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

[redacted]

Our Refs:
FOI2024/00326
FOI2024/00327
FOI2024/00328
FOI2024/00329
FOI2024/00330
FOI2024/00331
FOI2024/00332
FOI2024/00333
FOI2024/00334

15 August 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) requests received on 19 July, numbered FOI2024/00326, FOI2024/0032, FOI2024/00328, FOI2024/00329, FOI2024/00330, FOI2024/00331, FOI2024/00332, FOI2024/00333, FOI2024/00334

Your requests

On the 19 July you wrote:

FOI2024/00326

This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **845350**, titled "4-Hydroxycoumarin: Assessment of Ready Biodegradability; Manometric Respirometry Test."

Study No. 845350 was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 21 October 2020 and concluding on or about 10 March 2021.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA's investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. 845350.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00327

This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **8461794**, titled "Reaction products of fatty acids, C18 (unsaturated) alkyl and epoxidized Fatty esters, with amines polyethylenepoly-, tetraethylenepentamine fraction: Assessment of Ready Biodegradability; Manometric Respirometry Test."

Study No. 8461794 was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 2 January 2021 and concluding on or about 7 October 2021.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA's investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. 8461794.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00328

This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **8478254**, titled "Phenol, polymer with formaldehyde, glycidyl ether polymers, with 1,2-cyclohexanediamine, TETA, and cycloaliphatic polyamine: Assessment of Ready Biodegradability; Closed Bottle Test."

Study No. 8478254 was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 20 July 2021 and concluding on or about 13 October 2021.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA's investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. 8478254.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00329

Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **BG92XJ**, titled "Phenol, polymer with formaldehyde, glycidyl ether polymers, with 1,2- cyclohexanediamine, TETA, and cycloaliphatic polyamine: Assessment of Ready Biodegradability; Closed Bottle Test" Study No. BG92XJ was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72

2GD, United Kingdom, starting on or about 26 February 2019 and concluding on or about 27 March 2019.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA’s investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. BG92XJ.

Please provide all materials related to this request within 20 working days from the MHRA’s receipt of the same.

On the 19 July you wrote:

FOI2024/00330

This FOI Request seeks information concerning the MHRA’s investigations of Labcorp Early Development Laboratories, Inc. (“Labcorp”), or its predecessors including Covance Laboratories Ltd. (“Covance”) and Envigo Research Ltd. (“Envigo”), or any of their affiliated entities, specifically relating to those entities’ compliance with or violations of the OECD’s Principles of Good Laboratory Practice (“GLP”) for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **BL11YK**, titled “APMMEA Assessment of Inherent Biodegradability: Modified Zahn-Wellens/EMPA Test.”

Study No. BL11YK was conducted under the supervision of [removed to protect personal information] at the Labcorp site located at Shardlow Business Park, London Road, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 5 March 2018 and concluding on or about 17 April 2018.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA’s investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. BL11YK.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00331

This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **BW24WM**, titled "JEFFTREAT XS 100: Assessment of Biodegradability in an Enhanced Test."

Study No. BW24WM was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA's investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. BW24WM.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00332

This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **CL58PM**, titled "BOPA: Assessment of Inherent Biodegradability; Modified Zahn-Wellens / EMPA Test." Study No. CL58PM was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 5 March 2018 and concluding on or about 17 April 2018.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA’s investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. CL58PM.

Please provide all materials related to this request within 20 working days from the MHRA’s receipt of the same.

On the 19 July you wrote:

FOI2024/00333

This FOI Request seeks information concerning the MHRA’s investigations of Labcorp Early Development Laboratories, Inc. (“Labcorp”), or its predecessors including Covance Laboratories Ltd. (“Covance”) and Envigo Research Ltd. (“Envigo”), or any of their affiliated entities, specifically relating to those entities’ compliance with or violations of the OECD’s Principles of Good Laboratory Practice (“GLP”) for testing and assessments of chemical substances.

This request specifically seeks information concerning Study No. **HM04SP**, titled “Jeffcat LE 30: Assessment of Inherent Biodegradability; Modified Zahn-Wellens / EMPA Test.”

Study No. HM04SP was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 5 March 2018 and concluding on or about 17 April 2018.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA’s investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. HM04SP.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

On the 19 July you wrote:

FOI2024/00334
This FOI Request seeks information concerning the MHRA's investigations of Labcorp Early Development Laboratories, Inc. ("Labcorp"), or its predecessors including Covance Laboratories Ltd. ("Covance") and Envigo Research Ltd. ("Envigo"), or any of their affiliated entities, specifically relating to those entities' compliance with or violations of the OECD's Principles of Good Laboratory Practice ("GLP") for testing and assessments of chemical substances.
This request specifically seeks information concerning Study No. **KP64DR**, titled "Tris(2-hydroxyethyl)methylammonium hydroxide CAS 33667-48-0: Assessment of Inherent Biodegradability; Modified Zahn-Wellens / EMPA Test."

Study No. KP64DR was conducted under the supervision of [removed to protect personal information] at the Labcorp site with the address of Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, United Kingdom, starting on or about 14 March 2018 and concluding on or about 17 April 2018.

Please provide electronic copies of all information related to MHRA's investigations concerning GLP compliance, the nature and extent of the non-compliance with GLP, any actions taken by MHRA in response to any finding of non-compliance with GLP, and all correspondence or reports related to this issue. To the extent MHRA's investigation into GLP also found non-compliance with other laws, regulations, principles, or practices governing laboratory testing or assessment of chemical substances, please provide that information as well.

If any of the requested information is exempt from disclosure, please provide a summary of the exempt information and the reasons for the exemption.

I have surveyed the MHRA's website for responses to previous FOI requests and determined that MHRA has neither previously published the requested information, nor previously responded to a FOI request concerning Study No. KP64DR.

Please provide all materials related to this request within 20 working days from the MHRA's receipt of the same.

MHRA Response
We can confirm that we hold the information falling within the description specified in your request.

Section 12(4) of the FoI Act and also the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 provides that requests can be aggregated for the purpose of estimating whether the cost limit applies, providing they relate to any extent to the same or similar information and the requests are received from the same individual or different persons who appear to the public authority to be acting in concert or in pursuance of a campaign.

This is where more than one request has been made within 60 consecutive working days relating to the same or similar information and the requests have been made by the same person [or separate persons acting in concert]. This includes adding to the estimated costs of complying with a later request, the cost of complying with a request that has already been answered. We have therefore aggregated the following requests under this provision:

We estimate that the cost of complying with your aggregated requests would exceed the appropriate limit for central Government, set by regulations at £600. 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(4) of the Freedom of Information Act the Agency is not therefore obliged to comply with your requests as we have aggregated the cost of processing them together and as such we will not be processing them any further.

The Agency is unable to provide any of the information you seek within the appropriate cost limit as you have asked for information that is contained across multiple sources including both physical (paper) records and electronic records which do not provide ready access to the study references which have been included with the requests. For context, there is a high volume of documentation and records gathered as part of inspections relating to the Test Facility included in the requests. For example, reviewing documentation of this nature to highlight specific references would be anticipated to take approximately 24 hours for physical records and further 128 hours for electronic records. This would exceed the costs limit of £600 set out in The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 and would take over 3 days to complete.

Under section 16 of the FoI Act we should help you narrow your requests so that they may fall beneath the cost limit. The following advice is to assist you in making a new, narrowed request for a smaller amount of information. In this case, we advise that you could narrow your request by restricting it to a particular inspection/investigation in a given time period and to its outcome or outputs.

We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit.

If you have any queries about this letter, please contact us quoting the reference numbers 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 FOI and EIR complaints 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/