

Datasheet for business formalities.

Technical Assistance for Business Regulation Review and Rationalization in Lao PDR

REGISTRATION DATA		
Name of formality	Registration of Cosmetic Products	
Type of formality	Registration	
Formality Code	Date of last modification	Responsible Authority
MoPH-FDD-11	03.10.2017	Food and Drugs Department

BACKGROUND DATA	
Means of presentation	At the Authority Offices
Specific sector linked to the formality	Q - Human health and social work activities
Purpose for enforcing the business formality	In order to control and ensure the cosmetic products that will be produced, imported or sold in Lao PDR will have a good quality and standard with an aim to assure safety of the consumer.
Who should complete this business formality?	Any person or legal entity that intends to produce, import and sale cosmetic products (products that used to any part of body to enhance beauty) In Lao PDR.
The formality has online information?	YES
Link to online information	http://www.fdd.gov.la
The formality has an application form?	YES
Any additional comment concerning the formality	Only the Department can issue this Formality – the provincial department of public health can only permit the importation of the registered cosmetic products that have been registered at the central government.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	90	Relevant legal act does not define the review period but the authority informed the team that the normal review period is not more than 3 months.
Qualifications needed by the business to get the formality	1. For the production of cosmetic products, the factory shall have the following qualifications: (i) have sufficient staffs (i.e. experienced pharmacist or chemical expert); (ii) have sufficient and necessary facilities (i.e. production room and storage); (iii) have safety and environment protection system; and (iv) prior to the production of the cosmetic products, it shall apply for the permit to produce a prototype from the Department first. 2. For the importation of cosmetic products, the importer shall have the following qualifications: (i) have enterprise registration certificate; (ii) obtain the approval for importation of such cosmetic	

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REQUIREMENTS AND SUPPORTING EVIDENCE	
	products from the Department; and (iii) have sufficient and necessary facilities (i.e. production room and storage).
Is there any reason for the authority to deny the issuing of the formality?	Deny in case that the cosmetic products that will be produced or imported does not pass the required standards.

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	60
What is the process and conditions to renew the formality?	Renewal shall be undertaken at least 90 days prior to the expiration date of this Formality.

ISSUING FEES				
Has application fees?	Service fees businesses need to disburse	Certificate fees businesses need to disburse	Application fees businesses need to disburse	Total fees businesses need to disburse
YES	0.00	150000.00	0.00	150000.00
Comments	Reference: Presidential Edict No. 03/PR			

RENEWAL FEES				
Has renewal fees?	Service fees businesses need to disburse	Certificate fees businesses need to disburse	Renewal fees businesses need to disburse	Total renewal fees businesses need to disburse
YES	0.00	150000.00	0.00	150000.00
Comments	Reference: Presidential Edict No. 03/PR			

LEGAL FRAMEWORK			
Name	Number	Date	Comment

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LEGAL FRAMEWORK			
Order on Management of Quality of Cosmetic Products	2580/ກຸຊສ	12.11.2003	
Law on Medicine and Medical Device (Revised)	07/ສພຊ	21.12.2011	Article 13

REQUIRED DOCUMENTS	
Document Name	Comment
Example of Product	ຜະລິດຕະພັນຕົວແບບ (ຈຳນວນຕາມກຳນົດ) ທີ່ຢູ່ໃນຫົວໜ່ວຍມັດຫໍ່ເດີມ
Certificate of the Sale	ໃບຢັ້ງຢືນການຈຳໜ່າຍຈາກປະເທດຜູ້ຜະລິດ ທີ່ຍັງມີຜົນບັງຄັບໃຊ້
Certificate of Product Quality	ໃບຢັ້ງຢືນຄຸນນະພາບຈາກປະເທດຜູ້ຜະລິດ (ໃບຢັ້ງຢືນການຜະລິດທີ່ດີ, ການວິໄຈ, ການຂັ້ນທະບຽນ) ທີ່ຍັງມີຜົນບັງຄັບໃຊ້
Certificate for Enterprise Registration of Company Limited	ໃບທະບຽນການຄ້າ/ທຸລະກິດ

STATISTICS (Issue or/and renewed number)		
Year	Issued	Renewed
2017		
2016		

LIST OF ATTACHED DOCUMENTS		
Name of document	Type of document	File of document