

FW: FOI 23/994

FOILicensing <FOILicensing@mhra.gov.uk>

Mon 22/01/2024 17:09

To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; FOILicensing <FOILicensing@mhra.gov.uk>

Cc: [REDACTED]

📎 5 attachments (391 KB)

Type1PostInspectionLetter_Insp GMP_IMP 4_3848-0042 redacted fixed.pdf; Type1PostInspectionLetter_Insp GMP_GDP 13606_4119-0023 redacted fixed.pdf; Type1PostInspectionLetter_Insp GMP_IMP 18606_11099-0014 redacted fixed.pdf; Type1PostInspectionLetter_Insp IMP 19819_4680309-0004 redacted fixed.pdf; Type2PostInspectionLetter_Insp GMP 5866_19598555-0001 redacted fixed.pdf;

Hi all,

This one has gone out.

Many thanks,
[REDACTED]

From: FOILicensing <FOILicensing@mhra.gov.uk>

Sent: Monday, January 22, 2024 5:08 PM

To: [REDACTED]

Subject: FOI 23/994

Dear [REDACTED]

As requested under the Freedom of Information Act, please find enclosed five of the post-inspection letters that you have referred to.

Please note, in terms of your request for the post-inspection letter for S. Zhaveri Pharmakem PVT. Ltd (Insp GMP 51239/18780508-0003), I can confirm the MHRA will consider the release of the post-inspection letter for this site, in accordance with the Freedom of Information Act 2000. However, following your request we have identified that elements of the letter that we hold require input from the site inspector before it is closed out and finalised on our internal systems. Until finalised, we consider post-inspection letters to be commercially sensitive, and s43(2) applies.

Redactions have been made under the below Sections of the FOIA.

- Section 40 – This information contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.

- Section 43(2) – Release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests.

We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity) .

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at;
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow

Cheshire
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
FOI Team

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