



Medicines & Healthcare products
Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](#)

Our Ref: **FOI2026/00129**
5 March 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 05 February 2026. You wrote:

I would like to see any and all information related to this study and it's endpoints specifically reduced behavioral reactivity and reproductive functional impairment.

All email correspondence between regulators and stakeholders or discussion with regulators regarding clinical relevance.

Here is the full study. Any information you have would be greatly appreciated.

"Beck MJ. 2004. A study in young CD(IGS) rats administered fluoxetine hydrochloride (LY110140) orally by gavage to evaluate general, reproductive and behavioral toxicity, study. Document ID WIL-353039. Eli Lilly and Company. Performing laboratory: WIL Research Laboratories."

MHRA Response

We can confirm we hold information requested relating to this study and subsequent variation to the product information of fluoxetine, but it is exempt from disclosure under section 12(1) of the Freedom of Information Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(1) of the Fol Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being our estimated time to identify, locate, retrieve, extract the information will exceed 24 hours. The MHRA holds information in a variety of databases which must be searched individually. A sampling exercise of archived emails from one assessor involved in the assessment of preclinical data identified 352 emails related to fluoxetine studies between 2006 and 2011. Reviewing 5 of

these emails to establish whether or not they were relevant to the Beck MJ. 2004 study took approximately 10 minutes, meaning locating, extracting and printing information from this single source would take over 11 hours.

Searches of emails held by two colleagues in Benefit Risk Evaluation who using "Beck" did not identify results. A search on "fluoxetine" identified 446 emails, the earliest was dated 2008. Similarly review of these emails took approximately 5 minutes to review 5 emails and therefore would take an estimated further 7 hours to review, extract and print.

A search of internal databases took approximately 2 hours and identified 118 folders relating to regulatory procedures for Prozac. This includes the variation approved in 2007 to amend the product information to add an indication for use in children and adolescents aged 8 years and above for moderate to severe major depressive episode. The Beck et al 2004 study as well as other studies formed the basis for this variation. This regulatory folder includes study reports from the marketing authorisation holder (MAH) and associated assessment reports, in relation to correspondence this is likely to be limited to correspondence between the MHRA and the MAH and possibly the European Medicines Agency. Review of the documents within the variation folder to identify and extract anything relevant to the Beck et al 2004 study is estimated to be in excess of 6 hours.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit:

Any and all information associated with the study is a very broad request and there are several aspects you may wish to consider when narrowing the focus of your request. These include:

- Defining whether there are particular stakeholder types that you are interested in.
- Defining the time period for your request (e.g, between publication date of the study in 2004 and variation approval in 2007).
- Clarifying the specific types of information you are interested in, such as assessment reports or correspondence.

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

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 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 Contact Information](#) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>