

GENERAL INFORMATION	
Name of formality	Certificate of Registration for Domestic Manufactured Dietary Supplement
Type of formality	Other
Date of last modification	08.12.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Those who have the right to register health supplements are factories or import-export companies with an enterprise registration certificate issued by the Ministry of Industry and Commerce. On the backside of such certificate must state: import and distribute health and food supplement product.
Qualifications needed by the business to get the formality	All procedures must in accordance with the regulations of the Ministry of Health

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	Article 13, 15
Presidential Ordinance on Fees and Service Fees	003/PO	26.12.2012	Chapter IX, Article 45-47, Pages 89-92

REQUIRED DOCUMENTS FORMALITIES		
Name	Type	Comment
\$_{SUPPORT_NAME}\$	\$_{SUPPORT_TYPE}\$	\$_{SUPPORT_COMMENT}\$

LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION		
Name of document	Type of document	File of document
\$_{ATTACHMENT_NAME}\$	\$_{ATTACHMENT_TYPE}\$	\$_{ATTACHMENT_FILE}\$

LIST OF ATTACHED DOCUMENTS FOR RENEW APPLICATION		
Name of document	Type of document	File of document
\${ATTACHMENT_NAME_RENEW}	\${ATTACHMENT_TYPE_RENEW}	\${ATTACHMENT_FILE_RENEW}

MEAN OF PRESENTATION		
Means of presentation	At the Authority Offices	
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	180	The law does not specified the consideration period, but the official states that the usual consideration period will not exceed 180 days.Each time the applicant has to submit Form 1 first, which will take 3 months to consider. After Form 1 has been considered, the applicant then will be able to submit Form 2 which will take 3 months to consider as well.

RENEWAL INFORMATION		
Does the formality have a validity or an expiration date?		How long will the formality be valid for? (in months)
YES		36
What is the process and conditions to get the formality?		
What is the process and conditions to renew the formality?	Health Supplement Registration Certificate is valid for 3 years; 3 months prior to the expiry date, the applicant must apply for the renewal in accordance with the documents required by Food and Drug Department.	

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	100000.00	600000.00	5000.00	705000.00
Comments	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			
ADDITIONAL ISSUING FEES				
Additional fee names				
NO	0.00	0.00	0.00	0.00
Additional fee comments				

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	100000.00	600000.00	5000.00	705000.00
Comments	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				