FOI 23/822

Dear

We note your FOI, requesting information from the MHRA.

The Derby-based business SureScreen Diagnostics Ltd. applied on on Sept. 23, 2021, to MHRA for an Exceptional Use Authorization for its product SARS-CoV-2 Antigen Rapid Test Cassette, SSDCOVID19AGVC. Please send me an electronic copy of this application, redacting from the disclosure any information that is protected by British law.

The product described in your request with name SARS-CoV-2 Antigen Rapid Test Cassette and code SSDCOVID19AGVC was not granted an Exceptional Use Authorisation. SureScreen Diagnostics Ltd was granted an Exceptional Use Authorisation with product code SSD-COVID19AGVCGS7 and product name SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab – Gold). Please advise the product for which you are seeking information.

Once your reply is given the request will be logged as a new request, and the 20-day FOI processing period will restart.

We look forward to hearing from you.

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely

MHRA Customer Experience Centre

Communications and engagement team Medicines and Healthcare products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU