

Medicines & Healthcare products Regulatory Agency

> 10 South Colonnade Canary Wharf London E14 4PU United Kingdom gov.uk/mhra

30 May 2024

MHRA reference: FOI2024/00081

Dear

Thank you for your information request, which we received on 30 April 2024. You asked for:

Please provide the post inspection letters related to the following inspections:

* Sterling Pharma Solutions Limited on June 9, 2021, located in Dudley Lane, Dudley, Cramlington, NE23 7QG, United Kingdom (Insp GMP 29350/292119-0006) * Almac Clinical Services Limited on September 1, 2021, located in Seagoe Industrial Estate, 9 Charlestown Road, Craigavon, BT63 5PW, United Kingdom (Insp GMP/IMP 20377/13423-0029)

* Glaxosmithkline Research & Development on October 31, 2023, located in Ware, SG12 0GX, United Kingdom (Insp GMP/IMP 5866/27277-0036)

* Cipla Limited (UNIT V) on June 19, 2023, located in Unit V, Plot No L-139, S-103 & M-62, Verna Industrial Estate, Verna, IN-403 722, India (Insp GMP 14694/1071938-0005)

* DSM Nutritional Products (UK) Limited on November 15, 2023, located in Drakemyre, Dalry, KA24 5JJ, United Kingdom (Insp GMP 19108/29211-0007)

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for. In response to your request, we are providing the available inspection reports for the inspections that you referred to.



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We consider that some information is exempt from disclosure. Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

Redactions have been made under the following 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).

This concludes our response to your request.

If you have a query about this response, please contact us at <u>foi.request@mhra.gov.uk</u>

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: <u>foi.request@mhra.gov.uk</u>

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: <a href="https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-c

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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