FOI 23/642

Dear

Thank you for your request of 30 August 2023 under the Freedom of Information Act. You requested:

> *"Adex gel is "An easily absorbed, highly moisturising gel emollient with an **ancillary** anti-inflammatory **medicinal substance** to help reduce inflammation and redness." Adex gel contains 4% nicotinamide and is regulated as a Class 3 medical device.* ***This is to ask for information on the assessment process and its conclusions by which Adex gel was regulated as a Class 3 medical device by MHRA.***
>
> *Briefly, under MHRA rules, if a product has a therapeutic purpose, for example to reduce inflammation and redness, it may be classed as a Medicine or a Medical Device. The decision for which of these is most appropriate is made by consideration of the Principal Mode Of Action (PMOA). Mode(s) of Action may be defined as "the means by which a product achieves the intended therapeutic effect." For classification as a Medical Device, the PMOA must be achieved by physical, rather than pharmacological means.*
>
> *I would like to evaluate any information on MHRA files that describe the information or basis of decision relating to the conclusion that the PMOA of Adex was by physical means."*

We confirm that we do not hold this information.

Manufacturers establish the classification of their products and then follow the relevant conformity assessment route for that classification. You may wish to make further enquiries with the manufacturer in relation to this information, who has established the classification of their product in documentation provided to their Approved or Notified Body.

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 two months of the date you receive this response and addressed to: info@mhra.gov.uk
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
Medicines and Healthcare products Regulatory Agency
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