FDA ANNOUNCEMENT

KVK Tech Inc., Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5mL Due to Temperature Abuse

Summary

Company Announcement Date:

August 06, 2021

FDA Publish Date:

August 06, 2021

Reason for Announcement:

Temperature abuse

Company Name:

KVK Tech, Inc.

Brand Name:

KVK Tech, Inc.

Product Description:

Atovaquone Oral Suspension, USP 750 mg/5mL

FDA Announcement

KVK Tech, Inc., is voluntarily recalling two lots of Atovaquone Oral Suspension, USP 750 mg/5mLto the consumer level. The recall is based on customer complaints of unusual grittiness in the product, which KVK has determined was most probably caused by prolonged exposure of these product lots to extremely cold weather during shipment.

Exposure of Atovaquone Oral Suspension to extremely low temperatures, during shipment (the product is required to be protected from freezing temperatures), may result in changes to the effectiveness, appearance, taste and thickness of the liquid. Severely immunocompromised patients who receive less effective Atovaquone Oral Suspension may experience inadequate treatment of serious and life-threatening infections. To date, KVK Tech is not aware of any adverse events associated with this problem.

Atovaquone is a prescription drug labeled to treat Pneumocystis jiroveci [Pneumocystis carinii] pneumonia, a type of pneumonia most likely to affect people with human immunodeficiency virus (HIV) in teenagers and adults and is also used to prevent immunocompromised patients from contracting this type of pneumonia.

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The product is packaged in 8 oz bottles (Bottle of 210 mL with child-resistant cap) packaged in a carton, NDC# 10702-223-21, the affected lots are labeled 16653A and 16654A, with both lots having expiration dates of December 2022. The lot numbers and expiration dates can be found on the Right Bottom Side of the labels on the bottles.

The two lots of product were shipped to a single distributor, which has been notified as part of the recall. KVK Tech will be working with the distributor to ensure that the distributor's customers return remaining inventory of the affected lots to KVK Tech for appropriate disposition. Patients or caregivers who have bottles of Atovaquone affected by this recall should stop using and are requested to return the product to KVK Tech at **110 Terry Drive, Newtown, PA 18940**, and KVK Tech will arrange to reimburse customers for their costs in purchasing the product.

Consumers with questions regarding this recall can contact KVK Tech at **215-579-1842 Ext: 6002 Monday – Friday, 8:00 am – 4:30 pm EST** or **recall@kvktech.com (mailto:recall@kvktech.com)**. 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/medwatch-forms-fda-safety-reporting) 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.

FDA Contact Information

Consumers:

KVK Tech

215-579-1842 Ext: 6002

recall@kvktech.com (mailto:recall@kvktech.com)

Media:

Susan DiCroce

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(215) 579-1842 Ext: 1260

Product Photos

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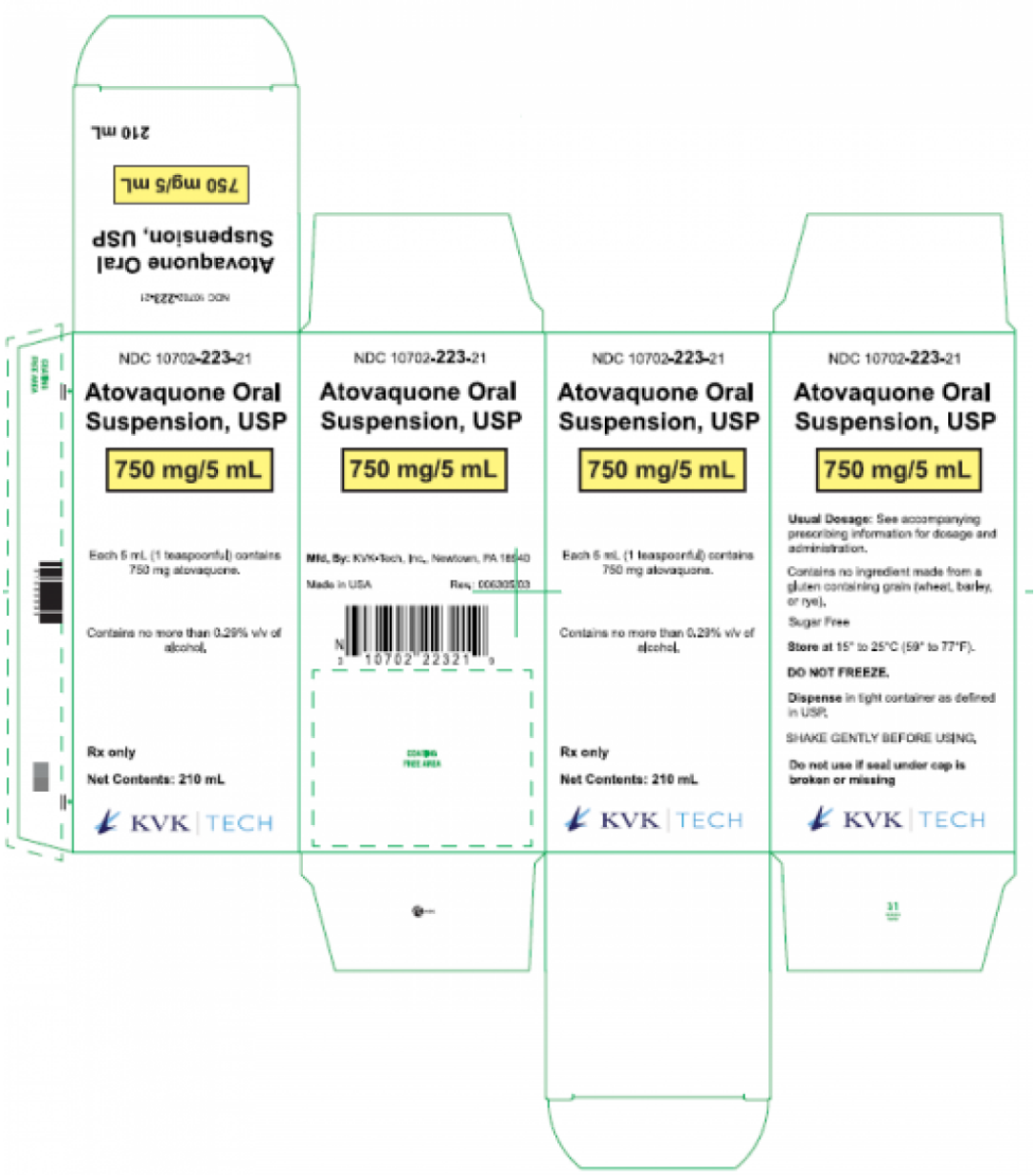

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