DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 1 5 2013

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

Re: Docket No. FDA-2013-P-0504

Dear Ms. Dixon:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition dated April 18, 2013. Your petition requests that the Agency amend FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book) to designate Nova-K's potassium citrate (new drug application 019647) as a reference listed drug.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Nancy K. Hayes

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research