DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Marlene Keeling
President
Chemically Associated Neurological Disorders
P.O. Box 682633
Houston, Texas 77268-2633

Re: Citizen Petition - Docket Number 03P-0530/CP1
Dated: November 18, 2003
Received: November 18, 2003

Dear Ms. Keeling:

This letter is in response to the above referenced Citizen Petition. In your petition, you requested that the Food and Drug Administration (FDA) delay approval of any and all premarket approval (PMA) applications for silicone gel-filled breast implants until additional valid long-term scientific data are collected. You identified specific "conditions" that you believe Inamed should address as part of their PMA. Lastly, you requested that, in accordance with 21 CFR 14.7, 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 delay approval of any and all PMAs, including Inamed's PMA, until additional valid long-term scientific data, including data from the "conditions" specified, are collected.

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 advisory committee recommended approval of Inamed's 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 deliberations and recommendations 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. We cannot respond to specific issues you have raised about the particular device currently under review.

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 intend to thoroughly review 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