Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

08 December 2023

Dear [redacted]

FOI 23/873

Thank you for your correspondence dated 10 November 2023, where you submitted a refined request for information, following our response dated 10 November 2023 to FOI 23/781. Please find below, our responses to your queries.

MHRA response

1. **From the last two years please select three applications each one representing a mesilate-, tosylate- or besilate-salt API focusing on any applications that mention *how* alkyl-sulfonate impurities might be formed (not just based on assumption/perception).**

Unfortunately, we estimate that compliance with this refined request would still exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000 and we are therefore refusing this part of the request.

In order to select the requested applications, would require us manually checking through the over 25 Marketing Authorisations that were referred to in our response dated 10 November 2023 to FOI 23/781; in this response we explained that conducting this manual check would exceed the appropriate costs limit under S.12 Freedom of Information Act 2000.

We would advise you to narrow this request and provide one or two specific Marketing Authorisation (MA) numbers as a refined request.

We appreciate that you do not want to miss valuable information by limiting the request to one or two MA numbers, but the appropriate limit is there to assist public authorities to

manage the burden of requests asking for large amounts of information in one go; however further MA numbers can be requested in future requests.

We would also like to re-iterate that detailed quality data (which includes detailed information concerning impurities associated with active pharmaceutical ingredients (APIs)) are likely to be considered and so may be exempt from release under Section 43 (Commercial Interests) of the FOI Act.

If you do submit a refined request, this will be a new request and the 20 working days statutory time limit will begin from the date your refined request is received.

2. **Training slide deck that deals with sulfonate salts**

In response to your request, please find attached selected slides that deal with sulphonate salts, taken from a larger MHRA training slide deck on impurities prepared in May 2019. Please note that as this training slide deck was prepared some time ago, the content may not be consistent with current knowledge.

3. **Update of minutes, correspondence, etc over the last two years regarding BPC deliberations on the BP production statement for sulfonate-salt APIs.**

This information has previously been provided on 17 October 2023, as part of the MHRA response to FOI 23/596 wherein you received BP Commission minutes and papers.

We trust that you will find this reply of use.

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 2 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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

or by writing to:

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

Yours sincerely,

HQA FOI Team

Email: FOILicensing@mhra.gov.uk