DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 26, 2015

Marcus J. Susen & Justin Parafinczuk
Koch Parafinczuk & Wolf, P.A.
110 E. Broward Blvd., Ste. 1630
Fort Lauderdale, FL 33301

Re: Citizen Petition – Docket Number FDA-2015-P-0569

Dear Mr. Susen & Mr. Parafinczuk:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your citizen petition filed on January 24, 2015. You requested that FDA take various actions against Bayer Healthcare Pharmaceuticals, Inc., and its subsidiaries regarding the "Essure" product. Specifically, you requested that the Commissioner issue orders relating to disclosures and findings, variously modify premarket approval (PMA) terms, and initiate a recall. You based your request on allegations that: the product sponsor perpetrated fraud with respect to clinical trials; the sponsor violated the terms of the PMA; and federal laws were violated.

After reviewing your petition, CDRH has determined that the request made in this citizen petition is a trade complaint because of the allegations against the "Essure" product: that it is adulterated or misbranded within the meaning of 21 U.S.C. §§ 351 and 352, so its introduction into interstate commerce is prohibited under 21 U.S.C. § 331 (including relevant implementing regulations). Therefore, the information in your request was forwarded to the Office of Compliance within CDRH. The Office of Compliance will enter the information into the Allegation of Regulatory Misconduct system, send you an acknowledgement, review the information, and investigate the complaint. The Office of Compliance will pursue actions as deemed necessary. However, CDRH does not provide information during the investigation, nor does it provide explanations of the outcome of the investigation to the correspondent who made the complaint.

For the aforementioned reasons, FDA is closing your petition. If you have any questions about this response, please contact Ian Ostermiller of our Regulations Staff at (301) 796-5678.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Deputy Center Director for Science
and Chief Scientist
Center for Devices and
Radiological Health