FOI 24/060

FOILicensing <FOILicensing@mhra.gov.uk>

Fri 21/06/2024 20:51

To:request-1073527-12058318@whatdotheyknow.com <request-1073527-12058318@whatdotheyknow.com>

Dear [redacted],

Many thanks for your request for information dated 19 January 2024, where you asked the following:

Up until 1995, melatonin supplements were available in health food shops, like in the US. But in 1995 MHRA changed this GSL status into POM.

Would it be possible to receive the assessment report that was the base for this decision.

Our response:

In the UK melatonin products are classed as medicines and require a marketing authorisation before they can be sold or supplied. Melatonin is a hormone produced by the pineal gland in the brain and which scientists believe acts as a timing device to synchronise the human body clock with the light/dark cycle. The Agency has previously determined that melatonin was a medicinal product on the basis of its known, significant pharmacological activity and its consequent effect on the human physiology. The agency's authority to make the determination was confirmed by the Court of Appeal (R. v. Medicines Control Agency ex parte Pharma Nord (UK) Limited 1998). The MHRA takes the view that a product with melatonin is a medicine requiring authorisation and there are licensed medicinal products available which can only be supplied by a registered pharmacist to fulfil a doctor's or dentist's prescription.

The European Commission granted a marketing authorisation valid throughout the European Union for Circadin (melatonin) to Neurim Pharmaceuticals EEC Limited on 29 June 2007. Prior to the authorisation of Circadin, melatonin was only available in the UK in unauthorised medicinal products, many of which were non-pharmaceutical grade products imported from the United States of America, where melatonin products are classed as supplements, not medicines.

We therefore do not hold an assessment report for the reclassification of melatonin from GSL to POM.

We now consider this request closed. 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/foi-and-eir-complaints/

or in writing to:

Information Commissioner's Office,

Wycliffe House,

Water Lane,

Wilmslow,

Cheshire,

SK9 5AF

Yours sincerely,

HQA FOI Team