000	Php 54,000	Php 90,000
Drug Manufacturers (including Traders)	Php 270,000	Php 81,000	Php 162,000	Php 270,000

Table 8

Product Registration	New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
New Drug/ Monitored Release	Php 350,000	Php 105,000	Php 210,000	Php 350,000
Regular Registration				
Unbranded	Php 142,500	Php 42,750	Php 85,500	Php 142,500
Branded	Php 180,000	Php 54,000	Php 108,000	Php 180,000

Table 9

Other CDRR Products		New Fees	Date Effective: 1 July 2013	1 January 2014	1 July 2014
4	**Variation**				
	Major	Php 145,000	Php 43,500	Php 87,000	Php 145,000
	Minor	Php 24,000	Php 7,200	Php 14,400	Php 24,000
	Notification	Php 2,000	Php 2,000	Php 2,000	Php 2,000
5	**Additional Copies of Authorization**	Php 2,500	Php 2,500	Php 2,500	Php 2,500
6	**Amendment**[7]	Php 5,000	Php 5,000	Php 5,000	Php 5,000
7	**Export Certificate**	Php 2,500	Php 2,500	Php 2,500	Php 2,500
8	**Import Clearance for Investigational Drugs**	Php 5,000	Php 5,000	Php 5,000	Php 5,000

[6]Drug Outlets refer to drug stores, industrial clinics, non-prescription drug retail outlets and Botika ng Barangay.
[7] Amendment – as per issuance from the Centre for Drug Regulation and Research

9	**Compassionate Special Permit to Import**	Php 1,000	Php 1,000	Php 1,000	Php 1,000
10	**Certificate of Pharmaceutical Product/ Free Sale/ Approved Label/ Summary of Product Characteristics**	Php 5,000	Php 5,000	Php 5,000	Php 5,000

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ANNEX II

Income Statement (Php '000s)

INCOME	FY 2009	FY 2010	FY 2011
National Government Subsidy	218,668	249,106	297,214
Less : Reversion of Unused Notice of Cash Allocation	(32)	(30,646)	(20,553)
Subsidy from Central Office	-	-	3,306
Total Subsidy from National Government	**218,636**	**218,460**	**279,967**
Add: Income from Nat'l. Government Operations			
Seminar Fees	6,169	2,144	4,257
Income from Grants and Donations	7,414	2,408	3,364
Other Income	338	536	527
Total Income from Nat'l Gov't Operations (outside of RA 9502)	***13,920***	***5,088***	***8,148***
Add: Income from Nat'l. Government Operations (RA 9502)			
License Fees (RA 9502)	57,931	63,287	67,164
Registration Fees (RA 9502)	90,157	103,113	101,571
Other Fees (RA 9502)	51,048	56,621	53,637
Fines, Penalties (RA 9502)	3,931	4,246	6,858
Interest Income (RA 9502)	344	2,142	2,440
Miscellaneous Income (RA 9502)	5,551	7,199	12,412
Total Income from Gov't Operations (RA 9502)	***208,963***	***236,607***	***244,082***
Total Income from National Gov't Operations	**222,883**	**241,696**	**252,230**
TOTAL INCOME	**441,519**	**460,155**	**532,197**

EXPENSES	FY 2009	FY 2010	FY 2011
Salaries and Wages	56,990	67,347	82,167
PERA	6,994	7,183	7,692
Additional Compensation	-	-	-
Representation Allowance	433	469	544
Transportation Allowance	354	338	320
Clothing & Uniform Allowance	1,200	1,184	1,316
Subsistence & Laundry Allowance	5,477	5,669	6,037
Productivity Incentive Bonus	579	561	619
Honoraria	395	416	337

Hazard Pay	13,445	15,833	18,483
Longevity Pay	2,447	2,924	3,359
Cash Gift	1,479	1,542	1,654
Year End Bonus	5,083	6,061	7,341
Life & Retirement Insurance Contributions	6,860	8,048	9,859
PAG-IBIG Contributions	387	333	389
PHILHEALTH Contributions	694	808	959
Employees Compensation Insurance Premium	338	351	379
Terminal Leave Benefits	1,104	1,172	1,598
Other Personnel Benefits	17,694	19,914	19,127
Total Personal Services Expenses	**121,954**	**140,154**	**162,179**
	FY 2009	FY 2010	FY 2011
Traveling Expenses - Local	3,392	2,764	4,497
Traveling Expenses - Foreign	3,058	3,049	2,576
Training Expenses	10,831	6,894	11,372
Scholarship Expenses	201	277	169
Office Supplies Expense	2,904	3,001	3,772
Accountable Forms Expenses	118	1,160	145
Medical, Dental and Laboratory Expenses	6,964	6,057	10,390
Gasoline, Oil and Lubricants Expenses	271	320	583
Other Supplies Expenses	800	831	891
Water Expenses	15	39	46
Electricity	7,503	11,831	12,224
Postage and Deliveries	278	201	300
Telephone Expense - Landline	824	710	2,352
Telephone Expense - Mobile	249	275	413
Internet Expenses	734	600	943
Advertising Expenses	1,911	2,372	903
Printing and Binding Expenses	389	175	140
Representation Expenses	169	113	110
Subscription Expenses	55	102	223
Legal Services	288	288	254
Consultancy Services	796	1,080	284
Environment/Sanitary Services	-	49	1,335
Janitorial Services	2,665	3,309	4,323
Security Services	4,480	5,258	6,399
Other Professional Services	1,019	2,097	3,037

Repair & Maintenance - Electrification	-	-	22
Repairs & Maintenance - Office Buildings	157	376	191
Repairs & Maintenance - Other Structures	73	15	200
Repairs & Maintenance - Office Equipment	216	407	561
Repairs & Maintenance - Furniture & Fixtures	2,846	-	-
Repairs & Maintenance - IT Equipment	29	-	217
Repairs & Maintenance - Communication Equipment	-	2	57
Repairs & Maintenance - Firefighting Equipment	-	275	4
Repairs & Maintenance - Technical Equipment	1,986	2,537	2,800
Repairs & Maintenance - Other Machinery & Equipment	6	-	-
Repairs & Maintenance - Motor Vehicles	36	46	237
Repairs & Maintenance - Other PPE	779	13	32
Repairs & Maintenance - Artesian Wells	35	234	27
Extraordinary Expenses	138	133	7
Taxes, Duties and Licenses	-	41	-
Fidelity Bond Premium	108	181	108
Insurance Expenses	539	454	633
Depreciation Expenses - Electrification	63	63	63
Depreciation Expenses - Office Buildings	9,005	4,637	4,963
Depreciation Expenses - Other Structure	104	15	-
Depreciation Expense - Office Equipment	-	484	690
Depreciation Expense - Furniture & Fixtures	-	767	381
Depreciation Expense - IT Equipment	-	272	877
Depreciation Expense - Library Books	-	92	-
Depreciation Expense - Communication Equipment	-	45	20
Depreciation Expenses - Firefighting Equipment	363	-	-
Depreciation Expense - Technical & Scientific Equipment	-	1,842	1,438
Depreciation Expenses - Motor Vehicles	335	328	2,970
Other Maintenance & Operating Expenses	2,220	1,530	2,797
Bank Charges	1	-	-
Total Maintenance Operating Expenses	**68,954**	**67,640**	**86,979**
TOTAL EXPENSES	**190,908**	**207,794**	**249,158**
Net Income	**250,611**	**252,362**	**283,039**