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December 5, 2003

VIA US MAIL

Ms. Jenny Butler
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2003P-0530: Silicone Gel-filled Breast Implants (November 19, 2003)

Ms. Butler:

Enclosed please find the first page of the document submitted by Edward M. Basile of King & Spalding LLP to Docket No. 2003P-0530: Silicone Gel-filled Breast Implants on December 4, 2003.

The document originally submitted via hand delivery was inadvertently marked "Privileged and Confidential." As you requested, we are providing a clean copy of this page to replace the one that you received.

Sincerely,

Rebecca E. Jones

2003P-0530

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December 5, 2003

VIA HAND DELIVERY

Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2003P-0530: Silicone Gel-filled Breast Implants (November 19, 2003)

To Whom It May Concern:

This letter is filed on behalf of Inamed Corporation ("Inamed") in response to a Citizen Petition filed by Marlene Keeling, President of Chemically Associated Neurological Disorders ("petitioner"). The petition requests that FDA delay approval of any and all premarket applications ("PMAs") for silicone breast implants ("SBIs"). Specifically, the petition requests that FDA stay any action on the PMA for Inamed's McGhan silicone breast implants until the PMA is amended to meet petitioner's conditions.

There is no basis for FDA to stay its review of Inamed's PMA or issuance of a decision on this PMA. The Food, Drug and Cosmetic Act ("FDCA") gives FDA the ultimate role of assessing the safety and effectiveness of medical devices.[1] The statute also specifies procedures for third-party participation in the process at the time of the advisory panel meeting and *after* an order approving or denying a PMA has been issued by FDA.[2] Rather than following the procedures mandated by Congress, petitioner incorrectly assumes that 21 C.F.R. § 10.35 allows her to step into the role intended for FDA and to compel an applicant to respond to her own assessment of the PMA's adequacy. For these reasons, further discussed below, FDA should deny this petition and proceed to make its own determination of the safety and effectiveness of Inamed's SBIs.

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[1] *See* 21 U.S.C. § 393(b)(2)(C) (2003).
[2] *See* 21 U.S.C. 360e(g); 360e(c)(2)(B) (2003).