FOI 24/053

FOILicensing <FOILicensing@mhra.gov.uk>
Tue 13/02/2024 15:06
[redacted]

1 attachments (11 MB)
RE: Production Statement on Alkyl Mesilates in Mesilate-Salt Drug Substances;

Dear [redacted]

I am writing to you in response to your freedom of information request received on 16th January 2024 [our ref: 24/053].
Under the FOI Act, the Agency has 20 working days to provide a response, which is 13th February 2024.

In your request you asked;

"I wish to make a request for any and all information relating to the following statement in the November 2021 minutes of the BPC:

Continued use of Production statements After a wide-ranging discussion it was agreed that the current risk-based approach remained the best option available to control alkyl sulfonate ester impurities. Although the risk of the impurities being present was very low, they had been detected in some instances and the statements made it clear that testing was only required if a potential risk of their formation had been identified.

In particular I am interested to learn:

1. ***What information led BPC to reach this decision?***
2. ***Was information on the mechanism of alkyl-sulfonate formation taken into account?***
3. ***What factors are considered relevant to the "risk-based approach"? [Chemical mechanisms appear not to have been discussed.]***
4. ***The current BP Production Statement refers to alkyl sulfonates that are formed during sulfonate-salt synthesis. A particular case relates to mesilate salts where methyl methanesulfonate (MMS) is a common contaminant in the starting material methanesulfonic acid (MSA). What due diligence has been undertaken by BPC to verify the origin of any MMS detected in a mesilate salt."***

To answer your questions in order:

1. We wrote to you on 31st January 2022, and shared all the information considered by the BP Commission (BPC) at this specific (November 2021) meeting (please see attached email). We have also shared all the papers and minutes from other BPC and Expert Advisory Group MC1, MC2 and PCY meetings in response to your previous FOI requests (FOI 21/967, 23/596 and others). This is all the information that has been considered by the BPC.

2. Information on the mechanism was considered along with other information available to the BPC (you will note several of your papers were included in the BPC papers).

3. In our response to FOI 21/697, we have previously shared with you the EMA letter to manufacturers on risk assessments for mesilate containing medicinal products (https://www.ema.europa.eu/en/documents/other/request-assess-risk-occurrence-

contamination-mesilate-esters-and-related-compounds-pharmaceuticals_en.pdf). As we previously stated, the BPC has not set out any different expectations.

4. The BPC has considered a wide range of information, as described above, which has been shared with you. The BPC has not done specific work to verify the origin of any MMS detected.

You have made a number of FOI requests recently and over the last few years, and we have now shared all relevant information the BPC holds on this subject with you. Under the specific provisions of the FOI Act, the information you have requested is already available to you (section 21 of the FOI Act). Since all relevant information has been provided previously, we would ask you to consider any future requests carefully, in line with the ICO recommendation on requesting information (https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/). Please remember that FOI requests do cost public bodies time and money to respond to, and we have a duty to make sure that public money is spent responsibly, and in a way that allows us to allocate our resources across the wider range of interests represented by all our requesters. It is important that people do not submit repeated requests, ask for the same information more than once (unless it is likely to have changed a lot) or make requests as a way of pursuing a private interest through requests to a public body if they disagree with the body or think that the body has done something wrong.

The MHRA treats our responsibilities under the FOIA seriously and endeavours to answer all requests, however please do be aware that we may occasionally need to refuse repeated or disproportionately burdensome requests, in line with the ICO guidance.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision. 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 have a query about the information provided, please reply to this email.

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
Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/"

Yours sincerely,
FOI Team