Avkare Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Potential *Bacillus Cereus* Contamination

Date: 04/01/2024

About this recall:
Avkare is voluntarily recalling lot # AW0221A (expiration 08/2025) of Atovaquone Oral Suspension, USP 750 mg/5 mL (NDC # 50268-086-12) to the consumer level due to the potential for *Bacillus cereus* contamination.

Atovaquone oral suspension is FDA-approved for prevention and treatment of a certain type of pneumonia, *Pneumocystis jiroveci* pneumonia (PCP), in adults and children 13 years of age and older who cannot take other medications, such as trimethoprim-sulfamethoxazole.

What this means to you:
In patients with a weakened immune system, the contaminated product could lead to serious, life-threatening infections, such as inflammation of the heart (endocarditis) or severe soft tissue infections.

Consumers that have product which is being recalled should stop using the product and return it to the place of purchase or discard. Consumers with questions regarding this recall can contact Avkare by phone at 1-855-3613993 or email drugsafety@avkare.com, Monday through Friday, 9 am to 5 pm Eastern Time. Consumers should contact their 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.
- Regular Mail or Fax: Download form 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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avkare-llc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp-750-mg5-ml-due

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.

