

THERAPEUTIC GOODS ACT 1989

Undertaking to the Secretary of the Australian Government Department of Health given for the purposes of section 42YL of the Act

By

NUTRITION WAREHOUSE PTY LIMITED

Person giving this undertaking

- (1) This undertaking is given to the Secretary of the Australian Government Department of Health by Nutrition Warehouse Pty Limited (ACN 17 128 438 755) of 20/22 Kohl Street, Upper Coomera, Queensland for the purposes of section 42YL¹ of the *Therapeutic Goods Act 1989* (the Act).

Background

- (2) Nutrition Warehouse Pty Limited carries on the business of importation and wholesale distribution in Australia of diverse consumer goods including cosmetic products. Some of these products are therapeutic goods within the meaning of the Act by virtue of the claims made on the product labelling.
- (3) The Therapeutic Goods Administration (TGA) is a part of the Australian Government Department of Health (Health), and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.
- (4) The meaning of 'sponsor' in the Act includes a person (including a corporation) who is a resident of or carrying on business in Australia, who imports or arranges the importation of therapeutic goods into Australia.
- (5) Unless otherwise exempt or excluded, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) by a sponsor prior to importation. Criminal offences and/or civil penalty provisions may apply if goods are imported and are not included in the ARTG.
- (6) In 2012, the TGA Regulatory Compliance Unit warned Nutrition Warehouse Pty Limited two times in relation to the importation into Australia variously of Cellucor D4 Thermal Shock, Cellucor L2 Extreme, Cellucor T7 Extreme, Cellucor P6 Extreme, Nutrex Research Lipo 6X, BPI

¹ For convenience, the terms of section 42YL of the Act are set out in Annexure B.

Solid Hardening Agent and Axis-HT products not included in the ARTG in the name of Nutrition Warehouse Pty Limited as sponsor as required by the Act.

- (7) In 2013, Nutrition Warehouse Pty Limited imported into Australia a quantity of Cellucor D4 Thermal Shock, Cellucor L2 Extreme, Cellucor T7 Extreme, Cellucor P6 Extreme, Nutrex Research Lipo 6X, BPI Solid Hardening Agent and Axis-HT products (the Contravening Goods) which were therapeutic goods which were not included in the ARTG in the name of Nutrition Warehouse Pty Limited or any of its subsidiaries as sponsor.
- (8) Consequently representatives of the TGA Regulatory Compliance Unit commenced investigations into the alleged importation by Nutrition Warehouse Pty Limited of the Contravening Goods not included in the ARTG in the name of Nutrition Warehouse Pty Limited or any of its subsidiaries as sponsor.
- (9) The TGA considers that the importation of the Contravening Goods into Australia by Nutrition Warehouse Pty Limited constitutes a criminal offence against section 19B(4) of the Act by reason of coming within section 19B(4)(a)(i) of the Act, and/or breaches the civil penalty provisions contained in section 19D(1) of the Act by reason of coming within section 19D(1)(a)(i) of the Act as Nutrition Warehouse Pty Limited were the “sponsor” of the Contravening Goods within the meaning of the Act, the Contravening Goods were not included in the ARTG in the name of Nutrition Warehouse Pty Limited as sponsor, and no exemptions or exclusions applied.
- (10) Since becoming aware of the TGA investigation, Nutrition Warehouse Pty Limited has ceased the importation into Australia, and distribution within Australia, of the Contravening Goods.
- (11) Nutrition Warehouse Pty Limited acknowledges that its conduct described at paragraph 7 above, involved the commission or the likely commission of a criminal offence and/or involved a breach or likely breach of the civil penalty provisions as described in paragraph 9 above.

Period of undertaking

- (12) This undertaking comes into effect when both of the following are satisfied:
 - (i) the undertaking is executed by Nutrition Warehouse Pty Limited; and
 - (ii) the Delegate of the Secretary signs the executed undertaking.
- (13) Upon this undertaking coming into effect, Nutrition Warehouse Pty Limited undertakes to assume the obligations set out in paragraphs 15 - 17 below.
- (14) This undertaking terminates on the third anniversary of the day on which it comes into effect.

Undertakings

- (15) Nutrition Warehouse Pty Limited undertakes for the purposes of section 42YL of the Act that within one month from the date of this undertaking coming into effect it will, at its own expense, engage a qualified compliance professional to advise and assist with the implementation of regulatory procedures to ensure that Nutrition Warehouse Pty Limited does not commit any future breaches of the Act.
- (16) For the purposes of this undertaking a 'qualified compliance professional' will be someone with a minimum of 5 years of experience in advising on regulatory compliance matters concerning therapeutic goods in Australia.
- (17) Nutrition Warehouse Pty Limited further undertakes for the purposes of section 42YL of the Act that it will at its own expense:
- (i) Establish and implement a Therapeutic Goods Compliance Program in accordance with Australian Standard AS 3806-2006 and the requirements set out in **Annexure A** to this undertaking, being a program designed to minimise Nutrition Warehouse Pty Limited and its subsidiaries risk of future breaches of sections 19B, 19D, 41MI and 41MIB² of the Act and to ensure their awareness of their responsibilities and obligations in relation to the requirements of sections 19B, 19D, 41MI and 41MIB of the Act; and
 - (ii) Maintain and continue to implement the Compliance Program for a period of 3 years from the date of this undertaking coming into effect; and
 - (iii) Provide a copy of any documents required by the TGA in accordance with **Annexure A**.

Acknowledgements

- (20) Nutrition Warehouse Pty Limited acknowledges that:
- (i) this undertaking is given voluntarily; and
 - (ii) the Secretary may make this undertaking publicly available on a public register and is obliged under the Act to publish details of the undertaking, as in force from time to time, on the internet; and
 - (iii) the Secretary and/or the Commonwealth or officers thereof may from time to time, publicly refer to this undertaking including through, but not limited to, news media statements, and in TGA or Health publications; and

² Sections 41MI and 41MIB being the equivalent offence and civil penalty provisions to sections 19B and 19D, respectively, but in relation to medical devices.

- (iv) this undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or any other person arising from the conduct of Nutrition Warehouse Pty Limited.

Executed by

Nutrition Warehouse Pty Limited (ACN 17 128 438 755)

by its authorised officers pursuant to
section 127(1) of the *Corporations Act 2001*

.....
Grant Mayo (Director)

for and on behalf of Nutrition Warehouse Pty Limited
ACN: 17 128 438 755

This 17th day of December 2014

**ACCEPTED BY THE NATIONAL MANAGER OF THE THERAPEUTIC GOODS ADMINISTRATION AS
DELEGATE OF THE SECRETARY OF THE DEPARTMENT OF HEALTH, UNDER SECTION 42YL OF THE
THERAPEUTIC GOODS ACT 1989.**

.....
Professor John Skerritt

TGA National Manager
Delegate of the Secretary

This 23rd day of December 2014

THERAPEUTIC GOODS COMPLIANCE PROGRAM (see clause 17)

Nutrition Warehouse Pty Limited will, in order to meet its obligations under clause 17 of the undertaking, establish a Therapeutic Goods Compliance Program (Compliance Program) in accordance with AS 3806-2006 that also complies with each of the following requirements:

Appointment

- (1) Within one month of the date of this undertaking coming into effect, Nutrition Warehouse Pty Limited will appoint the director or a senior manager, of the company to be responsible for the development, implementation and maintenance of the Compliance Program (the Compliance Officer).
- (2) Nutrition Warehouse Pty Limited will within 14 days of the Compliance Officer's appointment notify the TGA of the Compliance Officer's name and contact details.
- (3) Nutrition Warehouse Pty Limited, for a period of 3 years from the date of the Undertaking coming into effect, will advise the TGA within 28 days of any change of Compliance Officer or the Compliance Officer's contact details.

Compliance Officer Training

- (4) Nutrition Warehouse Pty Limited will, at its own expense, ensure that within 3 months of the date of this undertaking coming into effect, the Compliance Officer attends practical training focusing on the identification of categories of consumer goods likely to be imported by Nutrition Warehouse Pty Limited or any of its subsidiaries that, as therapeutic goods, may be subject to regulation by the TGA, and the statutory obligations applicable to importers (sponsors) of therapeutic goods.
- (5) Nutrition Warehouse Pty Limited shall ensure that the training is administered by a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation.
- (6) Nutrition Warehouse Pty Limited will within 14 days of that completion of training provide the TGA with a written statement from the qualified compliance professional or legal practitioner who conducts the training, confirming the completion of the training and that it was conducted as required by paragraphs 4 - 5 above.

Staff Training

- (7) For the period of 3 years from the date of this undertaking coming into effect Nutrition Warehouse Pty Limited shall, at its own expense, cause all employees of Nutrition Warehouse Pty Limited and its subsidiaries whose duties could result in them being concerned with conduct that may contravene sections 19B, 19D, 41MI and 41MIB of the Act

to receive regular (at least once a year) practical training focusing on the identification of categories of consumer goods likely to be imported by Nutrition Warehouse Pty Limited or any of its subsidiaries that, being therapeutic goods, may be subject to regulation by the TGA and the statutory obligations applicable to importers (sponsors) of therapeutic goods. This training is to be administered by the Compliance Officer (once trained) or a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation.

Review

- (8) Nutrition Warehouse Pty Limited shall, at its own expense, cause two annual reviews of the Compliance Program (the Review) to be carried out by a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation and Nutrition Warehouse Pty Limited shall ensure that the Review is broad and rigorous enough to:
 - (i) Provide Nutrition Warehouse Pty Limited and the TGA with a supportable verification that the Compliance Program complies with the requirements of this undertaking and is suitable for the size and structure of Nutrition Warehouse Pty Limited and its subsidiaries; and
 - (ii) Provide the Compliance Program Review Report and opinions detailed at paragraph 10 below.
- (9) Nutrition Warehouse Pty Limited shall ensure that the first review is completed within one year and one month of this undertaking coming into effect and that a second review is completed one year after the first review.

Reporting

- (10) Nutrition Warehouse Pty Limited shall require the person undertaking an annual review ('the Reviewer') to set out his or her findings in a Compliance Program Review Report, which will provide particular and specific information regarding the scope of the review and the effectiveness of the Compliance Program including:
 - (i) Details of the evidence gathered and examined during the review; and
 - (ii) The name and relevant experience of the person appointed as Nutrition Warehouse Pty Limited's Compliance Officer; and
 - (iii) The Reviewer's opinion on whether Nutrition Warehouse Pty Limited has in place effective staff training that complies with the requirements of this undertaking; and
 - (iv) Actions recommended by the Reviewer to ensure the continuing effectiveness of Nutrition Warehouse Pty Limited's Compliance Program.

- (11) Nutrition Warehouse Pty Limited shall require that each Compliance Program Review Report is completed and provided to Nutrition Warehouse Pty Limited within one month of completion of the review.
- (12) Nutrition Warehouse Pty Limited will cause the Compliance Program Review Report to be provided to the TGA within 14 days of its receipt from the Reviewer.
- (13) Nutrition Warehouse Pty Limited shall implement promptly and with due diligence any recommendations made by the Reviewer or required by the TGA that are reasonably necessary to ensure that Nutrition Warehouse Pty Limited maintains and continues to develop the Compliance Program elements in accordance with this undertaking and effectively implements and follows the Compliance Program.
- (14) If requested by the TGA, Nutrition Warehouse Pty Limited shall, at its own expense, provide copies of documents and information in respect of matters which are the subject of the Compliance Program.
- (15) In the event the TGA has reason to suspect that the Compliance Program is not being implemented effectively, Nutrition Warehouse Pty Limited shall, at its own expense and if required by the TGA, cause an interim or additional review to be undertaken to which paragraphs 10 to 13 above apply as if it were an annual review.

THERAPEUTIC GOODS ACT 1989 - SECTION 42YL

Enforcement of undertakings

- (1) The Secretary may accept a written undertaking given by a person in connection with a matter in relation to which the Secretary has a power or function under this Act or the regulations.
- (2) The person may withdraw or vary the undertaking at any time, but only with the consent of the Secretary.
- (3) The Secretary must publish details of the undertaking, as in force from time to time, on the internet.
- (4) If the Secretary considers that the person who gave the undertaking has breached any of its terms, the Secretary may apply to the Federal Court for an order under subsection (5).
- (5) If the Court is satisfied that the person has breached a term of the undertaking, the Court may make all or any of the following orders:
 - (a) An order directing the person to comply with that term of the undertaking;
 - (b) An order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach;
 - (c) Any order that the Court considers appropriate directing the person to compensate any other person who has suffered loss or damage because of the breach;
 - (d) Any other order that the Court considers appropriate.