DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 2, 2013

Amanda Dixon
Director of Regulatory Affairs and Quality
Nomax, Inc
9734 Green Park Industrial Drive
St. Louis, MO 63123

Dear Ms. Dixon:

Your petition to the Food and Drug Administration request that the FDA 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, was received by this office on 05/02/2013. It was assigned docket number FDA-2013-P-0504/CP1, and it was filed on 05/02/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)