Medicines & Healthcare products
Regulatory Agency

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[redacted]

14 December 2023

Dear [redacted]

FOI 23/800:

Thank you for your email, dated 20 October 2023, in which you requested the associated Quality Overall Summary (Module 2.3), Clinical Overview (Module 2.5) and Clinical Summary (Module 2.7) for Beclu 100 micrograms per actuation pressurised inhalation solution (PL 35507/0206) and Beclu 200 micrograms per actuation pressurised inhalation solution (PL 35507/0207).

In response to your request, please find attached the Clinical Overview (Module 2.3) and Clinical Summary section (Module 2.7) submitted to support the initial application for Beclu 100 micrograms per actuation pressurised inhalation solution (PL 35507/0206) and Beclu 200 micrograms per actuation pressurised inhalation solution (PL 35507/0207). The documentation has been redacted under Section 40 (Personal information), Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information (FOI) Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption, and no consideration of the public interest is required.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case,

release of information would enable the competitors to overcome several regulatory hurdles in the research and development of their own products. 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. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

The Quality Overall Summary is being withheld under Section 41 (Information given in Confidence) and Section 43 (Commercial interests) of the FOI Act, as this information is considered commercially confidential.

As stated above, Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

Section 43 (Commercial interests) applies to the Quality Overall Summary as the release of the information would, or would be likely to, cause harm to the third party's commercial interests. We consider that the public interest in releasing the information does not outweigh 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).

As non-confidential parts of the Quality Overall Summary are published in the Summary of Product Characteristics (SmPC) and Public Assessment Report, we are also applying Section 21 (Information accessible by other means). Please note that the FOI Act's Section 21 exemption states that there is no right of access to information via FOI if it is reasonably available to the applicant by another route. The SmPC and Public Assessment Reports for Beclu 100 micrograms per actuation pressurised inhalation solution (PL 35507/0206) and Beclu 200 micrograms per actuation pressurised inhalation solution (PL 35507/0207) are published on our website and accessible via the below electronic link: https://products.mhra.gov.uk/.

We now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email address listed below.

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, quoting reference FOI 23/800.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Licensing Team
Email: FOILicensing@mhra.gov.uk