



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

May 24, 2005

**FILE COPY**

Mr. William B. Schultz  
Zuckerman Spaeder LLP  
1201 Connecticut Avenue, N.W.  
Washington, D. C. 20036-2638

Dear Mr. Schultz:

Your petition requesting the Food and Drug Administration to deny the pre-market approval applications of Mentor Corporation and Inamed Corporation for approval of silicone-gel filled breast implant products, was received by this office on 05/23/2005. It was assigned docket number 2005P-0204/CP 1 and it was filed on 05/24/2005. 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  
Office of Management Programs  
Office of Management

2005P-0204

ACK 1