KVK Tech – Recall of atovaquone oral suspension

- On August 6, 2021, KVK Tech announced a voluntary, consumer-level recall of two lots of atovaquone oral suspension due to prolonged exposure to extremely cold weather during shipment.

- There were customer complaints of unusual grittiness in the product, which was probably caused by exposure to extremely low temperatures.

Product Description	NDC#	Lot# (Expiration Date)
Atovaquone oral suspension, 750 mg/5 mL 8 oz. bottle	10702-223-21	16653A (12/2022)
		16654A (12/2022)

- Atovaquone is indicated for the prevention and acute treatment of *Pneumocystis jiroveci* in adults and adolescents who cannot tolerate trimethoprim-sulfamethoxazole.

- 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 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.

- Patients who have the recalled atovaquone should stop use and contact their pharmacy or KVK Tech for return and replacement information. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled atovaquone.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

- Contact KVK Tech by phone **1-215-579-1842 (ext. 6002)** or by email at **recall@kvktech.com** for any questions related to the recall.