COMPANY ANNOUNCEMENT

Fitoterapia USA Inc. Issues Voluntary Nationwide Recall of MERO MACHO ARTIFICIAL PASSION FRUIT FLAVORED VITAMIN C LIQUID SUPPLEMENT Due to Presence of Active Ingredient Tadalafil

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement

Summary

Company Announcement Date:

September 16, 2019

FDA Publish Date:

September 16, 2019

Product Type:

Drugs

Reason for Announcement:

Undeclared Tadalafil

Company Name:

Fitoterapia USA Inc.

Brand Name:

Macho

Product Description:

MACHO ARTIFICIAL PASSION FRUIT FLAVORED VITAMIN C LIQUID SUPPLEMENT

Company Announcement

Fitoterapia USA Inc., is voluntarily recalling 19,000 bottles of MACHO ARTIFICIAL PASSION FRUIT FLAVORED VITAMIN C LIQUID SUPPLEMENT, liquid dietary supplement to the consumer level. FDA analysis has found the product to be tainted with Tadalafil. Tadalafil is an

active ingredient in a FDA- approved prescription drug that is used for the treatment of male erectile dysfunction. The presence of Tadalafil in Mero Macho renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Consumers who take dietary supplements for erectile dysfunction could have underlying diseases such as diabetes, hypertension, or high cholesterol. Consumers with diabetes, hypertension, high cholesterol or heart disease often take nitrates; concomitant use of nitrates and phosphodiesterase 5- inhibitors can lead to fatal cardiovascular collapse. To date, Fitoterapia USA Inc. has not received any reports of adverse events related to this recall.

The tainted product is marketed as a dietary supplement for sexual enhancement and is packaged in fl oz liquid and 8.5 fl oz, per bottle. The affected MACHO ARTIFICIAL PASSION FRUIT FLAVORED VITAMIN C LIQUID SUPPLEMENT lots include the following, LOT: ZD-160-18 EXP: 09-07-2019, LOT: ZD-078-19 EXP: 27-04-2020, LOT: ZD-159-17 EXP: 31-05-2018. The product can be identified as a white bottle with a high print at the bottom (fitoterapia –logo), plastic label heated sealed, each bottle with its bar code. The product was distributed Nationwide to retail stores and via internet (www.fitoterapiausa.com (http://www.fitoterapiausa.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) since April, 2019.

Fitoterapia USA Inc. is notifying its distributors and customers by mail and email and is arranging for return of all recalled products. Consumers/distributors/retailers that have MACHO ARTIFICIAL PASSION FRUIT FLAVORED VITAMIN C LIQUID SUPPLEMENT, which is being recalled should stop using it, and should contact the Distributor to arrange returns.

Consumers with questions regarding this recall can contact Fitoterapia USA Inc. by e-mail at info@fitoterapiausa.com (mailto:info@fitoterapiausa.com) from Sunday through Saturday, 24 hours per day. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

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