Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (11)dlm .BPFK/PPP/ 09 / 06
Tarikh : 26 MAY 2014

SEMUA PEMEGANG PENDAFTARAN,

Tuan/Puan,

PER: PEMBAHARUAN PROSEDUR PERMOHONAN VARIASI BAGI PRODUK BERDAFTAR PRODUK TRADISIONAL DAN SUPLEMEN KESIHATAN (QUEST 2 dan QUEST 3)

Perkara tersebut di atas dirujuk

2. Pihak Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) telah menerima banyak permintaan supaya proses variasi bagi produk tradisional dan suplemen kesihatan dipercepatkan. Salah satu langkah yang diambil oleh BPFK adalah melalui pengenalan penerimaan permohonan variasi secara separa manual.

3. Oleh yang demikian, mulai 1 June 2014, bagi tujuan variasi produk berdaftar kategori tradisional/ suplemen kesihatan melalui sistem QUEST 2 dan QUEST 3, semua pemohon perlu melengkapkan borang BPFK 416.4 (seperti dalam lampiran). Borang yang lengkap bersama-sama dengan salinan dokumen baru kemudiannya perlu dihantar ke alamat seperti yang terkandung dalam borang tersebut.

4. Semua urusan variasi ini akan dijalankan secara *'online'* melalui emel dan dokumen pembaharuan yang diluluskan mesti dikemaskini dan dimuat-turun di bahagian variasi berkaitan. Bagi produk berdaftar QUEST 3 maklumat untuk muat-turun akan dijalankan oleh Unit ICT, Pusat Pembangunan Organisasi, BPFK, manakala bagi produk berdaftar QUEST 2, muat –turun dokumen ini perlu dilakukan oleh pemegang pendaftaran produk sendiri. Pada masa yang sama, bagi produk tradisional / suplemen kesihatan yang berdaftar di QUEST 2, borang BPFK 416.4 yang lengkap ini perlu dimuat-turun juga di bahagian F12. Tuan/ puan boleh merujuk kepada carta aliran kerja untuk proses pemohonan variasi baru yang dicetakkan bersama.

5. Untuk makluman tuan/ puan, permohonan variasi produk akan ditolak sekiranya borang BPFK 416.4 yang tidak lengkap dikemukakan. Pihak tuan/ puan boleh menghubungi Unit Produk Tradisional/ Suplemen Kesihatan di talian 03-78018433/ 03-78835514 untuk mendapatkan penjelasan lanjut sekiranya perlu.

Sekian, terima kasih.

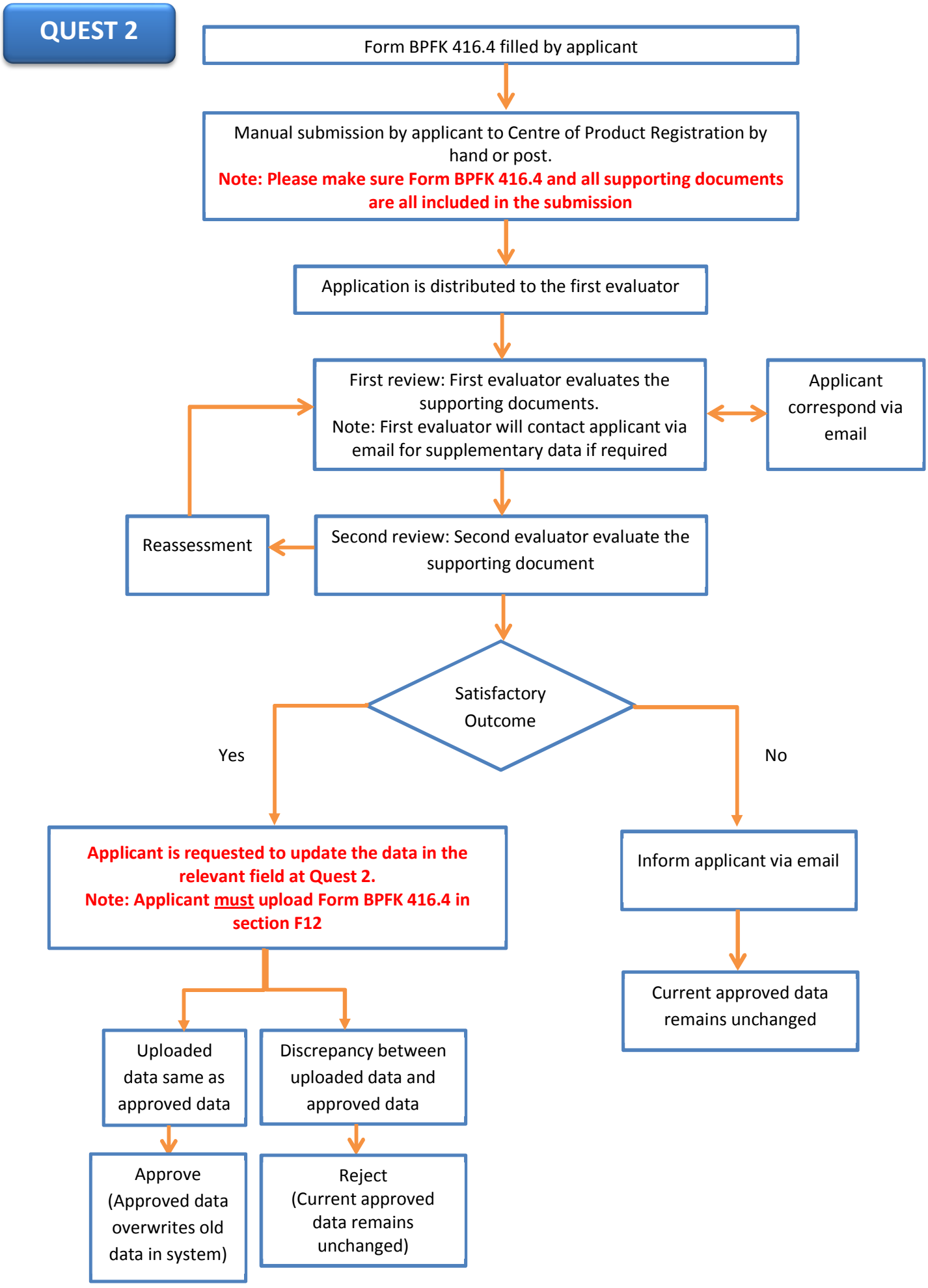
"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

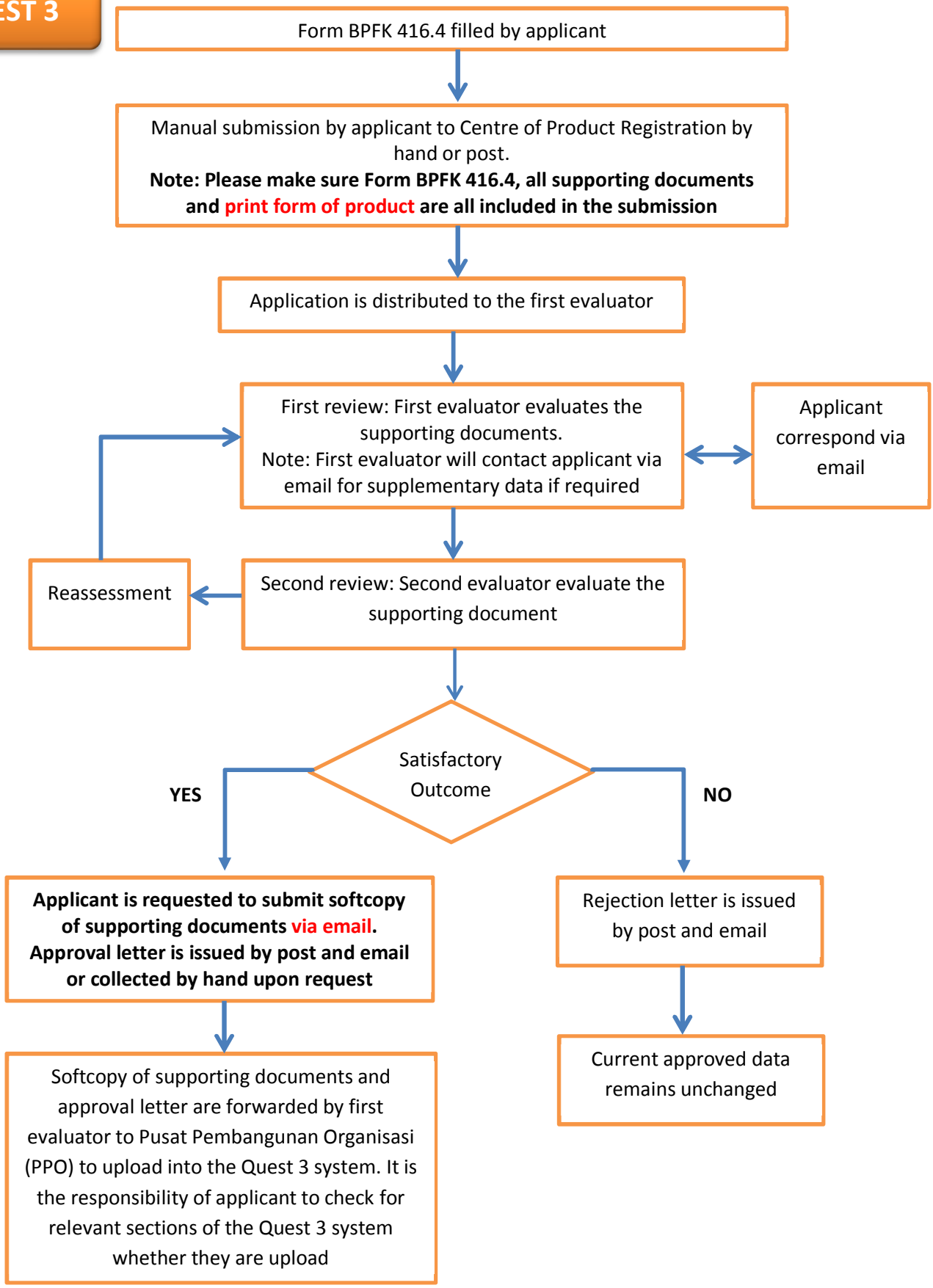
TAN ANN LING
Pengarah Regulatori Farmasi
Biro Pengawalan Farmaseutikal Kebangsaan,
Kementerian Kesihatan Malaysia
ppt/dst/prosedurvariasi2014

S.K. Timbalan Pengarah Pusat Pendaftaran Produk, BPFK
Timbalan Pengarah Pusat Pasca Pendaftaran Produk, BPFK

Jalan Universiti. P. O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
Tel. : + 603 7883 5400 Fax : + 603 7956 2924 / 7958 1312
http : //www.bpfk.gov.my


QUEST 2
Form BPFK 416.4 filled by applicant
Manual submission by applicant to Centre of Product Registration by hand or post.
Note: Please make sure Form BPFK 416.4 and all supporting documents are all included in the submission
Application is distributed to the first evaluator
First review: First evaluator evaluates the supporting documents.
Note: First evaluator will contact applicant via email for supplementary data if required
Applicant correspond via email
Second review: Second evaluator evaluate the supporting document
Reassessment
Satisfactory Outcome
Yes
No
Applicant is requested to update the data in the relevant field at Quest 2.
Note: Applicant must upload Form BPFK 416.4 in section F12
Inform applicant via email
Current approved data remains unchanged
Uploaded data same as approved data
Discrepancy between uploaded data and approved data
Approve (Approved data overwrites old data in system)
Reject (Current approved data remains unchanged)

QUEST 3


Form BPFK 416.4 filled by applicant
Manual submission by applicant to Centre of Product Registration by hand or post.
Note: Please make sure Form BPFK 416.4, all supporting documents and print form of product are all included in the submission
Application is distributed to the first evaluator
First review: First evaluator evaluates the supporting documents.
Note: First evaluator will contact applicant via email for supplementary data if required
Applicant correspond via email
Reassessment
Second review: Second evaluator evaluate the supporting document
Satisfactory Outcome
YES
NO
Applicant is requested to submit softcopy of supporting documents via email.
Approval letter is issued by post and email or collected by hand upon request
Softcopy of supporting documents and approval letter are forwarded by first evaluator to Pusat Pembangunan Organisasi (PPO) to upload into the Quest 3 system. It is the responsibility of applicant to check for relevant sections of the Quest 3 system whether they are upload
Rejection letter is issued by post and email
Current approved data remains unchanged

APPLICATION FOR VARIATION OF REGISTERED TRADITIONAL AND HEALTH SUPPLEMENT PRODUCTS

Instructions:

1. Please refer to **Appendix 12** of the Drug Registration Guidance Document (DRGD) for the conditions and supporting documents required for variation application.
2. Submission of relevant revised draft of package insert and labeling is subject to current regulatory requirements as per the latest Drug Registration Guidance Document (DRGD) and Circulars from NPCB.
3. The completed form must be

Quest 2 & Quest 3	submitted to :	**Seksyen Ubat Komplementari**, Pusat Pendaftaran Produk, Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor

4. Incomplete submission will be rejected.

Product Category:	☐ Traditional ☐ Health Supplement	☐ Quest 2 ☐ Quest 3	
Product name:			
Product registration holder:			
Reference no.:		MAL No.	

Tick (✓) on the variation changes required. Multiple selections are allowed.

No.	**MINOR VARIATION**	Tick
1.	Change in name of manufacturer and/or other manufacturers without any change in address of site.	
2.	Replacement, addition or deletion of company logo on the packaging component. (without any changes on graphic and label content)	
3.	Change in product owner.	
4.	Change in importer/ store address.	
5.	Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking.	
6.	Change in shape or dimensions of the container or closure.	
7.	Change in pack size of the drug product (Finished product), without change in primary packaging material.	
	Change in the number or units (e.g. tablets) in a pack.	
8.	Tightening of specification limits of the product (finished product) and/or active ingredient.	
9.	Change in particulars of the manufacturer of an active ingredient without any change in specification. a. Change in manufacturer of active ingredient	
	b. Addition of manufacturer of active ingredient	
	c. Change in name and/or rephrasing of address of a manufacturer of active ingredient	
10.	Change in secondary packaging material (or change in any part of the primary packaging material that is not in contact with the finished product)	

	MAJOR VARIATION	
1.	Change of product name.	
2.	Change in content of leaflet or prescribing information/ PIL.	
3.	Change in content of label inclusive of change in graphics/ artwork.	
4.	Change in manufacturing process of the finished product.	
5.	Change in overage of the active ingredient. (only applicable to Health Supplement)	
6.	Replacement of an EXCIPIENT with a comparable excipient and/or change in content of excipient.	
7.	Change in batch size.	
8.	Change in hard capsule shell. (colour, size or source)	
9.	Change in finished product or active ingredient specification. (includes addition of a new test parameter)	
10.	Change to in-process tests or limits applied during manufacture of the product.	
11.	Change or addition in primary packaging material.	
12.	Change in shelf life of finished product:- a) As packaged for sale	
	b) After first opening	
	c) After dilution/ reconstitution	
13.	Change in storage conditions.	
14.	Appointment, deletion or change of OTHER manufacturers.	
15.	Addition or deletion of scoring/ break line on tablet.	
16.	Change in test procedure or analytical protocols of finished product.	

Kindly specify the ALL the affected fields and their relevant details using the format below, in a Microsoft Word document (Font size:12). Kindly attach this document during the variation application.

Table 1			
Field	**Existing data**	**Proposed change data**	**Reason for changing**
Example: A5	Take 10ml daily	Adult: Take 10ml once daily before meal	To fix the frequency and the method of taking product in regards of meals

Tick (✓) on the documents attached. Multiple selections are allowed.

	Field		**ATTACHED SUPPORTING DOCUMENTS**	Tick
No.	**Quest 2**	**Quest 3**		
1.	A1	F12	Letter of Authorization from Product Holder (For Variation of Product Name only)	
2.	A3.2	A3.2	CoA Of Capsule Shell/ TSE/BSE Free Certificate	
3.	B1.2	B1.4	Batch Manufacturing Formula	
4.	B2.2	B2.2	Manufacturing Process Documentation	
5.	B3	B3	In Process Quality Control	
6.	B4	B4	Finished Product Specification Documentation	
7.	B5	B5	Stability Data	
8.	C	C	Attachment Container Type	
9.	D1	D1	**Proposed** and **Current Existing** Labels For Immediate Container	
10.	D2	D2	**Proposed** and **Current Existing** Labels For Outer Carton	
11.	D3	D3	**Proposed** and **Current Existing** Package Inserts	
12.	F1	F1	Letter Of Authorization From Product Owner	
13.	F2.1	F2.1	Letter Of Appointment Of Contract Manufacturer From Product Owner	
14.	F2.2	F2.2	Letter Of Acceptance From Contract Manufacturer	
15.	F6	F6	GMP Of Foreign Manufacturers	
16.	F12	F12	Other Supporting Documentations; Please Specify …… ……	
17.			Print form of product (only applicable to Quest 3 product)	

APPLICANT DECLARATION

I, undersigned , as representing the company who applied for the application declare that:

a) All the above information and attachments of supporting documents are true.
b) The information written in other languages such as Chinese/ Tamil/ Arab carry the **same meaning** as the data approved/ proposed in English/ Malay.
c) There is no other change except for the proposed variation.
d) The required supporting documents as specific in Appendix 12 in Drug Registration Guidance Document (DRGD) have been submitted.
e) The change(s) will not adversely affect the quality, efficacy and safety of the product
f) I will submit relevant documents pertaining to this application upon request.
g) I am aware on the consequences of rejection of this application if I failed/ refused to submit document(s)/ information as requested by the NPCB.

Signature of Applicant			
Full name of Applicant			
Identification Card No.			
Title/ Position in Company			
Telephone No.		Date of Application	
Email address			
Company name Company Official Stamp			