

**AKTA JUALAN DADAH 1952 (DISEMAK 1989)
PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
PERATURAN 8**

*SALE OF DRUGS ACT 1952 (REVISED 1989)
CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984
REGULATION 8*

**PERMOHONAN PERTUKARAN PEMEGANG PENDAFTARAN
UNTUK PRODUK BERDAFTAR (BPFK-430.5)**

*APPLICATION FORM FOR CHANGE OF PRODUCT REGISTRATION HOLDER
FOR A REGISTERED PRODUCT*

ARAHAN:

INSTRUCTIONS:

Sila baca arahan ini sebelum mengisi borang permohonan.

Please read this instruction before completing the application form.

1. Untuk maklumat lanjut mengenai prosedur terutamanya syarat dan keperluan permohonan, pemohon wajib merujuk kepada prosedur *Change of Product Registration Holder* seperti yang dinyatakan dalam *Drug Registration Guidance Document*, yang boleh didapati di laman sesawang BPFK <http://npra.moh.gov.my>
For details on procedure especially application conditions and supporting documents, applicant is compulsory to refer procedure of Change of Product Registration Holder as stated in Drug Registration Guidance Document, which is available at NPCB website <http://npra.moh.gov.my> .
2. Borang ini digunapakai hanya untuk permohonan pertukaran pemegang pendaftaran bagi produk yang didaftarkan melalui sistem QUEST dan perlu dilengkapi oleh pemegang pendaftaran sedia ada.
This form is solely used for application on change of product registration holder for product which is registered via QUEST system and shall be completed by the existing product registration holder.
3. Borang ini hendaklah DITAIP DENGAN JELAS DENGAN HURUF BESAR.
This form shall be typed in capital letters.
4. Sila gunakan lampiran sekiranya ruang dalam borang tidak mencukupi.
Please use attachment if there is insufficient space in the form.
5. Borang yang telah dilengkapi berserta dokumen yang diperlukan seperti dalam senarai semak hendaklah dihantar ke Biro Pengawasan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia (u.p. Setiausaha Pihak Berkuasa Kawalan Dadah) di alamat: Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.
A copy of completed form shall be sent to National Pharmaceutical Control Bureau, Ministry of Health, Malaysia (Attn. Secretary of Drug Control Authority) at address of Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.
6. Hanya permohonan yang lengkap dan mematuhi syarat seperti yang dinyatakan dalam prosedur *Change of Product Registration Holder* akan diterima untuk pemrosesan.
Only complete application which complies with all conditions as stated in the procedure of Change of Product Registration Holder shall be accepted for processing.
7. Sila pastikan setiap borang diisi dengan maklumat satu produk sahaja.
Please use one form for each product.

<p align="center">SENARAI SEMAK (untuk diisi oleh pemohon) <i>CHECKLIST (to be completed by applicant)</i></p>		
Bil. No.	Dokumen-Dokumen Yang Perlu Disertakan Bersama Dengan Borang Ini <i>Documents Required To Be Submitted With This Form</i>	Tandakan (√) <i>Tick (√)</i>
1.	Letter of Authorisation from <u>product owner</u> certified by Notary Public for overseas company or Commissioner For Oath for local company	
2.	Company/ Business Registration Certificate of proposed new holder	
3.	Statement of Acceptance As Product Registration Holder; BPFK-430.5(3)	
4.	Resolution by Company Board of Directors of <u>local product owner</u>	
5.	Certified by Commissioner for Oath of the latest document issued by Companies Commissioner of Malaysia indicating details of director/s and shareholder/s of <u>local product owner</u>	
6.	Resolution by Company Board of Directors of <u>existing PRH</u>	
7.	Certified by Commissioner for Oath of the latest document issued by Companies Commissioner of Malaysia indicating details of director/s and shareholder/s of <u>existing PRH</u>	
8.	Borang Penyerahan Permohonan; BPFK-001 (<i>Dua salinan</i>)	
9.	Other supporting documents; please specify _____	

1. SEBAB PERMOHONAN PERTUKARAN <i>REASON(S) FOR TRANSFER APPLICATION</i>			
2. BUTIR-BUTIR PRODUK <i>PRODUCT DETAILS</i>			
Nama Produk Yang Didaftarkan <i>Registered Product Name</i>			
No. Rujukan Pendaftaran <i>Registration Reference No. (LOI No.)</i>			
No. Pendaftaran Produk <i>Product Registration No.</i>	MAL		
*Tempoh Sahlaku Pendaftaran Produk <i>Period of Product Registration Validity</i>			
<p><i>*Nota:</i> Tempoh sahlaku hendaklah sekurang-kurangnya enam (6) bulan sebelum luput. <i>*Note:</i> Shall have a remaining validity period of at least six (6) months.</p>			
3. BUTIR-BUTIR PEMOHON/ PEMEGANG PENDAFTARAN SEDIA ADA <i>APPLICANT/ EXISTING PRODUCT REGISTRATION HOLDER DETAILS</i>			
Nama Syarikat <i>Company Name</i>			
No. Pendaftaran Syarikat <i>Company Registration No.</i>			
Alamat Syarikat <i>Company Address</i>			
Poskod <i>Postcode</i>		Negeri <i>State</i>	
No. Telefon Syarikat <i>Company Telephone No.</i>		No. Faks Syarikat <i>Company Fax No.</i>	
Emel <i>Email</i>			

4. BUTIR-BUTIR PEMEGANG PENDAFTARAN BARU PROPOSED NEW PRODUCT REGISTRATION HOLDER DETAILS			
Nama Syarikat <i>Company Name</i>			
No. Pendaftaran Syarikat <i>Company Registration No.</i>			
Alamat Syarikat <i>Company Address</i>			
Poskod <i>Postcode</i>		Negeri <i>State</i>	
No. Telefon Syarikat <i>Company Telephone No.</i>		No. Faks Syarikat <i>Company Fax No.</i>	
Emel <i>Email</i>			
5. BUTIR-BUTIR PEMILIK KELUARAN PRODUCT OWNER DETAILS			
Nama Syarikat <i>Company Name</i>			
No. Pendaftaran Syarikat <i>Company Registration No.</i>			
Alamat Syarikat <i>Company Address</i>			
Poskod <i>Postcode</i>		Negeri <i>State</i>	
No. Telefon Syarikat <i>Company Telephone No.</i>		No. Faks Syarikat <i>Company Fax No.</i>	
Emel <i>Email</i>			
6. BUTIR-BUTIR PENGILANG PRODUK PRODUCT MANUFACTURER DETAILS			
Nama Syarikat <i>Company Name</i>			
No. Pendaftaran Syarikat <i>Company Registration No.</i>			
Alamat Syarikat <i>Company Address</i>			
Poskod <i>Postcode</i>		Negeri <i>State</i>	
No. Telefon Syarikat <i>Company Telephone No.</i>		No. Faks Syarikat <i>Company Fax No.</i>	
Emel <i>Email</i>			

7. BAYARAN PEMROSESAN <i>PROCESSING FEE</i>											
<p>7.1 Kategori Produk <i>Category of Product</i></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 5%; text-align: center;">(a)</td> <td style="width: 60%;">Keluaran Racun/ Bukan Racun <i>Poison/ Non-Poison Product</i></td> <td style="width: 15%; text-align: right;">RM 1,000.00</td> <td style="width: 20%;"></td> </tr> <tr> <td style="text-align: center;">(b)</td> <td>Keluaran Tradisional <i>Traditional Product</i></td> <td style="text-align: right;">RM 500.00</td> <td></td> </tr> </table> <p>7.2 Bayaran pemprosesan dalam bentuk draf bank/ wang pos/ kiriman wang hendaklah dibuat atas nama 'Biro Pengawalan Farmaseutikal Kebangsaan'. <i>Processing fee in the form of bank draft/ banker's cheque/ money order/ postal order shall be made payable to 'Biro Pengawalan Farmaseutikal Kebangsaan'.</i></p>				(a)	Keluaran Racun/ Bukan Racun <i>Poison/ Non-Poison Product</i>	RM 1,000.00		(b)	Keluaran Tradisional <i>Traditional Product</i>	RM 500.00	
(a)	Keluaran Racun/ Bukan Racun <i>Poison/ Non-Poison Product</i>	RM 1,000.00									
(b)	Keluaran Tradisional <i>Traditional Product</i>	RM 500.00									
8. PERAKUAN PEMOHON <i>APPLICANT DECLARATION</i>											
<p>Saya yang bernama dan beralamat di bawah sebagai mewakili syarikat yang memohon mengaku bahawa: <i>I, undersigned, as representing the company who apply for the application declare that:</i></p> <p>8.1 Semua maklumat di atas dan lampiran-lampiran dokumen sokongan yang disertakan adalah benar. <i>All of the above information and attachments of supporting documents are true.</i></p> <p>8.2 Saya akan mengemukakan maklumat/ dokumen berkaitan dengan permohonan ini apabila diperlukan. <i>I will submit relevant documents pertaining to this application when needed.</i></p> <p>8.3 Saya menyedari bahawa kegagalan atau keengganan saya mengemukakan dokumen/ maklumat yang diperlukan oleh Setiausaha Pihak Berkuasa Kawalan Dadah dalam masa yang ditetapkan boleh menyebabkan permohonan ini ditolak. <i>I am aware on the consequences of rejection of this application if I failed/ refused to submit document(s)/ information as requested by the Secretary of Drug Control Authority.</i></p>											
Tandatangan Pemohon <i>Signature of Applicant</i>											
Nama Penuh Pemohon <i>Full Name of Applicant</i>											
No. Kad Pengenalan <i>Identification Card No.</i>											
Jawatan dalam Syarikat <i>Title/ Position in Company</i>											
No. Telefon <i>Telephone No.</i>		Tarikh Permohonan <i>Date of Application</i>									
Cop Rasmi Syarikat <i>Company Official Stamp</i>											

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