

Email Message

From: [REDACTED]@tga.gov.au
 To: [REDACTED]
 Cc:
 Sent: 6/03/2012 at 4:09 PM
 Received:
 Subject: RE: Additional information regarding PIP implants (DIR 25692)
 [SEC=UNCLASSIFIED]

The implants we are referring to are for Device Incident Report 25692. The details of the implants are:

Model IMGHC-TX-H
 Batch # 38206 (Left) 34606 (Right)
 Serial # 003 (Left) 128 (Right)
 Implant date 21/05/2008

Hope this helps

Kind Regards

[REDACTED]
 | Departmental Officer Post Market Reviews | Signal Investigation Unit
 Devices |
 | Office of Product Review | Therapeutic Goods Administration [REDACTED]

From: [REDACTED]
 To: [REDACTED]@tga.gov.au
 Date: 06/03/2012 04:04 PM
 Subject: RE: Additional information regarding PIP implants (DIR 25962)
 [SEC=UNCLASSIFIED]

Just to make sure we are talking about the same implants, do you have the references of the implants we are talking about as we sent you a few ?

Regards

[REDACTED]
 To: [REDACTED]
 CC: [REDACTED]@tga.gov.au; [REDACTED]@tga.gov.au; [REDACTED]@tga.gov.au;
 [REDACTED]@tga.gov.au
 Subject: Additional information regarding PIP implants (DIR 25962)
 [SEC=UNCLASSIFIED]
 From: [REDACTED]@tga.gov.au
 Date: Tue, 6 Mar 2012 15:59:44 +1100

Dear [REDACTED]

Thank you for your time on the telephone this afternoon. As we discussed the

implants you have provided from [REDACTED] have been examined by our laboratory staff and have identified that the gel inside the intact shell is of an unusual consistency.

As a result we would like to ask for some more information regarding this case to help in our investigations. If a response to the following questions could be provided by COB on Thursday 8 March that would be greatly appreciated.

What was the primary reason for removal of the implants?
Was any imaging (Ultrasound or MRI) performed prior to explantation? If so please provide results. Was there any evidence of gel bleed from the intact implants at the time of explantation? At the time of removal were there any immediately local or more remote unusual or abnormal clinical findings in this patient? Is there any other clinical information you can provide on this patient that you feel is relevant? (eg systemic illness, injury to breast etc)

Thank you for your ongoing assistance with this investigation. The TGA values your assistance.

If you have any questions regarding this request feel free to contact me.

Kind Regards

[REDACTED]
| Departmental Officer Post Market Reviews | Signal Investigation Unit
Devices | | Office of Product Review | Therapeutic Goods Administration [REDACTED]
[REDACTED]

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