

Kurt R. Karst Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W. Suite 1200 Washington, D.C. 20005-5929

September 2, 2020

Re: Docket No. FDA-2020-P-0438

Dear Mr. Karst:

This letter responds to your citizen petition received on January 27, 2020, requesting that the Food and Drug Administration (FDA) determine whether Micro-K LS Packets (potassium chloride) extended-release liquid suspension, 20 milliequivalents (mEq)/packet, approved under new drug application (NDA) 019561 was withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Micro-K LS Packets (potassium chloride) extended-release liquid suspension, 20 mEq/packet, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Micro-K LS Packets (potassium chloride) extended-release liquid suspension, 20 mEq/packet in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-9674.

Sincerely,

Sungjoon Chi Office of Regulatory Policy Center for Drug Evaluation and Research

Enclosure