



Nov 10, 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

0032 5 DEC -1 P1:51

Mr. William B. Schultz
Mr. Carlos T. Angulo
Zuckerman Spaeder, LLP
1201 Connecticut Avenue NW
Washington, DC 20036

Re: Citizen Petition – Docket Number 2005P-0204
Dated: May 23, 2005
Received: May 24, 2005

Dear Messrs. Schultz and Angulo:

This is an interim response to your petition dated May 23, 2005, which was filed by the Food and Drug Administration (FDA) on May 24, 2005. In your petition, you ask that FDA deny the pending pre-market approval (PMA) applications for silicone-gel filled breast implants submitted by Mentor Corporation and Inamed Corporation because, according to the petition, those applications cannot provide reasonable assurances of safety and effectiveness for such devices.

We are continuing to review the issues and expect to issue a final response in the near future.

If you have any questions about this interim response, please contact Myrna Hanna of our Regulations Staff at (240) 276-2347.

Sincerely yours,

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

2005P-0204

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