Document 1

Email Message

From:	[redacted] s22 [redacted]
To:	ocm [SMTP:ocm@tga.gov.au]
Cc:	
Sent:	20/07/2011 at 9:53 AM
Received:	20/07/2011 at 9:53 AM
Subject:	Peptides Enquiry - [redacted]

Hi s22 [redacted]

Thank you for your time yesterday. The three peptides that we interested in providing are CJC-1295; AOD-9604 and GHRP-6. All are very short chain peptides. There are not listed or scheduled with the Therapeutic Good Administration and are not considered to be an active biological or hormone.

Regards

[redacted]

s22 [redacted]

From: s22 [redacted]
Sent: Thursday, 7 February 2013 3:28 PM
To: s22 [redacted]
Subject: TGA Warning Letter [SEC=UNCLASSIFIED]

Dear s22 [redacted], s22 [redacted]

Please find attached TGA warning letter. As outlined in the letter you must respond within 5 workings days. Please do not hesitate to contact me if you have any questions or concerns. The original is being sent to you via registered mail.

14320-TGA Warning Letter....

Kind Regards,

s22 [redacted]
Senior Investigator
Regulatory Compliance Unit
Therapeutic Goods Administration
s22 [redacted]

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Our Reference: RCU 14320

[redacted]

Re: Advertising and Supply of unapproved & unevaluated therapeutic goods generally known as 'Peptides'

Dear Directors [redacted]
s22 [redacted]
s22 [redacted]
s22 [redacted]

It has come to the attention of the Therapeutic Goods Administration (TGA) that you are advertising and supplying via the website, [redacted] the following in Australia for human therapeutic use:

- AOD 9604 Cream;
- SARM S22;
- GHRP 6;
- CJC 1295;
- MGF Peg Mechano Growth Factor;
- Hexarelin;
- Melanotan II;
- Sarm S22 Cream;
- GHRP 6 Cream;
- Melanotan II Cream; and
- CJC 1295 Cream.

These products, generally known as 'Peptides', are considered to be therapeutic goods. Therefore these products cannot be imported, manufactured, advertised or supplied by yourself and/or your company as it may pose an unacceptable health risk to consumers.

CJC 1295 and GHRP 6 are a synthetic analogue of Growth Hormone Releasing Hormone. PEG MGF is a variant of insulin-like growth factor (IGF). CJC 1295, GHRP 6 and PEG MGF are identified as Prohibited Imports in accordance with Schedule 7A Item 3 of the Customs (Prohibited Import) Regulations 1956.

SARM S22 is a Selective Androgen Receptor Modulator. Sarms S22 is identified as a Prohibited Import in accordance with Schedule 8 Item 3C of the Customs (Prohibited Import) Regulations 1956. As of the 1 May 2013 SARM S22 will also be identified as a

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone 02 6232 8444 Fax 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Schedule 4 prescription-only medicine in accordance with the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Melanotan II has been identified as containing alpha-melanocyte stimulating hormone (a-MSH) which is an analogue of Afamelanotide. Afamelanotide is identified as a Schedule 4 prescription-only medicine in accordance with the Standard for the Uniform Scheduling of Medicines & Poisons (SUSMP).

The SUSMP outlines:

- Schedule 4 Prescription Only Medicine, or Prescription Animal Remedy – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

You should be aware that in Australia these products, when presented with claims for therapeutic use, may be classified as a Therapeutic Good, requiring entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

Section 3 of the Therapeutic Goods Act 1989 broadly defines a therapeutic good as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use. The definition of therapeutic use in Section 3, in relation to humans, includes use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury. It also includes use in or in connection with influencing, inhibiting or modifying a physiological process.

Chapter 3 of the Therapeutic Goods Act 1989 and various parts of the Therapeutic Goods Regulations 1990 deal with the regulation of medicines. Medicines for human use are defined in Section 3 of the Therapeutic Goods Act 1989 as therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human. This includes complimentary medicines.

Part 3-2 of Chapter 3 of the Therapeutic Goods Act 1989 requires medicines, unless exempted, to be listed or registered on the Australian Register of Therapeutic Goods (ARTG).

Our records indicate that these products are not included in the ARTG in respect to you or your company as required by law. You are therefore to cease any importation or manufacture along with advertising and supply immediately of these products, together with any other unregistered or unlisted product, which is not exempted from this requirement.

You are to provide **written** confirmation within 5 working days of receipt of this letter that advertising and supply will cease until such time as the products have been included in the ARTG for human therapeutic use.

Application forms for Listing or Registration of Therapeutic Goods are available from the TGA Publications Office at the above address or by phoning 1800 020 653. Further information on the TGA is available from the Internet website www.tga.gov.au

Legislation:

I would draw your attention to the following legislative provisions contained in Therapeutic Goods Act 1989.

Under Section 19B of the Therapeutic Goods Act 1989, it is an offence for a person who is a sponsor of therapeutic goods, to intentionally import, export, manufacture or supply the goods in Australia for use in humans unless those goods are listed or registered in the ARTG in respect to the importer, or the goods are exempt goods or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes persons who import or arrange for the importation of therapeutic goods, or who manufacture or arrange for another person to manufacture the goods for supply.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

The maximum penalty upon conviction is Imprisonment for 5 years or a fine of $680,000 or both for an individual, or a fine of $3,400,000 for a corporation in respect of each offence.

Please also note that Section 19D of the Therapeutic Goods Act 1989, may also subject sponsors of therapeutic goods not included in the Australian Register of Therapeutic Goods to the civil penalties provisions contained in the legislation. Contravention of a civil penalty can attract maximum fines of $850,000 for individuals and $8,500,000 for a body corporate.

In addition, it is an offence for a person to advertise a therapeutic good, which is not included in the ARTG. It is also an offence for a person to make a claim by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods) that are not listed or registered in the ARTG. The maximum penalty upon conviction in this instance is $10,200 for a person or $51,000 for a corporation in respect of each offence.

Any correspondence on this matter should be addressed to myself, [redacted] at the address listed above. In order to speed up this process a copy of the letter can be faxed to s22 [redacted] prior to mailing. I can also be contacted by email at s22 [redacted].

If you need any further assistance or clarification on this matter please do not hesitate to contact me on s22 [redacted].

s22 [redacted]

Senior Investigator
TGA Regulatory Compliance Unit
7 February 2013