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April 10, 2013

Via Overnight Courier

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

Re: Dockets FDA-2012-P-1103 and FDA-2013-P-0070
Request for Non-Confidential Treatment of Submitted Materials

Dear Sir/Madam:

The undersigned, on behalf of Ikaria, Inc. ("Ikaria"), submitted Citizen Petitions assigned the above referenced dockets on November 1, 2012 and January 11, 2013, respectively. Both Petitions attached as an exhibit a document authored by GeNO LLC entitled "Executive Summary."¹ GeNO has indicated to Dockets Management that it considers this document to be confidential and has stated in its comments to the dockets that Ikaria's use of the document in support of its Petitions was improper. Public access to the Executive Summary, as well as Ikaria's Petitions and the other exhibits to those Petitions has been blocked, presumably in response to GeNO's claim of confidentiality for the Executive Summary.

Ikaria obtained the GeNO Executive Summary from public sources and was not under any obligation to keep the document confidential. While the document may at one time have been confidential to GeNO, once it entered the public domain, GeNO no longer had any legitimate claim of confidentiality. Accordingly, Ikaria believes its use of the document as an exhibit to its Petitions was entirely appropriate, and objects strongly to any suggestion that the document was used for a purpose other than providing the Agency with publicly available information relevant to the Petitions.

In any event, if the Agency accepts GeNO's claim of confidentiality for the Executive Summary, Ikaria will not dispute that determination. Ikaria does object, however, to treatment of its Petitions as confidential. The Petitions include a great deal of information unrelated to GeNO, and much of the information in the Petitions concerning GeNO and its products is freely available on the GeNO website. All of that information should be available to the public via www.regulations.gov and directly from Dockets Management. Ikaria therefore requests that public access to its Petitions and

¹ Exhibit B in Docket FDA-2013-P-0070 and Exhibit A in Docket FDA-2012-P-1103.

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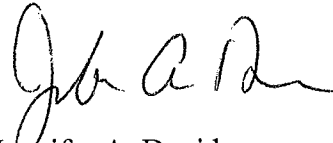
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accompanying exhibits, other than the Executive Summary, be promptly restored. Based on information available to Ikaria, this appears to be consistent with GeNO's request that "FDA withdraw from public view a confidential GeNO document."²

Should you have any questions concerning this request, please do not hesitate to contact me.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. A. Davidson".

Jennifer A. Davidson
Counsel to Ikaria, Inc.

² See Letters from John K. Whiting, IV, General Counsel & Vice President of Administration GeNO LLC to Dockets Management Branch (March 14, 2013). According to these letters, GeNO first claimed confidentiality in letters dated February 28, 2013. The February 28th letters, however, are not available in the Dockets because they themselves contain information GeNO claims as confidential. Based on the text of the March 14, 2013 letters, it appears that GeNO claims confidentiality only for the Executive Summary and not for the Ikaria Petitions or the other exhibits to those Petitions.