



Medicines & Healthcare products
Regulatory Agency

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[REDACTED]

27 December 2023

FOI 23/806

Dear [REDACTED]

Thank you for your information requests, dated 12th and 16th October 2023, in which you requested all study results for Debendox/Bendectin that were performed by Merrell Dow Pharmaceuticals in USA and UK that may be held by MHRA and CSM, amongst our electronic files.

We have considered the public interest in disclosure, and we are pleased to provide you with the information requested. We reviewed the 23 PDF electronic files held by the MHRA relating to Debendox and of these, 18 include information which is within the scope of your request. We have therefore provided these 18 files, with the names of those involved in the conduct of studies in animals redacted under section 40(2) of the FOIA.

For your information:

- Files 1-6 include results of embryotoxicity/teratogenicity studies with doxylamine in mice, largely in German with some pages in English;
- File 7 includes data from an 8-way Debendox study;
- Files 8-13 and 16-18 include results of embryotoxicity/teratogenicity studies with doxylamine in rats, largely in German with some pages in English;
- Files 14 and 15 include the final study report of the doxylamine 90 day subchronic study in B6c3f1 mice.

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If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review



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will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email

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 two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied 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 at:

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

Yours sincerely,

Safety and Surveillance