

<b>GENERAL INFORMATION</b>	
<b>Name of formality</b>	Certificate of Registration for Domestic Manufactured Dietary Supplement
<b>Type of formality</b>	Other
<b>Date of last modification</b>	08.12.2020
<b>Responsible Authority</b>	Food and Drugs Department
<b>Who should apply for this formality?</b>	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.
<b>Qualifications needed by the business to get the formality</b>	All procedures must in accordance with the regulations of the Ministry of Health

<b>LEGAL FRAMEWORK</b>			
<b>Name</b>	<b>Number</b>	<b>Date</b>	<b>Comment</b>
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

<b>REQUIRED DOCUMENTS FORMALITIES</b>		
<b>Name</b>	<b>Type</b>	<b>Comment</b>
#{SUPPORT_NAME}	#{SUPPORT_TYPE}	#{SUPPORT_COMMENT}

<b>LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION</b>		
<b>Name of document</b>	<b>Type of document</b>	<b>File of document</b>
#{ATTACHMENT_NAME}	#{ATTACHMENT_TYPE}	#{ATTACHMENT_FILE}

**LIST OF ATTACHED DOCUMENTS FOR RENEW APPLICATION**

<b>Name of document</b>	<b>Type of document</b>	<b>File of document</b>
<code>#{ATTACHMENT_NAME_RENEW}</code>	<code>#{ATTACHMENT_TYPE_RENEW}</code>	<code>#{ATTACHMENT_FILE_RENEW}</code>

**MEAN OF PRESENTATION**

<b>Means of presentation</b>	At the Authority Offices	
<b>Address of authority</b>	Food and Drugs Department, Ministry of Public Health	
<b>Time it takes to the authorities to process the formality</b>	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**

<b>Does the formality have a validity or an expiration date?</b>	<b>How long will the formality be valid for? (in months)</b>
YES	36
<b>What is the process and conditions to get the formality?</b>	
<b>What is the process and conditions to renew the formality?</b>	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**

<b>Has application fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Application fees businesses need to disburse</b>	<b>Total fees businesses need to disburse</b>
YES	100000.00	600000.00	5000.00	705000.00
<b>Comments</b>	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			
<b>ADDITIONAL ISSUING FEES</b>				
<b>Additional fee names</b>				
NO	0.00	0.00	0.00	0.00
<b>Additional fee comments</b>				

<b>RENEWAL FEES</b>				
<b>Has renewal fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Renewal fees businesses need to disburse</b>	<b>Total renewal fees businesses need to disburse</b>
YES	100000.00	600000.00	5000.00	705000.00
<b>Comments</b>	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			
<b>ADDITIONAL RENEWAL FEES</b>				
<b>Additional renewal fees names</b>				
NO	0.00	0.00	0.00	0.00
<b>Additional renewal fees comments</b>				