DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 10 2013

Ms. Jennifer A. Davidson
Kleinfeld, Kaplan and Becker LLP
1140 19th Street, N.W.
Washington, DC 20036

Re: Citizen Petition – Docket Number FDA-2013-P-0070

Dear Ms. Davidson:

This is an interim response to the petition dated January 11, 2013, filed by the Food and Drug Administration (FDA) on January 14, 2013. In the petition, you requested FDA do the following.

> (1) Reconsider and rescind the 510(k) clearance for the GeNOsyl™ MV -1000, dated May 16, 2012.
>
> (2) Require approval of a New Drug Application under 21 U.S.C. § 505 before marketing of any GeNO nitric oxide delivery system that manufactures any portion of the finished pharmaceutical at bedside *(in situ)* by chemically converting nitrogen dioxide into nitric oxide for patient administration, including the GeNOsyl™ MV - 1000.
>
> (3) Refuse to approve any New Drug Application for a GeNO nitric oxide delivery system that chemically converts nitrogen dioxide into the finished pharmaceutical nitric oxide at the patient's bedside unless it incorporates appropriate current Good Manufacturing Practices ("cGMPs") that provide the requisite assurance that the nitric oxide administered to patients meets NDA specifications for identity, strength, quality, and purity, per 21 U.S.C. §§ 355(d)(3).

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Jean Olson of our Regulations Staff at (301) 796-6467.

Sincerely yours,

Nancy Stade, J.D.
Deputy Director for Policy
Center for Devices and
Radiological Health