April 24, 2020

(b) (6)

Bayer U.S. LLC
100 Bayer Boulevard
Whippany, NJ 07981

Request Number: E2020002
Product Code: HHS

Re: Medical Device Reporting Variance Request for Essure (P020014)

Dear (b) (6) :

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your letters dated (b)(4) and (b)(4) requesting a variance under 21 CFR 803.19(b) from certain medical device reporting requirements prescribed in 21 CFR Part 803 for your device, the Essure System ("Essure"), approved under Premarket Approval (PMA) Application P020014, on November 4, 2002.

FDA is granting your request for a variance, in part, subject to the conditions outlined below, pursuant to 21 CFR 803.19(c). This variance (E2020002), effective as of the date of this letter, applies only to the subset of MDR reportable events described below. The conditions of the variance supersede the regular reporting requirements in 21 CFR 803.10(c)(1), 21 CFR 803.20(a)(3), 21 CFR 803.20(b)(3)(i)-(ii), 21 CFR 803.50(a) and 21 CFR 803.52 that would otherwise apply to these MDR reportable events. **This variance is granted through April 30, 2021, after which date all of the medical device reporting requirements in 21 CFR Part 803 will again apply to Essure, unless an extension of this variance is granted by FDA.**

Your firm must continue to submit MDR reportable events that you become aware of through sources other than those described below as individual reports using FDA Form 3500A in accordance with the reporting requirements in 21 CFR Part 803.

The conditions of this variance are as follows:

1. This variance is limited to MDR-reportable events for Essure that you are or become aware of from information received November 2016 through November 2020 in

connection with litigation regarding Essure and that is derived from the following two sources:

a. publicly available social media information regarding certain Essure plaintiffs identified by Bayer's outside legal counsel; and

b. social media documents produced by the plaintiffs' lawyers to Bayer's outside legal counsel.

2. Information regarding MDR-reportable events identified through review of this information must be provided to FDA in three separate documents: a line-item tabular data spreadsheet, an FDA Form 3500A, and an adverse event analysis report. These reporting elements must be submitted in electronic format to FDA per the following schedule:

   a. Line-item tabular data spreadsheet that includes all reportable events identified during each one-month period from the information described in item 1 above. You must send the spreadsheet on a monthly basis, ten days after the close of the one-month period, starting July 10, 2020 for the one-month period of June 1, 2020 – June 30, 2020.

   b. Initial FDA Form 3500A for each spreadsheet: You must send an initial FDA Form 3500A on a monthly basis, ten days after the close of the one-month period for the associated spreadsheet (e.g., by July 10, 2020 for the spreadsheet that includes June 1, 2020 - June 30, 2020).

   c. Quarterly and final adverse event analysis report: You must send a quarterly analysis report, within 30 days after the close of a three-month period (e.g., by October 1, 2020 for June 1, 2020 – August 31, 2020) and a final analysis report within 90 days after the expiration of the variance.

   The required format and contents of these reporting elements, which are to help ensure protection of the public health, are discussed below.

3. The line-item tabular data shall be provided in electronic spreadsheet format (e.g., Excel) and shall include the following information for each reportable event identified over the prior one-month period, along with a unique event number assigned to each event. FDA believes that provision of the information listed below is necessary to ensure adequate analysis of the reported events. If no information is available for a field for a given event, the field shall be left blank:

   a. Patient demographic fields for age (years), date of birth, sex, weight (lbs), and country in which the event occurred;

   b. Report source;

c. Date of event;

d. Date your firm became aware of the event;

e. Type of reportable event (death, serious injury, malfunction);

f. Description of event or problem, with as much specificity as possible;

g. Device identification, including model and/or catalog number and lot number(s) and/or serial number(s);

h. Implantation date;

i. Was an explant reported? (binary yes/no);

j. If explanted, the explantation date;

k. If explanted, the time to removal from implantation (days);

l. If not explanted, the time to event from implantation (days);

m. Was a pregnancy reported? (binary yes/no);

n. Was a pregnancy loss reported? (binary yes/no);

o. Was a live birth reported? (binary yes/no);

p. Was an ectopic pregnancy reported? (binary yes/no);

q. Was an elective termination of pregnancy reported? (binary yes/no);

r. Was a death reported? (binary yes/no);

s. If there was a death report, specification of adult death vs. pregnancy loss vs. death of infant after birth;

t. If an explant was reported, was the reason/s for removal reported? (binary yes/no); was information regarding patient outcomes reported? (binary yes/no); was any complication/s related to device removal reported? (binary yes/no);

u. Date event was posted to social media;

v. Date event was reported to FDA;

w. Summary of device evaluation by manufacturer;

x. Device and patient problem codes. Enter the evaluation code(s) for the categories of method, results, and conclusions. Enter a conclusion code(s) even if the device was not evaluated. For all patient and device problem codes, include descriptor of code in addition to code;

y. If remedial action initiated; and

z. If any action was reported to FDA under 21 USC 360i(f), the correction/removal reporting number.

To facilitate tracking of the line-item tabular data spreadsheets, submit them to FDA as reports to PMA P020014. These spreadsheets will be made publicly available by FDA.

4. The FDA Form 3500A shall reference the events identified in the line-item tabular data spreadsheet for the previous period of one month and shall include the following information in Section H10 (Additional Manufacturer Narrative) of the form:

a. total number of events by report type (i.e., death, serious injury and malfunction) and patient or device problem code;

b. averages of patient demographics, including the average age of the patient population that were the subject of the events being summarized;

c. report source;

d. entities submitting events; and

e. device(s) involved.

For each Form 3500A you submit as part of this condition, you must include the variance number (E2020002) and a reference in Section H10 (Additional Manufacturer Narrative) to where the related line-item tabular data spreadsheet can be found on FDA.gov. Prior to submission of the first Form 3500A, please work interactively with FDA to determine the appropriate reference.

5. The quarterly adverse event analysis report shall include an analysis of the line-item tabular data spreadsheets for that quarter as well as cumulatively, and the final adverse event analysis report shall include an analysis of all adverse event information submitted as part of this variance. At a minimum, the adverse event analysis reports shall include the following:

a. Comprehensive analysis of the information described in item 4 above, including the following:

i. Synopsis of the nature of the events being reported, including the types of events (death, serious injury, or malfunction) and the specific patient or device problems identified.

ii. Analysis of the information, including whether the events have been reported through other means, whether the events are consistent with expected outcomes, the investigations that you have completed related to these events or that are in-process, the corrective actions that you have implemented related to these events or that are in-process, and any additional information that would be helpful in understanding how you addressed or plan to address the events summarized in the analysis;

b. The number of devices that were returned to you, if any, for evaluation. If available, provide a summary of the results of your investigation for the returned devices, including a discussion of any related corrective actions taken or an explanation of why corrective action was not taken; and

c. Presentation of event trends by event type and problem in a comparative graphical display (e.g., bar graph). In the first quarterly adverse event analysis report, provide a comparison of trends for the events reported under this variance to trends for all other Medical Device Reports (MDRs) for Essure. Thereafter, the quarterly adverse event analysis reports must provide a comparison of trends for events reported under this variance during the most recent quarter to trends for cumulative reported events for Essure. The final adverse event analysis report must provide a comparison of trends for all events reported under this variance to trends for all other MDRs for Essure.

To facilitate tracking of the adverse event analysis reports, submit them to FDA as reports to PMA P020014. In addition, you stated during a (b)(4) teleconference with FDA that Bayer intends to make each adverse event analysis report (quarterly and final) publicly available. We recognize that there could be portions of an analysis report that may not be appropriate to make public, such as if the report included information that would identify an individual who reported experiencing an adverse event.

6. If your firm wishes to request a modification of the terms of this variance, including an extension of the time it is in effect, or to end the variance and resume reporting for this information in accordance with the regular reporting requirements in 21 CFR Part 803, your firm must submit such a request in writing as a report to the PMA. We will then issue follow-up correspondence indicating our decision regarding this request.

Should FDA revoke or modify the conditions of this variance as described in 21 CFR 803.19(d), we will notify you in writing. If you have any questions regarding this variance, please contact (b)(4) by telephone at (b)(4), or by email at (b)(4).

Sincerely yours,

CAPT Sean M. Boyd, MPH, USPHS
Director
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health