30 January 2014

Re: FOI 14/004

Dear Mr Black,

Thank you for your communications of 3 January 2014, where you requested the specific clinical trials cited as evidence of efficacy for the granting of a licence for Ritalin for Attention-Deficit Hyperactivity Disorders (ADHD) symptoms.

Ritalin was granted a Marketing Authorisation to Ciba-Geigy PLC on 30 August 1988 (PL 00008/0205). A variation was submitted to update the therapeutic indications to include ADHD. This variation was approved on 28 January 1997 (PL 0008/0205-0002). On 15 January 1997, the Marketing Authorisation underwent a change of ownership from Ciba-Geigy PLC to Novartis Pharmaceuticals UK limited (PL 00101/0539), who is the current marketing authorisation holder for this product. You should also be aware that there are two Product Licences of Right for Ritalin Tablets (PLR 00008/5049) and Ritalin Ampoules (PLR 00008/5082). Product Licence of Rights are licences automatically given to products that were already marketed when the Medicines Act came into effect in 1970. These licences were subsequently cancelled.

We have searched our records for all of the above product licences and, unfortunately, are unable to obtain the information you requested. We have checked our records, and we do not appear to hold the information requested. We have exhausted all the usual avenues in our search - including a check in our archived paper records - for this information and must conclude that, it is no longer on our systems in a retrievable form.

In line with the National Archive (TNA) recommendation, the Agency policy is for a default retention period of 7 years for all Agency records except where there is a legal, regulatory or business requirement for a shorter or longer period. There are a variety of such exceptions in place which either set a shorter or longer retention period than the default 7 years. For example, ‘safety data’ is retained for 15 years. Therefore, it is very unlikely that information on licences granted more than 15 years ago will be held by the Agency

I now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email listed below.

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 2 months of the date of receipt of the response to your original letter and should be addressed to the Communications Directorate, 5th Floor, Medicines and Healthcare products Regulatory Agency, quoting reference FOI 14/004.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely,

The FOI Licensing Team
Email: FOILicensing@mhra.gsi.gov.uk

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