

Official Information Act Request

Requester's details

Date: 2 June 2021

Name: [REDACTED]

Organisation: GE Free NZ

Email: [REDACTED]@gefree.org.nz

Reference number: ENQ-41539-R8X9F1

Tēnā koe [REDACTED]

Thank you for your request received on 17 May 2021 for the following information:

“Please could you provide me with the 6 month and 2019, 2020 June Annual reports relating to APP202854, as set out under Control 6 of the decision by Dr. Freeth on the 9 February 2018? Has this trial concluded? If so what date did it conclude? What was the outcome?”

APP202854 is an application to import for release Telomelysin¹ for use in a Phase 2 clinical trial for patients with stage IIIa and IV inoperable melanoma.

Control 6 in the decision document sets out the New Zealand sponsor must submit the first report to the Environmental Protection Authority (EPA) and the Ministry for Primary Industries six months after the commencement of the Phase 2 clinical trial. Once the first report has been submitted, further reports are required to be submitted on or before 30 June every year thereafter, until the Phase 2 clinical trial has concluded.

The Phase 2 clinical trial has not commenced, as a result the New Zealand sponsor has not submitted any reports and subsequently the EPA does not hold any information about your further questions.

Therefore, I am refusing your request under section 18(e) of the Official Information Act 1982 (OIA) as the information requested does not exist.

You have the right to seek an investigation and review by the Ombudsman of this decision. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz

¹ a human adenovirus that is genetically modified to replicate selectively in cancer cells

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz

We will publish your request and our response on our website, www.epa.govt.nz, within 10 working days from today. We make OIA responses available so others can read more about the work we do and the questions we are asked. Any information that might identify you will be removed to protect your privacy.

Nāku noa nā

A handwritten signature in blue ink that reads "SQuayle". The signature is written in a cursive, flowing style.

Siobhan Quayle
Group General Manager,
Regulatory Systems and Operations