Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File No: 2012/021025

[redacted]
Eska Australia
72 South Street
Rydalmere NSW 2116

Dear [redacted],

DEVICE INCIDENT REPORT DIR 28523 - ARTG # 118430 - Prosthesis, internal, joint, hip, resurfacing

Request for information under the authority of Section 41JA of the Therapeutic Goods Act

You were sent a letter dated 26/09/2012 requesting information about the device included under ARTG number 118430. According to our records, TGA has not received a reply to that letter.

I am writing to you to request information about a hip prosthesis. For the purposes of this request I am the Delegate of the Secretary with authority to request this information under Section 41JA of the *Therapeutic Goods Act 1989*. The information is required for the purposes of the investigation of the above incident report.

You are hereby requested to provide the required information, including details of any action you have taken in relation to this matter.

The requested documents must be provided in 10 working days from the date of this letter.

Address for sending the requested information

Electronic submission of all information is preferred. The requested information should be sent to [redacted] via:

- Email to iris@tga.gov.au
- fax to 02 6203 1713; or
- post to
  IRIS
  Device Vigilance & Monitoring
  Office of Product Review
  Therapeutic Goods Administration
  PO Box 100
  WODEN ACT 2606

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 1800 809 361 Facsimile: 02 6203 1713

If you have concerns with this request for information, you are encouraged to discuss the matter with the TGA prior to lodging an appeal. You should contact Ms Pam Carter, Director, Device Vigilance & Monitoring, OPR, TGA, email Pamela.carter@tga.gov.au.

Should you wish to appeal against my decision to seek information about the hip prosthesis, your appeal rights are outlined in Attachment A.

Please note that failure to comply with this request for information may attract a range of sanctions. These are outlined in Attachment B.

Please contact the undersigned on (02) 6232 8695 and iris@tga.gov.au if any aspect of this request for information requires clarification.

Yours sincerely,

[redacted]
Delegate of the Secretary
Database & Coordination Section
Office of Product Review
TGA

16/10/2012

ATTACHMENT A

Section 41JA Appeal Provisions

Formal Arrangements

Reconsideration by the Minister
The decision to request this information is an "initial decision" within the meaning of Section 60 of the Act. This means that if you are a person whose interests are affected by this decision, and you wish to appeal against this decision, you may do so in writing to the Minister under Section 60 of the Act. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

Parliamentary Secretary to
the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed:

"APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989"

In accordance with the Act the Minister may delegate the power to consider an appeal. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may apply to the Administrative Appeals Tribunal for a review of the Minister's/Delegate's decision.

ATTACHMENT B

Penalties for non-compliance with this request under Section 8 of the Act

Failure to comply with request for information under Section 8 of the Act is a strict liability offence and can attract a maximum penalty of 60 penalty points and is not subject to a Ministerial review under Section 60 of the Act.

Failure to comply with this request under Section 41JA of the Act

Failure to comply with a notice issued under Section 41JA of the Act constitutes an offence under section 41JB (3) of the Act with a maximum penalty of 500 penalty points. Failure to comply with this notice might also lead to cancellation of the medical device/s from the ARTG.

Providing false or misleading information may attract criminal and civil penalties. The criminal penalties are set out in subsections 41JB (4) to 41JB (7) of the Act.

It is a three tiered offence regime:

- Subsection 41JB (4) of the Act attracts a maximum penalty of 5 years imprisonment and/or 4,000 penalty units where a person gives false or misleading information in response to a section 41JA notice, and use of the medical device has resulted in, will result in, or would result in harm or injury to any person;

- Subsection 41JB(5) of the Act is a strict liability offence that attracts a maximum penalty of 2,000 penalty units where a person gives false or misleading information in response to a section 41JA notice, and harm or injury would be likely to occur to any person if that kind of medical device were used; and

- Subsection 41JB (7) of the Act attracts a maximum penalty of 12 months imprisonment and/or 1,000 penalty units where a person gives false or misleading information in purported compliance with a section 41JA notice.

The civil penalties for giving false or misleading information in purported compliance with a notice are set out in section 41JBA of the Act. The maximum penalties under this section are 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.