

GeNO LLC

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March 14, 2013

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, Maryland 20852

Re: Docket No. FDA-2013-P-0070
Request for Confidential Treatment of Submitted Materials

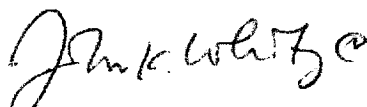
Dear Sir/Madam:

Enclosed are an original and three copies each of redacted and unredacted versions of a comment submitted by GeNO LLC ("GeNO") to the above-referenced docket in response to a citizen petition submitted by Kleinfeld, Kaplan and Becker, LLP, on behalf of Ikaria, Inc. ("Ikaria").

GeNO is submitting a redacted version of its comment because it contains trade secrets and confidential commercial and financial information, as defined by 21 CFR 20.61, which are protected from public disclosure by the agency under the Freedom of Information Act and the Trade Secrets Act. The redacted version is for public dissemination by posting on www.regulations.gov or availability in the Division of Dockets Management. The unredacted comment is for the agency's internal and confidential use.

By letter submitted to the docket on February 28, 2013, GeNO requested that FDA withdraw from public view a confidential GeNO document included as an attachment to Ikaria's petition. FDA has now restricted the availability of the above-referenced petition and all attachments in the public docket on www.regulations.gov. GeNO asks that the unredacted comment be restricted from public disclosure, and that only the redacted comment (and attachments) be made available on www.regulations.gov and at the Division of Dockets Management.

Respectfully submitted,



John K. Whiting, IV
General Counsel &
Vice President of Administration

Enclosures