FOI 23/887

Dear

Thank you for your emails of 16 and 20 November 2023. In your email of 20 November 2023 you asked for:

> *Any information from the FOI regarding the enquiry would be incredibly helpful, particularly in terms of these aspects: whether the MHRA did seize and test products from Luscious Aesthetics, what the conclusion of this was, and whether the LuhiLuhi filler ever had a CE mark on and lost it or if it never had a CE mark in the first place.*

As you know, we have dealt with your request under the Freedom of Information Act (FOIA) because you have asked for recorded information. While we can confirm that MHRA hold information that is relevant to your request, we are not able to provide information about any investigation on this occasion.

Two exemptions apply in this case. These are section 30, which protects any information which relates to an investigation, and section 43, which applies when disclosure would be likely to cause prejudice to the commercial interests of any third party.

> Section 30 (1) states:
> 30 -(1) Information held by a public authority is exempt information if it has at any time been held by the authority for the purpose of -
> (a) any investigation which the public authority has a duty to conduct with a view to it being ascertained -
> (i) whether a person should be charged with an offence, or
> (ii) whether a person charged with an offence is guilty of it,
>
> Section 43(2) exempts information whose disclosure would, or would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity).

Sections 30 and 43 are qualified exemptions, which means that we have considered the public interest in releasing the information.

We do recognise that there is considerable interest in the work which we undertake to ensure that medical devices placed onto the UK market are compliant with the applicable regulations. That said, we do not consider that the public interest is best served by releasing information which could prejudice any potential legal action taken under the regulations described above that we may pursue.

We also consider that providing commercially sensitive information (for example technical documentation relating to a product) could prejudice the commercial interests of the organisation or individual that owns that documentation.

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:

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

Kind regards,

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