FOI 23/333 - MHRA FOIA Request -Fludrocortisone Acetate 0.1 mg Tablets-Generics [UK]

REQUEST
08 May 2023

We would like to request for the Published Assessment report and information if its Initial application or MA transferred application of the following product under the Freedom of Information Act (FOIA):
Fludrocortisone Acetate 0.1 mg Tablets
Generics [UK] Ltd. t/a Mylan
PL 04569/1813

MHRA RESPONSE
19 May 2023

Dear

Thank you for your email.

Fludrocortisone Acetate 0.1 mg Tablets (PL 04569/1813) was authorised through a Change of Authorisation Holder (CoA) on 24 March 2020. The original product licence (PL 17299/0001) was authorised via a decentralised procedure with the UK as RMS (UK/H/6019/01/DC).

The link to the original PAR is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/a783260040d01a5e2ab4e8f068955ca5e494af7c

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
Communications and engagement team
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