COMPLEMENTARY MEDICINES FREQUENTLY ASKED QUESTION

FAQ / Applicant Questions	Response from Authority
I'm not sure I understand the purpose of the Section 21 application though.	The purpose of the application is to give access and authorize the use of unregistered medicines for personal use, medicines which are not available in South Africa for up to six month supply.
My consignment of supplements has been detained by Port Health. I would appreciate it very much if you could assist me in applying for a medicines supplement certificate for an FDA approved supplement.	Supplements are a subgroup of Medicines commonly referred to as Complementary Medicines, Health Supplements and are regulated under Medicines and Related Substances Act 101 of 1965. Please note that information on medicines registration process can be found on SAHPRA website at www.sahpra.org.za. The format of your application must be in **ZACTD format**. The website contains all the relevant guidelines, regulations and application forms to assist you with compiling application for medicines registration. All applications for medicines registration must be submitted to SAHPRA for evaluation to determine safety, quality and efficacy of your product.
These products are in an extremely small quantity and are solely for my own use and do not constitute "medicine" as defined on the form?	The South African Health Products Regulatory Authority (SAHPRA) is obliged to take precautionary measures in order to protect the public against the use of unsafe and unregistered products since safety, efficacy and quality of such products have not been validated.
I don't need a prescription to purchase these sports supplements, so why do I need to apply for this license?	The doctor's prescription is not a requirement when applying for authorization for use of unregistered medicine. However, the role of the doctor in this regard is to ensure professional oversight in case of any adverse effects which may occur as a result of the use of unregistered medicines.

	In terms of Section 21 policy, applicants may not import more than 6 month supply of medicine for personal use.
When you say that: “In terms of Section 21 policy, applicants may not import more than 6-month supply of medicine for personal use.” Does this mean you do not need to apply if it less than 6 months’ supply?	An application for the use of unregistered medicine for personal use still has to be made to the Authority even if it’s a once off request. In terms of Section 21 Policy, the maximum quantity of unregistered medicine allowed is limited to 6 months’ supply.
This seems crazy. The form asks for a diagnosis and a treatment regime? These are food products? I really do not understand how these products fit in with a Section 21 application? They are not treating anything, they are never administered by a doctor?	Products in pharmaceutical dosage forms (pills, tablets, etc), with medicinal or health claims are regulated under the Medicines and Related Substances Act. This is to ensure the safety, efficacy and quality of the products are substantiated and guaranteed.
My shipment was stopped/detained by Port Health/SARS. They say I must contact you. What must I do?	Kindly advise whether the products are for personal use or sale. You would need to apply to the Authority for permission to use the unregistered products for personal use through the Section 21 application process or in the event the products are for sale, application for the registration of medicine has to be submitted to the authority. Information in this regard is available on the website of the Authority (www.sahpra.org.za).
How long does it take for the permit to be issued?	A turnaround time of five (5) working days from receipt of complete application is allowed for a section 21 application.
Do I need to make another application for importation of the same products?	Yes, A renewal application that includes a completed Progress Report form is required for continued use of same products.

Am I guaranteed to receive my product should I submit the application form from my doctor?	The application will be reviewed by the Complementary medicines unit and can either be approved or rejected based on a number of factors.
If my section 21 application is rejected, will the application fee be refunded back to me?	No, the application fee is non-refundable.
These are natural medicines which are easily accessible to anyone, why should I now go to the doctor and send the application to SAHPRA?	Products that are of natural origin and purporting to be used for medicinal and or health purposes are regarded as Complementary medicines. It is the responsibility of the Authority to ensure that these are safe to use and oversight by a professional prescriber/medical doctor will be required
Similar products are available in S.A but they are expensive hence I decided to import from China.	Please note that you cannot import elsewhere based on the fact that it is cheaper, you need to source similar product/s locally.
I have imported a year supply.	A maximum limit of six months supply is allowed. Please arrange with Customs/Port Health to return it back to the supplier as it is more than 6months supply(allowable limit)
How much is the application fee for Section 21 for Complementary Medicines	The new fees as per Government Gazette No 42474 are R330.
Who should I contact for any Section 21 Enquiry?	Enquiries can be made to the following email addresses: 1. Ledile.Malesela@sahpra.org.za 2. Tondani.raulisa@sahpra.org.za 3. Percival.legoale@sahpra.org.za 4. Mamahlo.makuba@sahpra.org.za