FOI 24/010 re disclosure log request 10/233 and information

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

Mon 29/01/2024 17:33

FOI 24/010

Thank you for your request for information where you asked:

"Could I please request a copy of disclosure log request no. 10/233- A list of MHRA approved India manufacturers for primary packaging. Any updated lists of the same would be appreciated."

Your first question which related to the disclosure log was answered on 3 January 2024.

On the second aspect, "a list of MHRA approved India manufacturers for primary packaging. Any updated lists of the same would be appreciated".

We have interpreted your question in two ways:

- 1. The manufacturers of primary packaging, (based in India) that supply to manufacturers of medicinal products.
- 2. The manufacturers of medicinal products (based in India) that use primary packaging components.

The answers to both interpretations are thus:

- 1. We do not approve primary packaging component manufacturers, therefore, under Section 1(1)(a) of the FOIA we do not hold information on such approvals.
- 2. In accordance with section 21 of the FOI Act, we are not obliged to supply you with a copy of the requested information as it is already accessible to you elsewhere. Any site performing primary packing operations, that is inspected by MHRA, would be available on our database, see instructions below. Further, any site we have approved a Marketing Authorisation for a primary packing facility, would be available on their respective site i.e. EMA/Eudra.

MHRA website guidance/instructions

Please visit <u>GMP | MHRA</u>. Change the country to India, the results will populate with MHRA GMP certificated sites. Clicking on the certificate number to view the certificate, if the site is authorised for primary or secondary packaging this will be listed under part 1. 'Manufacturing Operations'. A sequential check of the pages of results can then be made to identify MHRA GMP certificated sites for primary packaging from the details on the certificates.

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HOME PIP PSUR	MHRA-GMDP ECIG	
MIA GMP WDA GDP	API REG	
Certificate Number	Search	
GMPC or Non Compliance	□ GMPC □ Non Compliant	
Site Name	Search	
Site Address	Search	
City	Search	
Postcode	Search	
Country	All Countries •	
Total Records 1 to 10 of 1636	All Countries United Kingdom United States India	

We trust that you will find this information of use. 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 above 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/

Or in writing to:

Information Commissioner's Office,

Wycliffe House,

Water Lane,

Wilmslow,

Cheshire,

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SK9 5AF

Yours sincerely,

HQA FOI Team

From:

Sent: Saturday, December 30, 2023 3:43 PM

To: MHRA Customer Services < MHRACustomerServices@mhra.gov.uk **Subject:** Disclosure request for FOI 10/233 - Disclosure log request

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Hello could I please request a copy of disclosure log request no. 10/233- A list of MHRA approved India manufacturers for primary packaging.

Any updated lists of the same would be appreciated.

Regards,

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