

Name
Title
Practice name
Practice address
Practice email
Your Email

Date

Dear US Customs and FDA Agents,

I have been treating (patient name) for (condition name) for (X period of time). To date, he/she has been treated with all treatments available in the United States that are known to be effective against (condition name), and none have been fully effective.

(Provide condition-specific information e.g. X ALD is primarily a disorder of the white matter of the nervous system, a disorder of the peroxisomes, and a condition that also often involves deficiencies of the adrenal cortex. Approximately 35% of boys with X-ALD develop the childhood cerebral form, a devastating disease marked by normal early development followed by loss of developmental skills and an early death. Lorenzo's oil is prescribed to lower the risk of developing cerebral disease. It helps lower very long chain fatty acids in the body, which play a significant role in disease pathogenesis.)

(Patient name) has been taking Lorenzo's oil since (month, year) and has done very well. (Patient name) was previously enrolled in the University of Minnesota's FDA and IRB approved Expanded Access Program. Lorenzo's Oil is no longer available through this mechanism and Lorenzo's oil is no longer available in the US. We are asking that it be imported in order to treat (patient name). Previous research from the Johns Hopkins University showed that Lorenzo's oil is effective in decreasing the chance of childhood cerebral disease and is safe to use as directed. Please see detailed product information below.

Lorenzo's Oil Product Information:

Lorenzo's Oil is a mix of oleic acid and erucic acid, extracted from rapeseed oil and olive oil, designed to normalize the accumulation of the very long chain fatty acids in the brain. Lorenzo's oil is a combination of glyceryl trierucate (an ester of erucic acid, a 22-carbon monounsaturated fatty acid) and glyceryl trioleate (an ester of oleic acid, an 18-carbon monounsaturated fatty acid), which are generally combined in an approximate ratio of 1:4 (glycerol trierucate:glycerol trioleate) when used for clinical evaluation.

Lorenzo's Oil is for use in children and adults for the dietary management of X-linked Adrenoleukodystrophy (X-ALD) and Adrenomyeloneuropathy (AMN). Lorenzo's Oil is usually given in conjunction with a low-fat diet restricting hexacosanoic acid (C26:0).

Lorenzo's Oil is in liquid form and should be administered orally. The quantity and the dilution administered should be determined by a clinician or a dietitian only. Some treatment protocols suggest that Lorenzo's Oil should provide 20% of the total calorie intake per day.

The oil should be refrigerated and, once opened, should be used within 1 month. The daily dose should be removed from the bottle every day and stored in a sealed container, in the dark, at room temperature, and should be taken throughout the day as instructed by a clinician or dietitian.

This product is produced in the UK for SHS International Ltd. and distributed by Nutricia Advanced Medical Nutrition.

SHS International Ltd. address: 100 Wavertree Boulevard Liverpool, United Kingdom
Nutricia Advanced Medical Nutrition address: White Horse Business Park,
Newmarket Ave,
Trowbridge BA140XQ, United Kingdom

AES Code-3004 909 140- Central Nervous System

I believe this importation meets the requirements of the guidelines issued by the FDA which can be found at the following address –

<https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> – and also outlined in the Personal Importation Policy (PIP) document attached. Therefore, the drug and this importation meets the criteria listed below:

- The drug is unapproved and intended for use in a serious medical condition for which there is no effective treatment domestically available.
- There will be no commercialization or promotion of the drug in the United States.
- The drug does not represent an unreasonable health risk to the patient
- The request is accompanied by an affirmation that the drug is for my patient's use only and we have provided my name and address, as the United States-licensed physician responsible for his/her
- The request is for less than a 3-month supply of the drug. (Patient name) will need 40ml of the oil once a day, which is 280ml a week, and a total of 3 bottle for 6 weeks.

I would appreciate if you would exercise your enforcement discretion to permit importation of this drug to help me treat my patient's condition.

Please do not hesitate to contact me should you require any additional clarification either by phone or email.

Yours sincerely,

Signature
Name