



Australian Government
Department of Health
Therapeutic Goods Administration

Mr Robert O'Dea
Email: foi+request-5386-f8b98362@righttoknow.org.au

Dear Mr O'Dea

FREEDOM OF INFORMATION REQUEST FOI 1132-1819
Estimate of Charges

I refer to your request dated 17 April 2019 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

“...the request submitted to the TGA for Scheduling of Thymosin Beta 4 and Tb500 as indicated in the link below.

<https://www.tga.gov.au/book-page/27-performance-and-image-enhancing-drugs>.

I am requesting specifically access to the application for inclusion of Thymosin Beta 4 and Tb500 on the Schedules List. I would request all supporting data that was presented in the application that supports the claims.

Any/all clinical and scientific evidence that supports the claims of performance and image enhancement.

Any evidence that supports any medical benefit at all from the use of Thymosin Beta 4 or Tb500.

I would ask for clarification on what appears to be a contradiction in the rationale for the acceptance of the application. The reasons state limited evidence of therapeutic benefits, not registered anywhere in the world (by definition no clinical evidence of efficacy or safety), experimental and yet it is accepted as being performance and image enhancing.”

Under the *Freedom of Information (Charges) Regulations 1982* (the Regulations) a charge can be levied in respect of a request for access to documents under the FOI Act. The charge is for the search and retrieval of documents, decision making and provision of access (for example, copying and postage).

I am an authorised decision maker under section 23 of the FOI Act and I have decided that you are liable to pay a charge in respect of the processing of your request for access.

A search and retrieval of documents relevant to your request has been undertaken and a preliminary estimate of charges has been calculated. It is set out in the table below.

1. Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.5 hours @ \$15.00 per hour	\$67.50
2. Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	7.99 hours @ \$20.00 per hour Less first 5 hours which are free	\$59.88
3. Photocopying of documents	27 pages	\$2.70
4. Postage charges		\$0.00
TOTAL		\$130.08

Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$130.08, I have decided you are required to pay a deposit of 25 percent, being \$32.52. Details of payment methods are outlined below.

Under subsection 29(1) of the FOI Act you have 30 calendar days from receipt of this notice to:

- pay the charge, being the deposit or full amount outlined above, and notify the FOI Team via the email below; or
- notify the TGA that you wish to contend that:
 - the charge has been wrongly assessed, giving reasons; or
 - the charge should be reduced or not imposed (for instance, where payment of the charge would cause you financial hardship or where you believe access to documents is in the general public interest), with reasons; or
- notify the TGA that you withdraw your request.

If you fail to notify the TGA within 30 days about what you propose to do, the FOI Act provides under subsection 29(2) that you are taken to have withdrawn your request. Please note that if you are arguing that the charge should be reduced or not imposed because the payment would cause you financial hardship, you believe access would be in the public interest or for any other reason, you must provide sufficient cogent reasons to provide a basis on which the decision maker could reduce, or not impose, the fee.

Timeframes

The time limit for processing your request is suspended, in accordance with section 31 of the FOI Act, from the date you receive this notice and resumes on the day you pay the charge or deposit (including any reduced charge or deposit), or the day on which the TGA makes a decision not to impose a charge.

Once your FOI request has been processed, the TGA will determine the actual charge you must pay before the documents can be provided to you. The final charge for processing your request may be different from the estimate quoted in this letter. If I decide to grant full access to all the documents within the scope of your request, you must pay the actual cost of processing your request ascertained in accordance with the table set out above (which may be greater or less than the estimate). However, if you are only granted partial access to the documents you will only be required to pay whichever amount is the lesser of the estimate quoted in this letter and the actual charge.

Please note that the decision maker can charge for search and retrieval that the TGA has already undertaken for the purposes of your request in its current form, but it may be possible to reduce the decision making and photocopying charges that might be incurred by the TGA in the future if you refine the scope of your request, for example, by limiting the date range of documents sought or excluding a particular category of documents.

If you agree to pay the charge, you are accepting liability for settlement of the debt upon completion of processing the FOI request. Once your FOI request has been processed the outstanding amount of the charge becomes a debt to the Commonwealth. The TGA is obliged to pursue recovery of the debt in accordance with the *Public Governance, Performance and Accountability Act 2013*.

Payment

If you accept liability for the estimated charge for your request, payment can be made via one of the following options:

- **Credit card payment:**

Complete the *attached* form (also available via the following link):

www.tga.gov.au/form/credit-card-payment-authorisation

- **Electronic Funds Transfer:**

Payment can be made in the form of electronic funds transfer to the following account:

Bank: Commonwealth Bank of Australia
Account Name: Therapeutic Goods Administration
BSB: 062909
Account: 10215498

- **Cheque:**

Please make cheques payable to Therapeutic Goods Administration, and post to

FOI Coordinator
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Please include reference to FOI 1132-1819 in all forms of payment.

Details of how to pay and other payment methods can be found at:

www.tga.gov.au/about/fees-payments-options.htm

IMPORTANT: Once payment has been made, please notify the FOI Team via the following email address: TGA.FOI@tga.gov.au.

Failure to notify the FOI Team of payment will result in delays to the processing of your FOI request.

Third Party Consultation

In the event your request relates to documents that include information about a person or their business or professional affairs or about the business, commercial or financial affairs of an organisation or undertaking, pursuant to section 27 and 27A of the FOI Act the TGA will be required to provide that person or organisation the opportunity to make submissions if it appears that they may wish to argue any document is exempt from release.

The statutory time limit for processing an FOI request will be extended by 30 days under subsection 15(6) of the FOI Act where a third party is to be consulted.

If you require clarification of any of the matters discussed in this letter you should contact the FOI Team on (02) 6232 8806.

Yours sincerely



Avi Rebera
Assistant Secretary
Regulatory Engagement & Planning Branch
Therapeutic Goods Administration

16 May 2019