DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Kirsten Gillibrand
United States Senate
Washington, D.C. 20510-3203

OCT 08 2014

Dear Senator Gillibrand:

Thank you for your letter of August 19, 2014, cosigned by Senator Charles E. Schumer, expressing concern about the use of power morcellation devices for the surgical removal of uterine tissue or fibroids. Please be assured that the Food and Drug Administration's (FDA or the Agency) primary concern as it considers the continued use of these devices for women is the safety and well being of patients.

FDA takes questions related to medical device safety very seriously. The Agency began to investigate this safety concern as soon as it was brought to our attention in December 2013 and immediately started to review the issue and available data and information.

Based on our analysis of currently available data, FDA determined that approximately 1 in 350 women who are undergoing hysterectomy or myomectomy for fibroids are found to have an unsuspected uterine sarcoma—this is a higher rate than was previously understood. For this reason, as you mention in your letter, FDA issued a public safety communication in April 2014, discouraging the use of laparoscopic power morcellators during hysterectomy or myomectomy for uterine fibroids.

Since that time, and as you also noted in your letter, FDA convened a panel meeting of outside experts on July 10 and 11, 2014, to discuss clinical roles, surgical techniques, labeling, and any risk mitigations related to these devices. At this meeting, patients and their families contributed significant information related to this issue, and the Agency garnered valuable information and perspective from the range of participants and panel members.

We plan to continue our internal analysis and review of the available scientific data and panel meeting information, as well as the public comments submitted to the docket we opened on this issue. FDA will take into account all available information when considering any future regulatory action. If the Agency decides to take further action, we will issue communications to inform manufacturers and the public, such as through notice in the *Federal Register*.

FDA continues to discourage the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids, and encourages women to discuss with their health care professional the risks and benefits of all available treatment options, before deciding which treatment is right for them.

Thank you, again, for contacting us regarding this matter. The same letter has been sent to Senator Schumer.

Sincerely,

Elaine Vining

for Thomas A. Kraus
Associate Commissioner
for Legislation