DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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January 14, 2013

Jennifer A. Davidson
Counsel to Ikaria, Inc.
Kleinfeld, Kaplan and Becker LLP
1140 19th Street, N.W.
Washington, D.C. 20036-6606

Dear Ms. Davidson:

Your petition to the Food and Drug Administration on behalf of Ikaria, Inc., requesting FDA to reconsider and rescind the 510(k) clearance for the GeNOsy1™ MV-1000, dated May 16, 2012 and require approval of a New Drug Application before marketing of any GeNO Nitric Oxide Delivery System, was received by this office on 1/14/2013. It was assigned docket number FDA-2013-P-0070/CP1, and it was filed on 1/14/2013. 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)