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10 August 2021

Paul Jones

By email: fyi-request-16106-a0ab2715@requests.fyi.org.nz
Ref: H202108644

Dear Paul

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 (the Ministry) on 16 July for information regarding the Pfizer Comirnaty vaccine. Information in response to each part of your request is as follows.

1) Has Pfizer provided Genotoxicity studies?
2) Please provide the Genotoxicity study document.

Pfizer has not provided genotoxicity studies, therefore the Ministry is unable to provide you with any study documents. As such, this part of your request is refused 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.

3) Has Pfizer provided Reproductive Toxicology Studies?
4) Please provide the Reproductive Toxicology study document.

Pfizer has provided Reproductive Toxicology Studies. These are itemised in Appendix 1 to this letter, and copies of the documents are enclosed.

5) Has the Ministry/Medsafe requested Genotoxicty study data from Pfizer?

Medsafe has not requested genotoxicity study data on the basis that it is not required according to international guidelines. Other information provided by Pfizer sufficiently justifies the lack of genotoxic potential of this vaccine and its ingredients.

6) Has the Ministry/Medsafe requested Reproductive Toxicology study data from Pfizer?

Reproductive Toxicology study data is included in the documentation provided in response to questions three and four. This Reproductive Toxicology study data was not specifically requested. Rather, it was included in the original dossier. Please note, this information is withheld under section 9(2)(b)(ii) of the Act as it is commercially sensitive.

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.

Yours sincerely

Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Title	Decision on release
1	22 December 2020	Study No. 20256434 - A Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) of BNT162b1, BNT162b2 and BNT162b3 by Intramuscular Administration in the Wistar Rat.	Some information withheld under section 9(2)(a) to protect the privacy of natural persons and 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information. An excerpt of this document has been provided, all pages deemed commercially sensitive under the Act have not been included.
2	15 December 2020	Summary of Results from Study No. 20256434.	Released in full.