APPENDIX 9

FEES

Outline:

1. Charges for USB Token of QUEST Membership;
2. Processing and Analysis Fees for Product Registration;
3. Charges for Application of Licenses;
4. Charges for Amendments to Particulars of a Registered Product;
5. Fees for Certificates; and
6. Charges for Product Classification.

1. CHARGES FOR USB TOKEN OF QUEST MEMBERSHIP

No.	Type	Validity Period	
		1 year (RM)	2 years (RM)
1.	Main User – New, Replacement, Change of Authorized Person (Certificate + USB Token)	260	290
2.	Supplementary User – New, Replacement, Change of Authorized Person (Certificate + USB Token)	245	275
3.	Change Authorized Person (Certificate Only)	48	95
4.	Renewal (Digital Certificate only – using existing MSC USB Token)	48	95
5.	Postage (*Semenanjung* Malaysia)	10	
6.	Postage (Sabah/ Sarawak)	20	

2. PROCESSING AND ANALYSIS FEES FOR PRODUCT REGISTRATION

Every application for registration shall be submitted with the appropriate processing and analysis fees, as specified below (effective 1 January 2007):

No.	Category of Product	* Processing Fees (RM)	Analysis Fees (RM)	Total Fees (RM)
1.	Pharmaceutical a) New Drug Products b) Biologics	1,000.00	Single active ingredient: 3,000.00	4,000.00
			Two or more active ingredients: 4,000.00	5,000.00
2.	Pharmaceutical a) Generic (Scheduled Poison) b) Generic (Non-Scheduled Poison) c) Health supplement	1,000.00	Single active ingredient: 1,200.00	2,200.00
			Two or more active ingredients: 2,000.00	3,000.00
3.	Natural Product	500.00	700.00	1,200.00
4.	Natural products with therapeutic claim	1,000.00	Single active ingredient: 3,000.00	4,000.00
			Two or more active ingredients: 4,000.00	5,000.00

** As stipulated under Regulation 8, CDCR 1984*

3. CHARGES FOR APPLICATION OF LICENSES

After a product is registered, the applicant shall apply for a manufacturer's/ import/ wholesaler's license.

The processing fees are as specified below:

License	Processing Fees (RM)	Timeline	Validity
1. Manufacturer's	1,000.00	4 working days upon receipt of complete application	1 year
2. Import	500.00	4 working days upon receipt of complete application	1 year
3. Wholesaler's	500.00	4 working days upon receipt of complete application	1 year

4. CHARGES FOR AMENDMENTS TO PARTICULARS OF A REGISTERED PRODUCT

4.1 CHANGE OF MANUFACTURING SITE & CHANGE OF PRODUCT REGISTRATION HOLDER

Types of Amendment	Processing Fees	
	Pharmaceutical (RM)	Natural Product (RM)
1. Change of Manufacturing Site (Type I)	1,000.00	100.00
2. Change of Manufacturing Site (Type II, III, IV, V)	1,000.00	500.00
3. Change of Product Registration Holder	1,000.00	500.00

4.2 VARIATION & ADDITIONAL INDICATION

Types of Amendment	Processing Fees	
	Full Evaluation (RM)	**Abridged Evaluation (RM)**
1. Minor Variation Prior Approval (MiV-PA)	150.00	50.00
2. Major Variation (MaV)	300.00	100.00
3. Additional Indication	1000.00	Not applicable

5. FEES FOR CERTIFICATES

Under Regulation 16, CDCR 1984:

"The Director of Pharmaceutical Services may issue such certification on any matter relating to any product where such certification is required by any country importing such a product."

Certificates	Fees (RM)	Validity
Issuance of one (1) Certificate of Pharmaceutical Product	50.00	2 years
Issuance of one (1) Certificate of Good Manufacturing Practice (GMP)	50.00	2 years
Issuance of one (1) Certificate of Declaration (*Sijil Deklarasi*)	50.00	-
Issuance of one (1) Certificate of Indication (*Sijil Indikasi*)	50.00	-

6. CHARGES FOR PRODUCT CLASSIFICATION

Processing Fees	Timeline
RM300 per product for each application	14 working days upon receipt of complete and satisfactory application