


FOI 24/109

FOILicensing <FOILicensing@mhra.gov.uk>

Fri 01/03/2024 12:44

To

 2 attachments (93 KB)

GMPReport_Aeropak_Nov 2023 redacted fixed.pdf; GMPReport_Stallion_Dec 2023 redacted fixed.pdf;

Dear 

As requested under the Freedom of Information Act, please find enclosed the following GMP inspection reports (Sections A and D):

- Aeropak Chemical Products Limited - Date of Inspection: 28/11/2023
- Stallion Laboratories PVT. Ltd - Date of Inspection: 14/12/2023

You will see that some information has been redacted. The relevant sections of the Freedom of Information Act are:

- 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 – 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