From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: RE: Draft Essure Wording [SEC=UNCLASSIFIED]
Date: Monday, 23 November 2015 4:12:24 PM

Hi [redacted]

Thanks for sending me the statement for IRIS reports.

I have suggested a couple of changes:

Strikethrough – I have suggested that these sentences are removed because it relates to unfinished work that we not yet able to articulate because the investigation by FDA and us to a small extent is ongoing. We also still considering ACSMD advice and as the sponsor has not been approached yet about any advice it is probably a bit premature to put it into our closing statement.

Additions – just preferences to appease me.

Regards
[redacted]

[redacted]
Director, Device Vigilance and Monitoring Section (DVM)
Medical Devices Branch (MDB)
Therapeutic Goods Administration

PO Box 100
Woden
ACT 2606

[redacted]

From: [redacted]
Sent: Monday, 23 November 2015 3:41 PM
To: [redacted]
Cc: [redacted]
Subject: Draft Essure Wording [SEC=UNCLASSIFIED]

Dear [redacted]
Please see the draft Essure wording below.

I will make any changes/amendments and send around a final version.
Warm Regards,
[redacted]

Thank you for your report regarding the Essure device. ~~Adverse event reports related to the Essure device are of particular interest to the TGA as this device is currently part of ongoing monitoring by the Post-Market Device Vigilance and Monitoring Team of the TGA.~~

Although individual adverse event reports may not be formally investigated, all reports are reviewed, recorded and contribute to the ongoing monitoring of this device. The majority of reports received for any device are known complications in most instances. However collectively, the rates and types of these adverse events may require further investigation.

Recently due to the TGA's concern regarding the number and types of adverse events being reported and the international and local attention this device has received, the TGA referred the device to the Advisory Committee on the Safety of Medical Device (ACSMD) for expert clinical ~~specialist~~ opinion ~~on the 26th of August 2015~~. After reviewing the issues and adverse event reports received by the TGA, it was decided~~termined~~ that there is insufficient evidence at this stage to identify a clear safety signal for the device. The majority of adverse event reports, of which there are very few, are for common and known adverse events that are noted in the device's Instruction For Use document. There have been some reports of more unusual adverse events including fatigue, weight gain, headache, nausea and alopecia. The Committee found that these unusual adverse events were few in number and describe a broad range of generalised symptoms that are difficult to define as being specifically related to the Essure device. As such, the committee agreed that there was no obvious link between the underlying performance of the device and the number and types of adverse events reported at this time.

Currently, the TGA is gathering all adverse events related to the Essure device to add to our understanding of the safety and performance of the device. ~~The TGA is also considering other regulatory actions to contribute to the ongoing monitoring processes, including potential further review by the ACSMD when more information becomes available. If this occurs, information will be posted on our website: http://www.tga.gov.au.~~

Thank you once again for your report.