ANNOUNCEMENT 2/13/MDS-AN012

SUBJECT: Publication of Marketing Authorization renew & update fees and review times.

ADDRESSEES: Manufacturers of medical devices (both local and overseas) and authorised representatives for both local and overseas manufacturers

Marketing Authorization renew and update fees will be handled through the following fees categories (The following fees categories are applicable on Tables: (1), (2) and (3)):

Category	Fees (SR)	Lead Time (Working Days)
Administrative Fees	1,100	15
Reduced Fees	5,000	15
Complete Fees	As shown in table (3)	35
Fees for Renewing Design Examination Certificates	1,500 per Design Examination Certificate	15

A. MDMA Renew :

Table (1): MDMA Renew Per Jurisdiction

Jurisdiction	Type	Class	Process
EU & Australia	MD	I non measure & non sterile	Administrative fees
		Is & Im	Reduced fees
		IIa	
		IIb	
		III	
		AIMD	
	IVD	GIVD	Administrative fees
		Self Test	Reduced fees
		List B	
		List A	
USA	MD	Unclassified	Administrative fees *
		Class I Exempt	
		Class II Exempt	
		I	
		II	
		III	
	IVD	Class I Exempt	Administrative fees *
		Class II Exempt	
		I	
		II	
		III	
CANADA	MD & IVD	I	Administrative fees
		II	
		III	
		IV	
JAPAN	MD& IVD	I	Reduced Fees
		II	
		III	
		IV	

*** Reduced fees will apply if the Establishment Inspection Report (EIR) has been updated**

B. MDMA Update

Table (2): Examples for Update Requests

Case	Jurisdiction	Type	Process
• Adding products • Adding Models • Brand Name Changes • Chang in manufacturer address • Change in device design	All Jurisdictions	MD & IVD	Reduced fees
Expired Design Examination Certificate	EU	MD & IVD	1,500 SR per DE renew
Minor update for Label, IFUs and advertising material	All Jurisdictions	MD & IVD	Administrative fees
Change jurisdiction OR Change in classification	All Jurisdictions	MD & IVD	Complete fees

Table (3): MDMA Processing Fees

Table for Medical Device Marketing Authorization (MDMA) Processing Fees

Fee Groups	The Basis of the application for SFDA Marketing Authorization	Three years or less (SR)	More than three years (SR)	Lead time (Working Days)
FG (1)	ALL CLASS I / General IVD (other)/ Exempt IVD (TGA)	15000*	N/A	35
FG (2)	ALL CLASS II / CLASS IIa / Self-test IVD, Listable IVD	19000	21000	35
FG (3)	CLASS IIb / CLASS III (CA,PAL) /Annex II List B (IVD)	21000	23000	35
FG (4)	All other CLASS III/ CLASS IV / AIMD / Annex II List A (IVD) / Registrable IVD	23000	25000	35

Notes:

* For Class I, the Medical Device Marketing Authorisation issued by SFDA will be valid for Three (3) Years

• For all other classes, the Medical Device Marketing Authorisation issued by SFDA will be valid for the remaining validity of the original license or for Three (3) years for license with undefined validity.