DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JAN 28 2015

Angela Desa-Lynch
1622 Buchanan Street
Marysville, CA 95901

Re: Your correspondence to President Obama and the White House, dated November 5, 2014, regarding your concerns and complaints dealing with side effects of a contraceptive (ESSURE) approved by the Food and Drug Administration (FDA)

Dear Ms. Lynch:

Your correspondence to President Obama and the White House, dated November 5, 2014, regarding the Essure medical device, has been referred to me in my role as the Ombudsman for the Center for Devices and Radiological Health (CDRH) of the FDA.

I have read your correspondence, and would like to thank you for your efforts to express your concerns regarding the Essure medical device. Your correspondence described your role as the administrator of a Facebook group and described some of the adverse events and affects the women within your group experience on a daily basis and how it has affected their personal and family life. I was very sorry to read about the health problems experienced by your group after using the Essure medical device. Please know that the FDA takes your concerns and complaints very seriously. Patient feedback is critical to the Agency's understanding of the risks and benefits of medical devices as it continues to monitor medical devices after they are on the market.

Your correspondence discussed concerns with the clinical investigational studies used to evaluate the Essure medical device, specifically with the volume of individuals enrolled as well as the duration of these studies. I would like to provide you with information and further resources regarding the review process CDRH used to evaluate the safety and effectiveness of this medical device. Essure received FDA's most stringent and rigorous review prior to marketing, using our pre-market approval (PMA) process. The PMA process includes a scientific and regulatory review, including input from an outside panel of experts, to evaluate the safety and effectiveness of medical devices that pose the greatest risk to patients. The PMA process also includes a thorough review of information that should be included in the product labeling, such as warnings or a list of potential risks. The following website provides further, detailed information regarding the approval of the Essure medical device, to include the PMA Approval Order, Summary of Safety and Effectiveness, Professional Labeling, Patient Labeling, and other consumer information:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p020014. These documents contain summaries of the clinical investigational studies used to evaluate the safety and effectiveness of the Essure medical device as well as documents the adverse events experienced by the women in the clinical studies.

In addition to this information, I would also like to inform you of some of the steps the FDA has taken to follow-up on concerns expressed by some users of Essure so that the Agency can better understand the benefits and risks of this medical device.

The FDA has conducted a thorough review of the available information about Essure and the experiences of patients who have had Essure since the FDA approved it in 2002. This includes experiences of patients who have had positive outcomes with Essure as well as those who have experienced problems. Specifically, the FDA has taken the following actions:

- The FDA reviewed Essure patient reports of problems, including web-based testimonials, and reports of problems submitted to the FDA from other sources, including doctors, patients, and the manufacturer of Essure, Conceptus Inc.

- The FDA reviewed the results from a five-year study conducted by Conceptus and required by the FDA as part of the product's 2002 approval. This study evaluated:

  - how well Essure prevented pregnancy;
  - the safety of the procedure used to place Essure; and,
  - the safety of Essure once implanted, including patient comfort.

  Although there is evidence of complications, as there are with all medical devices, the FDA concluded that the overall results from this study did not demonstrate any new safety problems or an increased incidence of problems already known.

- The FDA evaluated the available clinical literature to determine what long-term complications may be associated with Essure. To date, there is no literature reviewed by the FDA that has indicated any new or more widespread complications definitely associated with Essure occurring more than five years after Essure placement.

To date, none of the above information the FDA has reviewed has established a causal connection between Essure and certain reported problems, such as extreme fatigue, depression, and weight gain.

Other reports of problems, including pain, abnormal bleeding, perforations, device migration or nickel allergy are known complications that are addressed in Essure labeling and product information for either patients or their physicians. For your ease of reference, the current labeling for the Essure medical device can be accessed at the following location: http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf.

In addition to describing the health problems experienced by the women in your group, your correspondence also stated that you have proof that the studies on Essure are biased, proof that the manufacture did not report all the adverse events, and proof that the medical device and its materials are toxic to the human body. Please know that the FDA takes these allegations very seriously. I would like to address each of these items by providing you with the following resources:

- Regarding your statement of having proof that the studies on Essure are biased, I respectfully request that you submit this information to the Center's Office of Compliance (OC), Division of Bioresearch Monitoring (DBM) at BIMO@CDRH.FDA.GOV. DBM will send you an acknowledgement letter. If more information is needed DBM or OC will contact you. Other than this interaction, you will not receive any notification from OC regarding what action, if any, is being taken. Center policy does not allow us to acknowledge current or contemplated enforcement actions taken by OC. Confidentiality regarding these actions is maintained in order to protect the integrity of our investigations.

- Regarding your statement of having proof that the manufacture did not report all the adverse events, I respectfully request that you file a trade complaint with the Center's Office of Compliance (OC) at OCMedicalDeviceCo@fda.hhs.gov. OC will send you an acknowledgement letter. If more information is needed, OC or the District Office will contact you. Other than this interaction, you will not receive any notification from OC regarding what action, if any, is being taken. Center policy does not allow us to acknowledge current or contemplated enforcement actions taken by OC. Confidentiality regarding these actions is maintained in order to protect the integrity of our investigations.

- Regarding your statement of having proof that the materials are toxic, I strongly encourage you to submit a voluntary report about any problems you have experienced with Essure through MedWatch, the FDA Safety Information and Adverse Event Reporting program. The FDA reviews the MedWatch reports and takes any necessary action to protect public health. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

  Directions on how to submit a MedWatch medical device report (MDR) are located at: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm. A MedWatch report can also be filed by telephone by calling 1-800-332-1088.

  If you have had any problems with Essure, please seek a thorough evaluation from your health care provider and be sure to receive the proper follow-up.

You also have the ability to request that the FDA change the way they regulate this medical device. An appropriate venue for filing such a request is via a Citizen Petition to the FDA Commissioner as described in the Code of the Federal Register, Title 21, Section 10.30 (21 CFR 10.30). As mentioned in this regulation, a Citizen Petition must follow the format specified for petitions in 21 CFR 10.20. You can obtain further information on this matter on the FDA Web site at this location: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. As of December 2013 Citizen Petitions can now be filed electronically, to be submitted to the docket at www.regulations.gov

Please note that you may request information regarding the status of CDRH's review of any of the actions discussed above under the Freedom of Information Act (FOIA). The process for submitting a FOIA request can be found at http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm. It is important to understand that the Center will not release information on current or ongoing enforcement actions. Therefore, if an investigation is in progress, that information cannot be release, even under the FOIA.

The FDA acknowledges that the use of any medical device involves some level of risk. The Agency continues to monitor the safety of Essure, as it does for all medical devices, to make certain that it does not pose an increased risk to public health and safety and that its benefits of providing women with a non-surgical sterilization choice continue to outweigh the risks of the device.