

Official Information Act Request

Requester's details

Date: 17 January 2025

Name: Jon Muller

Organisation: GE Free NZ

Email: secretary@gefree.org.nz

Reference number: ENQ-48850-J4C6H8

Tēnā koe Jon,

I refer to the first request in your letter received on 8 December 2024, for information relating to APP203750:

“Re: APP203750 Chimaeric Antigen Receptor T-cells

1. When did the New Zealand sponsor notify the EPA of the start of APP203750 Phase 1 clinical trial?
2. What were the outcomes on the safety and efficacy of the clinical trial?
3. How many participants were involved in the APP203750 trial?
4. Has a written notification of the conclusion of the trials been received?
5. Has APP203750 been lawfully approved for use under the Medicines Act 1981. in New Zealand?
6. Please could we have the outcome of the trial,
 - a. any adverse effects?
 - b. Any deaths?
 - c. the level of drop outs?
 - d. Any transmission events documented?”

The Environmental Protection Authority (EPA) believes the information you have requested in questions two, three, five and six (a, b, c, & d) is held by MedSafe – Ministry of Health (MoH). Therefore, we have transferred these parts of your request to MoH under section 14(b)(i) of the Official Information Act 1982 (OIA).

Since making the transfer to MoH, we have noted a document on our website that covers aspects of questions two and six: [APP204765-Application-Attachment-1-ENABLE-Phase-1-Clinical-Trial-Summary.pdf](#). You will also hear further from MoH regarding questions two and six, as well as the other parts of your request transferred to them. MoH may be contacted on: mohoia@health.govt.nz

For questions one and four, the EPA was advised of the start of the trial under APP203750 on 2 October 2019 and advised of the end of the trial on 30 May 2024.

I hope this information is helpful. You have the right to seek an investigation and review by the Ombudsman of this decision under section 28(3) of the OIA. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz

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

We may publish your request and our response on our website, www.epa.govt.nz. 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 "Chris Hill".

Dr Christopher Hill

General Manager, Hazardous Substances and New Organisms