

10 April 2026

Erika Whittome

By email: fyi-request-34080-329a56f4@requests.fyi.org.nz
Ref: H2026080093

Tēnā koe Erika

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 14 March 2026 for:

A report from the Federal Drug Administration in the US is called "Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation - COVID19 CBER Plans for Monitoring Vaccine Safety and Effectiveness" which is published here:

www.fda.gov/media/143557/download

This is an FDA report that was prior to the 30 Dec 2020 New England Medical Journal article, Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine

Would you please share any meetings, minutes, emails, memos, reports etc about this report, especially when discussed by Medsafe, MAAC or any Ministry committees on the covid-19 vaccine from 22 Oct 2020 ?

Possible keyword searches would be:

"www.fda.gov/media/143557/download "

"CBER"

"Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation"

Medsafe does not have records relating to discussion or review of these documents. As such, your request is refused in full under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

For reference, Medsafe regulates medicines (including vaccines) ensuring they meet safety and efficacy standards, through evaluated evidence and pre and post market approval/monitoring, not unprocessed adverse event reports.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā



Chris James
Group Manager
Medsafe