

From: TGA Website [REDACTED]@tga.gov.au>
Sent: Wednesday, 30 August 2017 4:58 PM
Subject: RE: [93728] - FW: www.tga.gov.au web publishing request - Essure recall web statement [SEC=UNCLASSIFIED]

Hi [REDACTED]

The alert, Essure contraceptive device, has been published.
<https://www.tga.gov.au/alert/essure-contraceptive-device>

Kind regards
[REDACTED]

From: [REDACTED] On Behalf Of PSAB Communications
Sent: Wednesday, 30 August 2017 1:48 PM
To: [REDACTED]
Cc: PSAB Communications; [REDACTED] Recalls [REDACTED] TGA Website; TGA Info; HPRG
Parliamentary; News
Subject: [93728] - FW: www.tga.gov.au web publishing request - Essure recall web statement [SEC=UNCLASSIFIED]
Importance: High

Hi [REDACTED]

Please find attached for your review a web statement regarding Essure contraceptive devices.

If you are happy with it, please forward the final version to tga.website@tga.gov.au indicating your approval.

Please find the usual wording below.

To TGA Website,

Approval under subsection 61 (7) of the Therapeutic Goods Act 1989

Under subsection 61(7) of the Therapeutic Goods Act 1989, the delegate of the Secretary may release to the public therapeutic goods information where release is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for withdrawal of therapeutic goods from supply.

In relation to issues with Essure contraceptive device, I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under section 61(7) of the Act the release to the public of the therapeutic goods information relating to these actions as set out below.

Cheers,

From: Forms and templates [<mailto:SharePoint.Admin@health.gov.au>]
Sent: Wednesday, 30 August 2017 1:46 PM
To: PSAB Communications
Subject: www.tga.gov.au web publishing request - Essure recall web statement [SEC=UNCLASSIFIED]

Web Publishing Request

Instructions

You have been sent this email because [REDACTED] requested you review it before forwarding it to the approving officer.

Please review the information in the form, add any attachments required and forward this email to the appropriate approving officer. The approving officer must then send the email on to tga.website@tga.gov.au indicating approval

If you have any questions or need to make changes to the request, please email tga.website@health.gov.au.

Section 61 approval required

This request includes a section 61 publishing request. Under section 61 you must give **explicit authorisation** for the publication of this information. Please use the standard words below:

I, [insert name, insert work title], am a delegate of the Secretary under section 61 of the *Therapeutic Goods Act 1989* (the Act). As a delegate, I have decided to release the therapeutic goods information contained in the following attached document(s) for Internet publication to the public acting under [insert subsection, e.g., 61(5A), 61(5C) or 61(7)] of the Act.

Please ensure your email includes your electronic signature block.

Request details

Website to update: www.tga.gov.au

Description of job: Please find attached a web statement regarding Essure contraceptive device to go in the 'Safety information - Alerts' section of the website.

Please note the requests for links and hover text in comments.

Existing pages to be updated: none

Source documents to be approved: D17-630573

Date to upload: Standard timeframe

Public consultation: No

Title length declaration: I understand that web page titles can be no longer than 70 characters (including spaces) and if any of my titles are

longer than this the information will not be published until the title length is reduced.

Style manual declaration: I accept that minor changes (grammar, spelling, formatting) will be made if the content does not meet the standard requirements.

Review declaration: I am aware that content must be reviewed in accordance with the web content review requirements.

Add to news on homepage: Yes

News text:

Hazard alert - labelling update relating to potential risks

Requestor's details

Full name: [REDACTED]

Email address: PSAB.Communications@tga.gov.au

TGA Area: **Division:** Medicines Regulation Division
Branch: Pharmacovigilance and Special Access Branch
Section: Technical and Safety Improvement

Approval

Approver name: [REDACTED]

Position: [REDACTED]

Message to approver:

Section s.61 approval required: Yes