FOI 23/509

MHRA RESPONSE
26 JULY 2023

Dear

Thank you for your email.

> *"We would like to request a copy of the Public Assessment report (UK PAR) and information if its Initial application or MA transferred application of the following product under the Freedom of Information Act (FOIA) of MHRA:*
>
> *Product name:* ***Renvela® 800 mg film-coated tablets"***

There is no product called Renvela 800mg Film-Coated Tablets with an MA number PLGB 04424/0785.

There is Renvela 800mg Film-Coated Tablets (**PL 04425/0785**), which was authorised on 10 June 2009, following a positive decision from the European Commission (EC) to a centralised application (EMEA/H/C/000993). Further information, including the Public Assessment Report (PAR) for this product, is available from the European Medicines Agency (EMA) via the link below:
https://www.ema.europa.eu/en/medicines/human/EPAR/renvela

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre

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