DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Ms. Kim A. Gandy
President
National Organization for Women
733 15th Street N.W., 2nd floor
Washington, D.C. 20005

Ms. Sidney M. Wolfe, M.D.
Director
Public Citizen, Health Research Group
1600 20th Street, N.W.
Washington, D.C. 20009

Cynthia A. Pearson
Executive Director
National Women's Health Network
514 10th Street, N.W., Suite 400
Washington, D.C. 20004

Re: Citizen Petition - Docket Number 03P-0511/CP1
Dated: November 3, 2003
Received: November 3, 2003

Dear Ms. Gandy, Dr. Wolfe, and Ms. Pearson:

This letter is in response to the above referenced Citizen Petition. In your petition, you requested that the Food and Drug Administration (FDA) refrain from completing the review of Inamed Corporation's McGhan silicone gel-filled breast implant premarket approval (PMA) application until Inamed submits an amendment to the PMA responding to deficiencies you cited in your petition to demonstrate reasonable assurance of safety or effectiveness of Inamed's silicone gel-filled breast implant. You also requested that, in accordance with 21 CFR 14.7(a)(2), that the FDA Commissioner expedite the review of your petition.

As you can see from the timing of this response, we have expedited our review and consideration of your petition. FDA is, however, denying your request that we refrain from completing our review of Inamed's PMA until an amendment to the PMA is submitted that responds to the deficiencies identified in your petition.

On October 14-15th, FDA sought input from an advisory committee of outside experts on the data contained in the Inamed PMA during an open public meeting. In a 9 to 6 vote, the Panel recommended approval of the Inamed PMA with conditions. It is important to note that although

the advisory committee makes a recommendation to FDA, FDA has the responsibility for making the final decision on the PMA. In accordance with 21 CFR 814.44(c), FDA is now completing its review of the PMA and the advisory committee report and recommendation to determine whether the PMA contains adequate data to demonstrate reasonable assurance of the safety and effectiveness of Inamed's silicone gel-filled breast implants.

In accordance with 21 CFR 814.44(c), within the later of 180 days from the date of filing of the PMA or the date of filing of a major amendment, FDA intends to issue Inamed an approval order under 814.44(d), an approvable letter under 814.44(e), a not approvable letter under 814.44(f), or an order denying approval under 814.45.

The safety and effectiveness of silicone gel-filled breast implants are of great importance to FDA. We are committed to performing a thorough review of all information regarding the safety and effectiveness of Inamed's device prior to rendering any decision on their PMA. We will also fulfill our statutory obligation of ensuring that there is a sound evidentiary basis for our decision.

If you have any questions regarding this letter, please contact Ms. Samie Allen at 301-594-3090, ext. 139.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and Radiological Health