nomax inc

9735 Green Park Industrial Drive
St. Louis, Missouri 63123
(314) 815-5200
Fax (314) 815-5050
www.nomax.com

April 18, 2013

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Suitability Petition (Expedited Review Requested)
Effer-K (Potassium Citrate Effervescent Tablets)

Dear Sir or Madam,

On behalf of Nomax, Inc (Nomax), a suitability petition is provided which requests a change in strength from the reference listed drug. The reference listed drug cited in this ANDA is based on the approved drug, Urocit®-K Powder (potassium citrate, NDA 019647). Urocit®-K powder was approved in 1988 and was originally manufactured and distributed by Mission Pharma. In association with this suitability petition for a change in strength, Nomax is also submitting a citizen petition requesting that the FDA determine that the Urocit®-K Powder was not discontinued because of safety of efficacy concerns and a request that Urocit®-K Powder be designated as a reference listed drug.

A. Action Requested

Nomax, Inc is submitting a request for a change in the strength of the active pharmaceutical ingredient, Potassium Citrate, contained in each effervescent tablet used to prepare a solution containing potassium citrate for oral administration. Nomax, Inc. requests the FDA to consider this request and to issue a notification that will allow Nomax to submit an application that requests approval for a different strength. Nomax also respectfully asks that this request to processed in an expedited manner.

B. Statement of Grounds

Two types of oral dosage forms of potassium citrate were approved in the 1980's. NDA 019071 for potassium citrate extended release tablets (Urocit®-K) was approved in 1985. A copy of the prescribing information (downloaded from the DailyMed website) is provided in Appendix 1. It was followed by NDA 019647 (potassium citrate granules for solution, Urocit®-K powder) that was approved in 1988. Both dosage forms were originally manufactured by Mission Pharma. A copy of the FDA approved prescribing information for the Urocit-K Powder (NDA 19647), obtained from the summary basis of approval is provided in Appendix 2. The "Orange Book" presently lists the 15 meq extended release tablet as a reference listed drug. Urocit®-K powder is not listed as a reference listed drug. Mission Pharma continues to manufacture and distribute the extended release tablet, but discontinued the potassium citrate powder for solution. Nomax, Inc. is submitting two associated citizen petitions for Urocit®-K powder; the first requests the commissioner to determine that the product was not discontinued due to

concerns regarding either safety or efficacy. The second petition requests Urocit®-K powder be designated as a reference listed drug. The current "Orange book" lists two strengths (10 meq and 20 meq) of Urocit®-K Powder (NDA 019647) as indicated in the following table downloaded from the Electronic Orange Book. An exhaustive search of the internet did not disclose any information on a pharmaceutical entity doing business under the name of Nova K.

Application Number Search Results from "OB_Disc" Table for Query on "19647."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
N019647	POTASSIUM CITRATE	FOR SOLUTION; ORAL	10MEQ/PACKET	POTASSIUM CITRATE	NOVA K
N019647	POTASSIUM CITRATE	FOR SOLUTION; ORAL	20MEQ/PACKET	POTASSIUM CITRATE	NOVA K

Nomax, Inc. proposes a generic drug equivalent to Urocit®-K Powder in 3 distinct strengths: 10 meq, 20 meq and 25 meq. The 10 and 20 meq strengths provide the identical quantity of potassium as the Urocit®-K powder. The proposed 25 meq represents an increase in strength. It is important to note that the Urocit®-K powder is contained in packets that include the active pharmaceutical ingredient potassium in the designated strength and the powder includes sweeteners and flavoring agents. The powder is added and dissolved in water or a suitable beverage and is administered to the patient as an oral solution. As such the active pharmaceutical ingredient is potassium cations and citrate anions that are completely dissociated to form a true molecular solution.

The proposed generic product is a powder compressed into tablets. The compressed tablets are formulated with potassium bicarbonate, citric acid, and sweeteners and flavoring agents. Upon addition to water, the bicarbonate anion reacts with citric acid to produce carbon dioxide gas, which facilitates dissolution of the compressed tablets and the carbonation enhances the taste. The resulting solution contains a true molecular solution of potassium cations and citrate anions (equivalent to the true molecular solution prepared from Urocit®-K powder).

Nomax, Inc. seeks FDA agreement to submit an ANDA which includes the 25 meq strength effervescent tablet in addition to the 10 and 20 meq strengths that have been approved for NDA 019647.

*C. **Environmental Impact***

The petitioner claims a categorical exclusion under 21 CFR 25.31

*D. **Economic Impact***

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

E. Certification

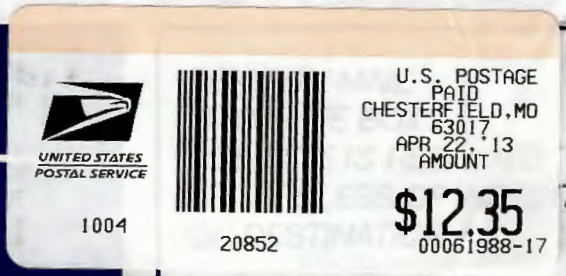
The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

We respectfully request expedited review of this suitability petition. If you have any questions or comments regarding this submission, please contact me using the contact information listed below.

Regards,

Amanda L Dixon

Amanda Dixon
Director of Regulatory Affairs and Quality
Nomax, Inc
9734 Green Park Industrial Drive
St. Louis, Missouri 63123
Phone: (314) 815-5200
Fax: (314) 815-5050
Email: Amanda@nomax.com



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