

Date: 30/11/2021

From: [REDACTED]

To: [REDACTED]

cc: [REDACTED]

[REDACTED]@bbbraun.com>

bcc

Subject: UPD [REDACTED] er information request MHRA

Ref: [REDACTED]

-----Original Message-----

From: [REDACTED]

Sent: 30 November 2021 13:06

To: [REDACTED]

Cc: [REDACTED]; [REDACTED]

[REDACTED]@bbbraun.com>

Subject: RE: FSN/FSCA Further information request MHRA Ref: [REDACTED]

Dear [REDACTED],

Thank you for your e mail.

Please find attached the reconciliation list for the Histoacryl recall. We are continuing to contact those customers who have not responded so far.

We confirm that in accordance with our responsibilities as manufacturer B. Braun sent the FSNs for Histoacryl to all our direct customers.

Our records show that Great Ormond Street Hospital purchased Histoacryl from NHS Supply Chain and did not purchase the product directly from B. Braun.

Here is a summary of the 3 FSNs related to curing of the glue issued by B. Braun with MHRA informed:

- 1) FSN issued on 8th March - all customers who received affected batches were contacted by B. Braun
- 2) FSN issued on 15th March - all customers who received affected batches were contacted by B. Braun
- 3) FSN issued on 27th April - all customers who purchased affected batches were contacted by B. Braun. This includes NHS Supply Chain who then contacted all their customers who purchased the product. Great Ormond Street Hospital purchased the product directly from NHS Supply Chain therefore they received the FSN from NHS Supply Chain and not directly from B. Braun.

BBraun has explained this matter to Great Ormond Street Hospital and we believe this question has now been answered.

In summary B. Braun informed our direct customers of the FSN in a timely manner and in accordance with our responsibilities as manufacturer.

Please let me know if you need any more information.

Kind Regards

[REDACTED]

[REDACTED]

[REDACTED]

Tel: [REDACTED]
Email : [REDACTED]

B. Braun Medical Ltd, Brookdale Road, Sheffield, S35 2PW.

We believe in improving people's health through everything we do. Through constructive dialogue, B. Braun develops high quality product systems and services that are both evolving and progressive. B. Braun is one of the world's leading manufacturers of medical devices, pharmaceutical products and services.
B. Braun - Sharing Expertise

-----Original Message-----

From: [REDACTED]
Sent: 23 November 2021 14:44
To: [REDACTED]
Cc: [REDACTED]; [REDACTED]@bbbraun.com>

Subject: FSN/FSCA Further information request MHRA Ref: [REDACTED]
Importance: High

Dear B. Braun,

Regarding the FSN/FSCA we have still not received a response to outstanding request for further information.

Please could you provide an update of the number of total acknowledgements to date.

I have also received an email from Great Ormond Street Hospital regarding this FSN enquiry as to why they did not receive the alert from the manufacturer and patients were treated with faulty batches after the alert was issued. Please can you clarify as to why this hospital was not included in your customer list and did not receive the FSN?

Please be reminded that it is a requirement for the manufacturer to inform all customers of the FSN and coordinate with the competent authority where further clarification or information is required.

I look forward to your response by Friday 26th November.

Kind regards

[REDACTED]
Higher Medical Device Specialist
Medical Devices - Safety & Surveillance

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU Direct line: [REDACTED]
[REDACTED]

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Read our guidance on coronavirus (COVID-19)

MHRA launched a public consultation on future UK medical device regulations on 16 September 2021, which will close on 25 November 2021. Find out more here. The consultation documents can be found here.

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MHRA Ref: [REDACTED]
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Dear [REDACTED],

Regarding the FSN/FSCA we have still not received a response to the most recent email.

Please can you provide the requested further information and update outlined in the email below by Friday 5th November.

Kind regards

[REDACTED]
Higher Medical Device Specialist
Medical Devices - Safety & Surveillance

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU Direct line: [REDACTED]
[REDACTED]

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I look forward to your response by Tuesday 19th October.

[REDACTED]
Higher Medical Device Specialist
Medical Devices - Safety & Surveillance

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU Direct line: [REDACTED]
[REDACTED]

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Read our guidance on coronavirus (COVID-19)

MHRA launched a public consultation on future UK medical device regulations on 16 September 2021, which will close on 25 November 2021. Find out more here. The consultation documents can be found here.

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y awaiting acknowledgements from 7 customers on this.

The Reconciliation 22.04.2021 attached is for the third update to the recall. On this one we are currently awaiting 48 acknowledgements.

For both of these all customers have been chased today and have been given a deadline of the 16th July 2021 to respond to us. This is the fourth chase that has been completed for the recall.

We will provide you another update following the deadline of this chase.

Kind Regards

[REDACTED]
[REDACTED]
Regulatory Affairs & Quality Department

Tel: [REDACTED]

Email: [REDACTED]

Please note my normal working days are Thursday & Friday

B|BRAUN
B. Braun Medical Ltd, Brookdale Road, Sheffield, S35 2PW.

-----Original Message-----

From: [REDACTED]

Sent: 04 May 2021 15:34

To: [REDACTED]

Cc: aic@mhra.gov.uk

Subject: FW: FSN/FSCA First Reminder MHRA Ref: [REDACTED]

Dear [REDACTED],

Please see attached the updated risk assessment. An update for the corrective actions as follows:

Corrective Actions / Activities Update:

Currently, the investigation is focused in determining the fine tuning adjustment of the S02 concentration in the raw material, a task made in collaboration with the supplier that is performing their own investigation.

On the other hand, the optimal transport and storage conditions are being evaluated in order to assess the influence in the S02 equilibrium to avoid the modification of the usual polymerization profile.

Attached is a copy of the acknowledgements we have received to date.

We have provided a further update with additional batches at the end of April. We have therefore also attached for your information the list of acknowledgements that we have received to date from this additional update on the 22.04.2021.

Kind Regards

[REDACTED]
[REDACTED]
Regulatory Affairs & Quality Department

Tel: [REDACTED]

Email: [REDACTED]

Please note my normal working days are Thursday & Friday

B|BRAUN
B. Braun Medical Ltd, Brookdale Road, Sheffield, S35 2PW.

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-----Original Message-----

From: [REDACTED]
Sent: 22 April 2021 09:41
To: [REDACTED]
Subject: FSN/FSCA First Reminder MHRA Ref: [REDACTED]

22/04/2021

MHRA ref: [REDACTED] quote this in any reply
Your ref: [REDACTED]

To date we have not received your final report.

Why we're writing to you now

We need an update on acknowledgements and progress on any corrective action.

If you haven't already done so, please provide the information requested in our last email.

What you need to do now

Send us the information within 10 days of this email so we can decide whether to take further action.

You don't need to re-send copies of correspondence you have sent us previously.

Yours sincerely
Adverse Incidents & Communications Team
MHRA, Devices

Note

Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

You can access the Medical Device Safety Officer (MDSO) contact list via the Manufacturer Online Reporting Environment (MORE) in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO's organisation.

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[attachment "Reconciliation.xlsx" deleted by [REDACTED]/MHRA] [attachment "Reconciliation 22.04.2021.xlsx" deleted by [REDACTED]/MHRA]

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