

FOI 22/1110 – Fresenius

MHRA RESPONSE

1 February 2023

Dear

Thank you for your email of 31 October, which we are handling under the Freedom of Information Act. Please accept our sincere apologies that this reply has taken longer than the 20 days required by the Act.

We've included your original request in below, to which we have added our responses in blue text beneath each section.

Please could you provide us with the following in relation to the above:

- A list of enforcements or any knowledge of the MHRA where Fresenius Kabi/Calea have:

Supplied medication containing Insulin by error, when the medication should not contain Insulin

We have not received any reports of non-insulin medication containing insulin.

Supplied Insulin medication without Insulin being contained within

Yes. There was a successful MHRA prosecution in relation to such a case in 2010. See the following link [Fresenius Kabi fined £500,000 after patient death \(outsourcing-pharma.com\)](#)

Any errors at all with the production/supply of TPN (Total Parenteral Nutrition) including but not limited to:

Wrongly contained medication

0 reports received

Wrongly containing insulin

0 reports received

Wrongly measured contents i.e. contents in wrong strength

1 report received

Any other errors in the knowledge of the MHRA specifically related to TPN bags

Please see the table below for a breakdown of reports received:

Contamination – Micro	3
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Contamination – Other	3
Contamination – other particulates	2
Device Failure	1
Fill volume incorrect	2
GMP Failures	4
Non-compliance to License (other)	1
Non-Compliance to Product Spec – Analytical	2
Non-Compliance to Product Spec – Stability	4
Other	8
Packaging - Carton – artwork error	2
Packaging - Container/primary pack defect	5
Packaging - Label – artwork error	2
Packaging - Label – Wrong product	2
Packaging – Other	8
Precipitation	1

Any recall of TPN bags by Fresenius Kabi/Calea and if recalled, for what reason

Any recalls we issue, including company-led recalls are published on our website at the link below. We have included the search term 'Fresenius' to give you a filtered set of results:

[fresenius - Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/alerts?search=fresenius)

Any supply of medication which contained contents/medication which ought not to have been present

Can you please confirm if you are referring to:

- Any initial reports we have received, before any root cause analysis has confirmed any form of contamination.
- Reports we have received for which a root cause analysis has identified contamination.
- Both of the above
- Or something else – please let share further details by reply if so

Any knowledge as to employees of Fresenius Kabi/Calea deliberately tampering with medication

We have not received any reports of such activity.

Details of any fines or disciplinary action which has been taken against Kabi/Calea, or any of its employees by yourselves

In addition to the case referred to above, following identification of critical deficiencies at MHRA GMP inspections, Calea has been referred to MHRA's Inspection Action Group for oversight and in the most recent of these, in 2019, the company was brought into regulatory compliance at the end of 2020.

If you have a query about the information provided, please reply to this email

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

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. 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 ICO's address is:

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

Yours sincerely

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU