الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Date: 23/04/1432H (28/3/2011)

Subject: Fees of Regulatory Services of Pharmaceutical Products

To: General Director of the Company

To: Scientific Office Manager

Dear Gentlemen,

Referring to circular No. 3993 dated 15/10/1430H that was announced to all Pharmaceutical companies and Scientific Offices regarding the fees of Regulatory Services of Pharmaceutical Products, and after reevaluating the fees:

We would like to inform you that according to the fourth article of the Saudi Food & Drug Authority regulation, which was issued by the Royal act number (6) on (25/1/1428 H), "*the SFDA has the right to perform its tasks commercially with all necessary permissions to perform its tasks*." In addition to section No. 16 of the Authority's regulation that is related to its financial sources including the income it generates from the provided services to the beneficiaries and to the jurisdictions of His Excellency the CEO of SFDA. Therefore, the fees of Regulatory Services of Pharmaceutical Products have been approved by administrative decision No. (64/32) dated on 18/4/1432H according to the attached table. The payment of the fees shall be done through the SFDA account by the (SADAD) system.

Thank you for your corporation

Signed by

Vice-President for Drug Affairs

Prof. Saleh Abdullah Bawazir

Attaching table:

1. The SFDA will charge fees for Regulatory Services of Pharmaceutical Products, according to the following table:

No.	Service type	Fees by Saudi Riyal
1.	Issuing a Certificate of Pharmaceutical Product (CPP) or a Free Sale Certificate	200
2.	Issuing a certificate for Good Manufacturing Practice (GMP)	500
3.	Issuing a price list of company products	500
4.	Evaluating product advertisement application	14,000
5.	Product classification	1,000
6.	Changing the name of a manufacturer	2,500
7.	Re-pricing application	1,000
8.	Consulting services for labels and SPC/PIL	5,000
9.	Evaluating clinical trials	15,000
10.	Inspecting a pharmaceutical products warehouse to issue a license	1,000
11.	Inspecting a pharmaceutical consulting center to issue a license	1,000
12.	Inspecting a scientific office to issue a license	5,000
13.	Pre-registration price estimation	20,000
New Drugs and Biologicals		
14.	Evaluating and analyzing a drug application	95,000
15.	Evaluating the addition of a new pharmaceutical dosage form	95,000
16.	Evaluating the addition of a new concentration	24,000
17.	Evaluating the addition of a new pack type	24,000
18.	Evaluating the addition of a new pack size (in a new application)	5,000
19.	Evaluating the addition of a new indication	24,000
20.	License renewal	30,000
Generic Drugs		
21.	Evaluating and analyzing a drug application	40,000

No.	Service type	Fees by Saudi Riyal
22.	Evaluating the addition of a new pharmaceutical dosage form	40,000
23.	Evaluating the addition of a new concentration	10,000
24.	Evaluating the addition of a new pack type	5,000
25.	Evaluating the addition of a new pack size (in a new application)	1,000
26.	License renewal	10,000
Herbal and Health Products		
27.	Evaluating and analyzing a drug application	20,000
28.	Evaluating the addition of a new pharmaceutical dosage form	20,000
29.	Evaluating the addition of a new concentration	5,000
30.	Evaluating the addition of a new pack type	2,000
31.	Evaluating the addition of a new pack size (in a new application)	1,000
32.	License renewal	8,000
Veterinary Products		
33.	Evaluating and analyzing a drug application	5,000
34.	Evaluating the addition of a new pharmaceutical dosage form	5,000
35.	Evaluating the addition of a new concentration	1,000
36.	Evaluating the addition of a new pack type	1,000
37.	Evaluating the addition of a new pack size (in a new application)	1,000
38.	License renewal	1,000
Intravenous solutions		
39.	Evaluating and analyzing a drug application	15,000
40.	Evaluating the addition of a new concentration	1,000
41.	Evaluating the addition of a new pack type	1,000
42.	Evaluating the addition of a new pack size (in a new application)	1,000
43.	License renewal	5,000