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April 18, 2013

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Greetings,

The undersigned submits this petition under 21 C.F.R. §§ 10.25(a), 10.30, and 314.161(a)(3) to request the Commissioner of Food and Drugs to make a determination as to whether a listed drug that has been voluntarily withdrawn from sale in the United States was withdrawn for safety or effectiveness reasons.

A. Action Requested

According to publicly-available reports (see Orange book listing in Appendix 1), University of Texas Southwestern Medical Center at Dallas (Charles Y.C. Pak MD) voluntarily withdrew its drug Urocit®-K Powder (Potassium Citrate, NDA 019647) from commercial distribution. The undersigned is seeking a determination by the Commissioner that the University of Texas Southwestern Medical Center's voluntary withdrawal of Urocit®-K powder from sale was for reasons other than safety or effectiveness.

Nomax, Inc. respectfully requests that, if the Commissioner confirms our conclusion, the agency annotate the listing for Urocit®-K powder in the Orange Book to indicate that it was not withdrawn for reasons of safety or effectiveness. If instead, the Commissioner determines that Urocit®-K powder was withdrawn from distribution for safety or effectiveness reasons, we request that the agency publish a notice of this determination in the *Federal Register*. The petitioner respectfully requests that the Commissioner take the requested action as soon as possible.

B. Statement of Grounds

On October 12, 1988, the FDA approved NDA 019647 for Urocit®-K Powder. A full and complete copy of the summary basis of approval for this application is provided in Appendix 2. According to the approved prescribing information included in this document, Urocit®-K Powder was originally manufactured and distributed by Mission Pharmacal Company (San Antonio, Texas).

FDA-2013-P-0503

2013-3054

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The 31st Edition Cumulative Supplement Number 10: October 2011 ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST lists a firm name change for Urocit®-K Powder (potassium citrate, NDA 019647). This supplement deleted Mission Pharma as the manufacturer and added University of Texas Southwest Medical Center (see Appendix 3). Later, the 32ND Edition Cumulative Supplement Number 2: February 2012 ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT reports a second firm name change from University of Texas Southwest Medical Center to Nova K. An exhaustive internet search for Nova K failed to locate any pharmaceutical firm doing business by that name.

Urocit®-K Powder (potassium citrate, NDA 019647) continues to be listed in the "Discontinued Section" of the electronic Orange Book on FDA's web site as previously shown in Appendix 1. According to section 1.11 of the Preface to the Orange Book, a drug product in the Discontinued Section as to which a determination has already been made that withdrawal was not for safety and effectiveness reasons will have the following statement after its product strength: "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons." There is no such annotation next to the product strength for Urocit®-K Powder (potassium citrate, NDA 019647)

Information from the Urocit®-K Powder summary basis of approval NDA file obtained through freedom of information does not include any implication that the product was discontinued for reasons of safety or effectiveness. The initial prescribing information (approved in 1988) provided that Urocit®-K powder (potassium citrate) was indicated for the management of renal tubular acidosis (RTA) with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stones.

Contraindications include patients with hyperkalemia or who may be predisposed to hyperkalemia, that have active urinary tract infections or renal insufficiency. Collectively these contraindications would be clinically recognizable and manageable and would not present an unfavorable risk benefit balance.

In addition, an extensive review of the literature regarding commercially available potassium citrate preparations did not identify any publications or safety advisories suggesting either safety or efficacy concerns for potassium citrate powder. Nomax, Inc. therefore found no evidence of safety or efficacy concerns with regard to this agent.

Allergic reactions reported for patients taking potassium citrate include: hives; difficulty breathing; swelling face, lips, tongue, or throat.

Signs of hyperkalemia include muscle weakness (including frank skeletal muscle and diaphragm paralysis), peaked T waves on the ECG, and cardiac arrhythmias. Metabolic side effects have been reported rarely. Hyperkalemia may cause life-threatening cardiac arrhythmias, and can occur even when renal function is normal. Long-term therapy can result in metabolic alkalosis.

Gastrointestinal (GI) side effects are the most frequent reports. These have included nausea, vomiting, and epigastric or abdominal pain (in 3% to 17% of patients). GI side effects may be lessened by taking the drug with meals. There are numerous reports of GI ulceration and rare reports of gastric or small bowel obstruction associated with the use of solid potassium salt preparations. Patients at higher risk of GI lesions include the elderly and patients with scleroderma, diabetes mellitus, mitral valve replacement, cardiomegaly, esophageal stricture, or impaired GI motility or diverticulae.

No information was found on the Internet suggesting the product was withdrawn for safety or effectiveness reasons. Quite the contrary, as Urocit®-K potassium citrate tablets were also approved in 1988 and this dosage form remains in commercial distribution. On the basis of the research outlined above, that discontinuation of Urocit®-K Powder (potassium citrate, NDA 019647 was undertaken voluntarily and for reasons of business and market strategy.

C. *Environmental Impact Statement*

A claim for categorical exclusion from the requirement of submission of an environmental assessment is made pursuant to 21 C.F.R. § 25.31, on the basis that the use of the active moiety would not be increased.

D. Economic Impact

Information on the economic impact of this request will be provided on request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Amanda L Dixon

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