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April 18, 2013

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Greetings:

Nomax, Inc. submits this petition, in quadruplicate, pursuant to 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration to amend the "Approved Drug Products with Therapeutic Equivalence" list (the "Orange Book") as outlined below. This is a companion citizen petition for Urocit®-K Powder (NDA 019647), submitted on the same date requesting the FDA to determine that this drug product was not discontinued for reasons related to either safety or efficacy.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration amend the "Orange Book" to designate Nova-K's (formerly University of Texas Southwest Medical Center) Urocit®-K Powder (potassium citrate, NDA 019647) as a reference listed drug product.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA approved drug products. The FDA has decided through the comment and rule making process that it will designate all reference listed drug (RLD) products, and that the designated reference listed drug products will be the same drug products selected by the Agency as the reference standard for bioequivalence testing for a duplicate generic version of the RLD (57 FR 17950, 17954). FDA's intention in this regard was to designate a single reference listed drug against which all generic versions must be shown to be bioequivalent and thus avoid possible variations among generic drugs and their brand name counterparts (57 FR 17950, 17954). For multiple source NDA drug products or multiple source drug products without an NDA, the FDA has decided to generally designate the market leader as the reference-listed drug (57 FR 17950, 17958).

In the case of oral potassium citrate preparations, Urocit®-K 15 meq extended release tablets has been listed in the "Orange Book" as the designated reference listed drug. Urocit®-K 15 meq (NDA 019071, was approved 8/30/1985). A copy of the currently approved prescribing information for Urocit®-K 15 extended release tablets is provided in Appendix 1. This dosage form of Urocit®-K 15 meq is indicated as an extended release tablet. Urocit®-K powder (potassium citrate granules for solution) is a powder that is dissolved in water and administered as an oral solution. In recognition of the differences between the extended release tablets and the oral solution dosage forms, Nomax, Inc. respectfully requests the commissioner to designate Urocit®-K powder (NDA 019647) as a reference listed drug.

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.

Respectfully submitted,

Amanda L Dixon

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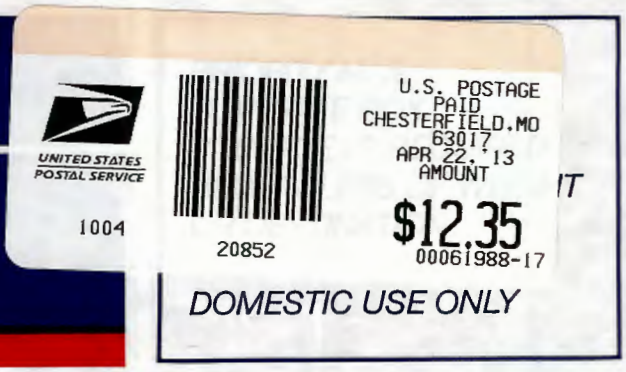

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