



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 7, 2003

Sidney M. Wolfe, M.D.
Public Citizen Health Research Group
1600 20th Street, N.W.
Washington, District of Columbia 20009-1001

FILE COPY

Dear Dr. Wolfe:

Your petition requesting the Food and Drug Administration to refrain from completing the review of the PMA submitted by Inamed Corporation for McGhan silicone gel-filled breast Implants until an amendment to the PMA is assuring safety and effectiveness was received by this office on 11/3/2003. It was assigned docket number 2003P-0511/CP 1 and it was filed on 11/06/2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management

2003 P 0511

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