

SENARAI KELULUSAN MESYUARAT PBKD 319 (PRODUK QUEST 2 & 3)

1. SILA SEMAK MAKLUMAT PRODUK, JIKA TERDAPAT SEBARANG KESILAPAN SILA HUBUNGI SEKSYEN KOORDINASI REGULATORI
2. Sebarang kesilapan (jika ada) sila maklumkan dalam tempoh DUA minggu daripada tarikh Mesyuarat PBKD. Jika tiada sebarang aduan kesilapan diterima dalam tempoh tersebut, maklumat-maklumat ini akan dianggap sebagai betul. Sebarang aduan selepas tempoh tersebut TIDAKAKAN DILAYAN.
3. Pihak tuan perlu memohon Sijil Indikasi bagi tujuan Iklan.
4. Sila ambil maklum bahawa sekiranya produk tuan telah diluluskan, sila berurusan terus dengan Bahagian APB & Perlesenan untuk tujuan permohonan lesen, memandangkan surat kelulusan TIDAK AKAN dikeluarkan.
5. Jika terdapat kesilapan pada maklumat produk, sila nyatakan dengan jelas perkara-perkara berikut:
 1. Nama Produk
 2. No. LOI
 3. No. Pendaftaran Produk
 4. No. Mesyuarat PBKD
 5. Maklumat yang sebenar :
 - a. Nama Produk
 - b. Nama & Alamat Pemegang
 - c. Nama & Alamat Pengilang
6. LESEN MENGI LANG:
 - A. BAGI PRODUK YANG DIKILANGKAN DI MALAYSIA, PENGILANGAN PRODUK TERSEBUT BOLEH DILAKUKAN HANYA SETELAH NAMA PRODUK DISENARAIKAN DI DALAM LESEN PENGILANG.
 - B. SILA HUBUNGI BAHAGIAN APB & PERLESENAN BAGI TUJUAN PERMOHONAN LESEN MENGI LANG
7. LESEN MENGIMPORT:
 - A. BAGI PRODUK YANG DIIMPORT, SILA PASTIKAN SEBELUM PRODUK DIBAWA MASUK KE DALAM MALAYSIA, NAMA PRODUK TERSEBUT MESTILAH DISENARAIKAN DI DALAM LESEN MENGIMPORT TERLEBIH DAHULU.
 - B. SILA HUBUNGI BAHAGIAN APB & PERLESENAN BAGI TUJUAN PERMOHONAN LESEN MENGIMPORT (PIHAK TUAN PERLU PASTIKAN E-MAIL TERSEBUT BOLEH MENERIMA FORMAT HTML)

**SENARAI PRODUK – PRODUK YANG TELAH DILULUSKAN OLEH PIHAK BERKUASA KAWALAN DADAH (PBKD) DALAM MESYUARAT PBKD KALI KE – 319
TARIKH MESYUARAT : 4 JANUARI 2018**

Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
1	20161107126T/ MAL17127001TC	CONFORER GLOBAL D-NEW CAPSULE	CONFORER MEDI-CARE ENTERPRISE, KUALA LUMPUR	WHITE HERON PHARMACEUTICAL SDN BHD, KUALA LUMPUR	06/12/2017 – 06/12/2022	New Registration Approval
2	20160906894T/ MAL17127002TC	PROLIV FENNELAID PLUS CAPSULE	PROLIV LIFE SCIENCES SDN BHD, TERENGGANU	SARI TANI DESA SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
3	20161007030T/ MAL17127003TC	HONG SHEN BRAND POH YEE POWDER	HONG SHEN MAJU TRADING, KEDAH	HO POH ONN MEDICAL HALL (M) SDN BHD, JOHOR	06/12/2017 – 06/12/2022	New Registration Approval
4	20161207222T/ MAL17127004TC	DYNAMIC NUTRITION ASHIGUARD CAPSULE 500MG	DYNAMIC NUTRITION SDN BHD, SELANGOR	REISHILAB SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
5	20161107130T/ MAL17127005TC	TIEH LO HONG TIEH TA WAN	WENG THYE HENG SDN BHD, PULAU PINANG	S.H. UNIFLEX CHINESE MEDICAL FACTORY SDN BHD, JOHOR	06/12/2017 – 06/12/2022	New Registration Approval

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TARIKH MESYUARAT : 4 JANUARI 2018**

Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
6	20161207178T/ MAL17127006T	ZECUF® HERBAL COUGH LOZENGES – HERBAL	SYNERGY MEDITECH (M) SDN BHD, SELANGOR	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B. CHEMICALS & PHARMACEUTICALS LTD.), INDIA	06/12/2017 – 06/12/2022	New Registration Approval
7	20161207218T/ MAL17127007T	ZECUF® HERBAL COUGH LOZENGES – ORANGE	SYNERGY MEDITECH (M) SDN BHD, SELANGOR	UNIQUE PHARMACEUTICAL LABORATORIES (A DIVISION OF J.B. CHEMICALS & PHARMACEUTICALS LTD.), INDIA	06/12/2017 – 06/12/2022	New Registration Approval
8	2015111905875T/ MAL17127008TC	EWAMAS UTARA AIR GAMAT 2.55GM/15ML	PERNIAGAAN EWAMAS UTARA, KEDAH	PENAWAR INDUSTRIES SDN BHD, KEDAH	06/12/2017 – 06/12/2022	New Registration Approval
9	20161107058T/ MAL17127009T	SHAFLI GARLIC 400MG SOFTGEL	SHAFLI LAGENDA SDN BHD, SELANGOR	SHAFLI LAGENDA SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
10	20161107067T/ MAL17127010TC	DMA SINUS RELIEF CAPSULE	DM AESTHETIC SDN BHD, SELANGOR	REISHILAB SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
11	20161207259T/ MAL17127011TC	LAC® PAPAYA LEAF EXTRACT 600MG	ONI GLOBAL (MALAYSIA) SDN BHD,	HIGH VALLEY CONTRACT	06/12/2017 – 06/12/2022	New Registration

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
		CAPSULE	KUALA LUMPUR	MANUFACTURING (GMP) SDN BHD, SELANGOR		Approval
12	20161107120T/ MAL17127012T	V-Lief Cough Syrup	CCM PHARMACEUTICALS SDN BHD, SELANGOR	AHNGOOK PHARMACEUTICAL CO., LTD, KOREA	06/12/2017 – 06/12/2022	New Registration Approval
13	20161107077T/ MAL17127013TC	WESTBERRY MANGOSTEEN EXTRACT 100MG CAPSULE	WESTBERRY SDN BHD, SELANGOR	REISHILAB SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
14	17090004TE/ MAL17127014TCE	Stemergy GM 2 Capsul	STEMERGY SDN BHD, KUALA LUMPUR	EXCEL HERBAL INDUSTRIES SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
15	17090006TE/ MAL17127015TCE	Kean Trading Kacip Fatimah Plus Capsule	KEAN TRADING SDN BHD, SELANGOR	EXCEL HERBAL INDUSTRIES SDN. BHD., SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
16	17090002TE/ MAL17127016TCE	Stemergy Daily Capsule	STEMERGY SDN BHD, KUALA LUMPUR	EXCEL HERBAL INDUSTRIES SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
17	17090003TE/ MAL17127017TCE	STEMERGY FEM- GLOW CAPSULE	STEMERGY SDN BHD, KUALA LUMPUR	EXCEL HERBAL INDUSTRIES SDN BHD, SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval
18	17090005TE/ MAL17127018TCE	Stemergy DE-T	STEMERGY SDN. BHD., KUALA LUMPUR	EXCEL HERBAL INDUSTRIES SDN. BHD., SELANGOR	06/12/2017 – 06/12/2022	New Registration Approval

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TARIKH MESYUARAT : 4 JANUARI 2018**

Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
	MAL17127018TCE	Capsule	KUALA LUMPUR	BHD., SELANGOR	06/12/2022	Approval
19	20161207199T/ MAL17127022TC	CELLLABS EZYFEMIN- 100 CAPSULE	CELLGEN LIFESCIENCES (M) SDN BHD, KUALA LUMPUR	QD HERBS SDN BHD, PERAK	21/12/2017 – 21/12/2022	New Registration Approval
20	20161207292T/ MAL17127025TC	CRYSTAGUARD VEGETABLE CAPSULE	CAMBERT (M) SDN BHD, SELANGOR	WHITE HERON PHARMACEUTICAL SDN BHD, KUALA LUMPUR	21/12/2017 – 21/12/2022	New Registration Approval
21	20161207188T/ MAL17127021T	SHEN TONO JWU IU TONG EXTRACT GRANULES "TI"	TIAN I BIOTECH INTERNATIONAL SDN BHD, SELANGOR	TIAN-I PHARMACEUTICAL CO LTD, TAIWAN	21/12/2017 – 21/12/2022	New Registration Approval
22	20161207276T/ MAL17127024TC	DAMO WELLNESS OXY-ACT CAPSULE	DAMO WELLNESS ENTERPRISE, SELANGOR	REISHILAB SDN. BHD., SELANGOR	21/12/2017 – 21/12/2022	New Registration Approval
23	20160906889T/ MAL17127019T	XIN SAN TZ YEANG CHIN TONG EXTRACT GRANULES "TI"	TIAN I BIOTECH INTERNATIONAL SDN BHD, SELANGOR	TIAN-I PHARMACEUTICAL CO LTD, TAIWAN	21/12/2017 – 21/12/2022	New Registration Approval
24	20161107112T/ MAL17127020TC	TICOFI MORINGA 450MG CAPSULE	HERBAL MIRACLE SDN BHD, SELANGOR	SARI TANI DESA SDN BHD, SELANGOR	21/12/2017 – 21/12/2022	New Registration Approval
25	20161207267T/ MAL17127023T	SHAFLI BIO- SKYFRUIT 500MG	SHAFLI LAGENDA SDN BHD, SELANGOR	SHAFLI LAGENDA SDN BHD, SELANGOR	21/12/2017 – 21/12/2022	New Registration

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TARIKH MESYUARAT : 4 JANUARI 2018**

Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
		SOFTGEL				Approval
26	20161207296T/ MAL17127026T	ERA ROOIBOS 2.5G SOD TEA	ERA HERBAL PRODUCTS SDN BHD, SELANGOR	ERA HERBAL PRODUCTS SDN BHD, SELANGOR	21/12/2017 – 21/12/2022	New Registration Approval
27	2006010500574/ MAL06071081AZ	MUCOPROM SYRUP	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD	XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD	04/01/2018 – 04/01/2023	Re- Registration (Renewal)
28	2000020557A/ MAL20014328AZ	TERAPRESS-1	JETPHARMA SDN BHD	INTAS PHARM LTD, INDIA	04/01/2018 – 04/01/2023	Re- Registration (Renewal)
29	2000020558A / MAL20014329AZ	TERAPRESS-5	JETPHARMA SDN BHD	INTAS PHARM LTD, INDIA	04/01/2018 – 04/01/2023	Re- Registration (Renewal)
30	201412172014A/ MAL18016019AZ	Estiva 600 (EFAVIRENZ TABLETS 600mg)	PHARMAMODE (M) SDN. BHD.	HETERO LABS LIMITED, INDIA	04/01/2018 – 04/01/2023	New Registration Approval
31	201504010001A/ MAL18016021AZ	Megex-I Suspension 800mg/20ml	IMEKS PHARMA SDN. BHD.	DAEWON PHARM. CO. LTD., KOREA	04/01/2018 – 04/01/2023	New Registration Approval
32	201505072013A/ MAL18016028AZ	hovid-lamivudine tablet 150mg	HOVID BERHAD	HOVID BERHAD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
33	201505072016A/ MAL18016020AZ	hovid-lamivudine tablet 300mg	HOVID BERHAD	HOVID BERHAD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
34	201506100001A/ MAL18016022AZ	Latanostill 50mcg/ml Eye Drops Solution	IMAGE PHARMA SDN BHD	BRUSCHETTINI S.R.L, ITALY	04/01/2018 – 04/01/2023	New Registration Approval
35	201509210001A/ MAL18016027ACZ	DESLORATADINE ACTAVIS ORAL SOLUTION 0.5MG/ML	ACTAVIS SDN BHD	SPECIFAR S.A, GREECE	04/01/2018 – 04/01/2023	New Registration Approval
36	201511232013A/ MAL18016023ASZ	Strepsils Max Pro Honey & Lemon 8.75mg Lozenge	RECKITT BENCKISER (M) SDN BHD	RECKITT BENCKISER HEALTHCARE MANUFACTURING LIMITED, THAILAND	04/01/2018 – 04/01/2023	New Registration Approval
37	201511252013A/ MAL18016024AZ	Rocuronium-hameln 10mg/ml Injection	IMEKS PHARMA SDN. BHD.	HAMELN PHARMACEUTICALS GMBH, GERMANY	04/01/2018 – 04/01/2023	New Registration Approval
38	201511262013A/ MAL18016029AZ	Cifflam Mouthwash 0.15 % w/v	HOVID BERHAD	HOVID BERHAD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
39	201601210001A/ MAL18016026AZ	Propofol-Lipuro 2% (20 mg/ml) Emulsion for Injection or Infusion	B.BRAUN MEDICAL INDUSTRIES SDN BHD	B.BRAUN MELSUNGEN AG, GERMANY	04/01/2018 – 04/01/2023	New Registration Approval

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
40	201602032023A/ MAL18016034AZ	FORSTAVIR (TENOFVIR DISOPROXIL FUMARATE TABLETS 300MG)	UNIMED SDN BHD	AUROBINDO PHARMA LIMITED (UNIT III), INDIA	04/01/2018 – 04/01/2023	New Registration Approval
41	201603220001A/ MAL18016033AZ	Ondavell Ondansetron 8mg Tablet	AVERROES PHARMACEUTICALS SDN BHD	PT NOVELL PHARMACEUTICAL LABORATORIES, INDONESIA	04/01/2018 – 04/01/2023	New Registration Approval
42	201603222012A/ MAL18016025AZ	Ondavell Ondansetron 4mg Tablet	AVERROES PHARMACEUTICALS SDN BHD	PT NOVELL PHARMACEUTICAL LABORATORIES, INDONESIA	04/01/2018 – 04/01/2023	New Registration Approval
43	201604012012A/ MAL18016031AZ	Vativio Tablet 100mg	ALCON LABORATORIES (MALAYSIA) SDN BHD	NOVARTIS PHARMA PRODUKTIONS GMBH, GERMANY	04/01/2018 – 04/01/2023	New Registration Approval
44	201604012013A/ MAL18016030AZ	Vativio Tablet 400mg	ALCON LABORATORIES (MALAYSIA) SDN BHD	NOVARTIS PHARMA STEIN AG, SWITZERLAND	04/01/2018 – 04/01/2023	New Registration Approval
45	201605262018A/ MAL18016032AZ	Apo-Mometasone Furoate Aqueous Nasal Spray 50mcg/metered spray	PHARMAFORTE (MALAYSIA) SDN BHD	APOTEX INC.- RICHMOND HILL SITE, CANADA	04/01/2018 – 04/01/2023	New Registration Approval
46	201605302045A/	Doxtored (Docetaxel)	DKSH MALAYSIA SDN	DR REDDY'S	04/01/2018 –	New

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Bil	No. rujukan/ No. pendaftaran produk	Nama produk	Pemegang Pendaftaran Produk	Pengilang	Tempoh Pendaftaran	Catatan
	MAL18016035AZ	20mg/ml concentrate for solution for infusion	BHD	LABORATORIES LTD, INDIA	04/01/2023	Registration Approval
47	20161107101A/ MAL18016038AZ	CLOBESOL OINTMENT 0.05%w/w	MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD	MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
48	20161207205A/ MAL18016037AE	hovid-Metformin Powder for Oral Solution 500mg	HOVID BERHAD	HOVID BERHAD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
49	20170307397A/ MAL18016036ACE R	hovid-Ondansetron Injection 4mg/2ml	HOVID BERHAD	Qilu Pharmaceutical Co Ltd (CHINA)	04/01/2018 – 04/01/2023	New Registration Approval
50	201603142012X/ MAL18016006XCZ	ODIBEND CHEWABLE TABLET 400 MG	HEALOL PHARMACEUTICAL SDN. BHD.	ZIM LABORATORIES LTD., INDIA	04/01/2018 – 04/01/2023	New Registration Approval
51	201509040001X/ MAL18016009XC	SULBRIMO Capsule 200mg	LIVE-WELL NUTRACEUTICALS SDN. BHD.	PAHANG PHARMACY SDN. BHD., MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
52	201512012014X/ MAL18016007XZ	Paracap Paracetamol 120mg/5ml Oral Suspension	HEALTH PHARM MARKETING SDN BHD	UMEDA, THAILAND	04/01/2018 – 04/01/2023	New Registration Approval

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53	20170107331X/ MAL18016054XC	AVEFLON TABLET	APEX PHARMACY MARKETING SDN BHD	XEPA-SOUL PATTINSON (M) SDN BHD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
54	201603310001X/ MAL18016008X	Axcel Glucosatin Dry Powder for Oral Solution	KOTRA PHARMA (M) SDN BHD	KOTRA PHARMA (M) SDN BHD, MALAYSIA	04/01/2018 – 04/01/2023	New Registration Approval
55	201605180001X/ MAL18016053X	Addaven Concentrate for Solution for Infusion	FRESENIUS KABI MALAYSIA SDN BHD	FRESENIUS KABI NORGE AS, NORWAY	04/01/2018 – 04/01/2023	New Registration Approval
56	20160906930H/ MAL18016003HXC	Univerm Total Tablets A.U.V.	TASEEN TRADING SDN.BHD.	PERNIX PHARMA GYOGYSZERGYARTO KFT., HUNGARY	04/01/2018 – 04/01/2023	New Registration Approval
57	20161006972H/ MAL18016072HA	LIFECOME BACITRACIN METHYLENE DISALICYLATE 50% W/W SOLUBLE POWDER	AGE D'OR SDN. BHD	LIFECOME BIOCHEMISTRY CO., LTD., CHINA	04/01/2018 – 04/01/2023	New Registration Approval