Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]
Solicitor
[redacted]
By email: [redacted]

15 January 2024

Dear [redacted],

FOI 23/976

Thank you for your information request, dated **13 December 2023**, where you clarified the information required from your original request dated 6 December 2023. Your request is outlined below:

"*We are requesting a copy of any document between the Medicines and Healthcare Products Regulatory Agency and B. Braun Medial Ltd referencing Histoacryl between January 2021 and December 2021 including emails between the MHRA and B. Braun Medical as well as regulatory reports such as Incidents or Field Safety Corrective Actions provided by B Braun Medical in the relevant time period."*

The MHRA received a Field Safety Corrective Action and Field Safety Notification (FSN) related to Histoacryl in 2021. The FSN was subsequently updated twice to provide additional updates and the FSNs are publicly available on the MHRA website via the following link: https://www.gov.uk/drug-device-alerts/field-safety-notices-26-to-30-april-2021. In addition, the MHRA received 6 adverse incident reports related to Histoacryl in this time period.

Please find a copy of the reports referencing Histoacryl submitted to the MHRA by B.Braun in 2021. In addition, please find attached all correspondence regarding Histoacryl between B. Braun and the MHRA sent and received between January 2021 and December 2021. A list of documents can be found in Annex 1. Please note that there is some information within the provided documents which we consider to be exempt and has been redacted.

Medicines & Healthcare products
Regulatory Agency

The redactions we have applied are under the following exemptions:

- Section 40(2) of the Freedom of Information Act. The redacted information is personal data (such as names of members of staff), and it's disclosure would lead to the identification of individuals.

- Section 43(2) Section 43(2) (Commercial interests) of the Freedom of Information (FOI) Act. Section 43 is a conditional exemption and requires a consideration of the public interest. The redacted information refers to customer lists and we have considered the public interest and cannot see any overriding public interest argument in releasing information into the public domain that may be of interest to competitors and could cause commercial harm to B.Braun. Please note that in line with the guidance from the Information Commissioner's Office (ICO) we consider a response or disclosure under FOI to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team
Safety & Surveillance
Medicines & Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London, E14 4PU

Medicines & Healthcare products Regulatory Agency

FOI 23/976 Annex 1

Documents Attached

1	Additional standard Annex 7 information sent 09.04.2021	27	Email dated 30.11.2021
2	Declaration of HHE_Histoacryl FSCA 04.05.2021	28	Follow-up 2 FSCA Histoacryl _lack of adhesivestrengeth
3	Declaration of HHE_Histoacryl FSCA sent 09.04.2021	29	Follow-up FSCA report
4	Email dated 02.07.2021	30	FSN 27.04.2021
5	Email dated 21.10.2021	31	Incident PDF1
6	Email dated 03.11.2021	32	Incident PDF2
7	Email dated 08.04.2021	33	Incident PDF3
8	Email dated 08.10.2021 acknowledgment	34	Incident PDF4
9	Email dated 08.10.2021 acknowledgment 2	35	Incident PDF5
10	Email dated 08.10.2021	36	Incident report 6 Final MIR
11	Email dated 09.04.2021	37	Initial FSCA Report
12	Email dated 12.10.2021	38	MHRA update 30.11.2021 full reconciliation
13	Email dated 12.11.2021	39	MHRA update 30.11.2021 non-affected customers
14	Email dated 14.10.2021	40	MHRA update 30.11.2021 not affected stock returned
15	Email dated 15.12.2021	41	Reconciliation 04.05.2021
16	Email dated 18.03.2021	42	Reconciliation as of 02.07.2021 first FSNs acks not customers
17	Email dated 22.04.2021	43	Reconciliation as of 02.07.2021 first FSNs
18	Email dated 23.11.2021	44	Reconciliation 22.04.2021 as of 02.07.2021 acks not customers
19	Email dated 23.11.2021 re reconciliation	45	Reconciliation 22.04.2021 as of 02.07.2021 customers no email
20	Email dated 25.08.2021 initial email	46	Reconciliation 22.04.2021 as of 02.07.2021 customers
21	Email dated 25.08.2021	47	Reconciliation information 09.04.2021
22	Email dated 28.04.2021	48	Reconciliation 22.04.2021
23	Email dated 28.10.2021 acknowledgement	49	Reconciliation 22.04.2021 tab 2
24	Email dated 28.10.2021 acknowledgement 2	50	UK Customer letter FSN 08.03.2021

26	Email dated 28.10.2021 acknowledgement 3	51	Updated UK Customer Letter FSN 15.03.2021
26	Email dated 29.07.2021		