



Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[Redacted]

[Redacted]

12 February 2024

Dear [Redacted]

FOI 24/051

Thank you for your communication, dated 15 January 2024, in which you requested Module 2.4, Module 2.5 and Module 5.3.1 submitted for Sodium Bicarbonate 500 mg Capsules (PL 30464/0063).

A marketing authorisation for Sodium Bicarbonate 500 mg Capsules (PL 30464/0063) was granted to Athlone Pharmaceuticals Limited on 06 September 2012. Subsequent to a change of ownership procedure, the marketing authorisation was transferred to RelonChem Limited (PL 20395/0124) on 01 April 2014.

We are responding to your request by providing the attached Module 2.4 (Non-clinical overview) and Module 2.5 (Clinical overview) submitted to support the initial application for Sodium Bicarbonate 500 mg Capsules (PL 30464/0063), redacted under Section 40 (Personal information) of the 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.

Please note that a Module 5.3.1 (Bioequivalence study report(s)) was not submitted to support Sodium Bicarbonate 500 mg Capsules (PL 30464/0063) or Sodium Bicarbonate 500 mg Capsules (PL 20395/0124). No bioequivalence studies were required, and none were provided with these applications; a biowaiver was granted.

We trust that you will find this information of use. If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

or in writing to:

Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.

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