FOI 24/193 Request Authorisation for Beyfortus (nirsevimab) PLGB 17901/0370 PLGB 17901/0371

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Sat 23/03/2024 17:53

To [redacted]

1 attachments (204 KB)

Beyfortus nonclinical-overview.pdf;

Dear [redacted]

Thank you for your request for information dated 26 February 2024 where you requested information on Beyfortus:

> *'Please may you provide me with information relating to the Marketing Authorisation for Beyfortus (nirsevimab) PLGB 17901/0370 PLGB 17901/0371. According to the Public Assessment Report for this product:*
>
> *"IV Non-Clinical Aspects - MHRA considered that the non-clinical data submitted for these applications is satisfactory."*
>
> *1) Did the non-clinical data submitted include safety studies in animals?*
>
> *2) Did the non-clinical data submitted include safety studies in neonatal animals?*
>
> *3) Please supply information concerning safety studies in neonatal and other animals submitted and considered prior to granting the Marketing Authorisation"*

We confirm we hold the information related to your request, please find attached the non-clinical overview that was submitted prior to granting the marketing authorisation. In this summary, there is an overview of the non-clinical data including safety studies in animals.

We now consider this FOI request closed. However, 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 **FOI 24/193** 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,

HQA FOI team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Monday, February 26, 2024 1:33 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/193 Request Authorisation for Beyfortus (nirsevimab) PLGB 17901/0370 PLGB 17901/0371

I am writing to you under the Freedom of Information Act 2000 to request the following information from the Medicines & Healthcare products Regulatory Agency

Please may you provide me with information relating to the the Marketing Authorisation for Beyfortus (nirsevimab) PLGB 17901/0370 PLGB 17901/0371

According to the Public Assessment Report for this product:

"IV Non-Clinical Aspects

MHRA considered that the non-clinical data submitted for these applications is satisfactory."

1) Did the non-clinical data submitted include safety studies in animals?

2) Did the non-clinical data submitted include safety studies in neonatal animals?

3) Please supply information concerning safety studies in neonatal and other animals submitted and considered prior to granting the Marketing Authorisation

Please provide the information in email or similar format

If it is not possible to provide the information requested due to the information exceeding the cost of compliance limits identified in Section 12, please provide advice and assistance, under the Section 16 obligations of the Act, as to how I can refine my request.

If you can identify any ways that my request could be refined I would be grateful for any further advice and assistance.

If you have any queries please don’t hesitate to contact me via email and I will be very happy to clarify what I am asking for and discuss the request.

Thank you for your time and I look forward to your response.

Best wishes,

[redacted]