



Medicines & Healthcare products  
Regulatory Agency

MHRA Central Freedom of  
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[MHRA Website](#)

**Our Ref: FOI2026/00313**

**1 April 2026**

Dear 

Thank you for your Freedom of Information (Foi) request received on 20 March. You wrote:

*I would like the exact dates of these documents. When the studies were called for and when they took place. Thank you*

**MHRA Response**

We confirm that we hold the information you have requested. The study was requested by CHMP in June 2006, the Emotional Behaviour Study (dated August 2008) was submitted to MHRA on 29th August 2008, and the assessment report was dated September 2011.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

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**Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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