DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

APR 12 2012

Mr. Thomas W. Nerney
Executive Director
Institute for Health Quality and Ethics
75 Sprague Hill Road
Chepachet, RI 02814

Re: Citizen Petition – Docket Number FDA-2011-P-0777

Dear Mr. Nerney:

This is an interim response to the petition dated October 21, 2011, filed by the Food and Drug Administration (FDA) on October 21, 2011. In the petition, you requested FDA "1. immediately and fully implement and enforce the patient notification amendment of the Mammogram Quality Standards Act of 1992, as amended in the Mammogram Quality [S]tandards Reauthorization Act of 1998 and 2004; 2. immediately terminate the unlawful practice of providing false and misleading information to women regarding their mammogram results; 3. immediately include all relevant and material information obtained from the mammogram in the report that is provided to patients as is statutorily required."

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 Abigail Corbin of our Regulations Staff at (301) 796-9142.

Sincerely yours,

Nancy Stade
Deputy Director for Policy
Center for Devices and
Radiological Health