ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989

Section 42YL

The commitments in this undertaking are offered to the Secretary of the Australian Government Department of Health and Aged Care (**Secretary**) under section 42YL of the *Therapeutic Goods Act 1989* (Cth)

by

The Aussie Gelatin Company Pty Ltd (ABN 34 616 264 950) trading as Nutra Viva.

Persons and authority

1. This undertaking is given to the Secretary of the Australian Government Department of Health and Aged Care (**Department**) under section 42YL of the *Therapeutic Goods Act 1989* (**the Act**) by The Aussie Gelatin Company Pty Ltd (ABN 34 616 264 950) (**Aussie Gelatin**) trading as Nutra Viva, of 9 Cherry Lane, Robin Hill, NSW, 2795.

Background

2. The Therapeutic Goods Administration (**TGA**) is a part of the Department and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.

3. Aussie Gelatin is an Australian Proprietary Company trading under the business name Nutra Viva, and operates an online store that supplies collagen and gelatin products and food supplements.

4. During the period 1 May 2023 to 17 November 2024, Aussie Gelatin, manufactured, supplied and advertised two products, Nutraviva Bone & Joint Formula - Unflavoured – 320g and Nutraviva Bone & Joint Formula - Berry Blend - 320g (**Products**), to persons in Australia through the website located at the following Uniform Resource Locator (**URL**) https://nutraviva.com.au/ (the **Website**). The Products were represented by Aussie Gelatin as assisting with areas of sports performance and injuries and having a range of nutritional applications, and are therapeutic goods within the meaning of the Act. The Products are not registered or listed in the Australian Register of Therapeutic Goods (the **Register**), or otherwise subject to any exemption, approval or authority under the Act.

5. Three samples of the two Products were tested by the TGA and were found to contain Vitamin D3 at levels significantly above those declared on the labels for the Products. The TGA has noted that the samples of the Products tested by the TGA contained between 950mcg and 1075mcg of Vitamin D, while the levels of Vitamin D declared on the labels of the Products advertised was 7.5mcg. An adverse event was reported to the TGA involving a patient whose routine blood tests revealed significantly elevated levels of Vitamin D and Calcium.

6. Based on the concentration of Vitamin D detected by the TGA, the Products would be classified according to the *Therapeutic Goods (Poisons Standard - October 2024) Instrument 2024* (**Poisons Standard**) as Schedule 4 – Prescription Only substances. The Poison Standard includes the following as the Schedule 4 – Prescription only medicine:

    VITAMIN D for human internal therapeutic use except:
    (a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose; or
    (b) when included in Schedule 3.

Relevant law

7. It is a contravention of subsection 19D(1) of the Act for a person to manufacture in Australia or supply in Australia, a therapeutic good (that is not a medical device) for use in humans, in circumstances where the goods are not registered or listed in the Register in relation to the person, not exempt from a requirement to be registered or listed in the Register, not the subject of an approval or authority under section 19 of the Act and not the subject of an approval under section 19A of the Act. Subsection 19D(1) is a civil penalty provision.

8. It is a contravention of subsection 42DLB(1) of the Act for a person to advertise, or cause to be advertised, therapeutic goods, if any of subsections 42DLB(2) to 42DLB(9) applies to the advertisement.

9. Subsection 42DLB(9) applies where the advertisement refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of subsection 42DLB(9), other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

10. Regulation 7(i) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) provides that therapeutic goods that are neither the subject of an exemption, approval or authority under the Act, nor an exemption, approval or authority under the Regulations, are prescribed therapeutic goods for the purposes of subsections 42DL(12) and 42DLB(9) of the Act.

11. It is a contravention of section 42EA of the Act for a person to manufacture or supply in Australia therapeutic goods that are counterfeit. Under subsection 42E(2), goods are counterfeit if the label or presentation of the goods, any document or record relating to the goods or their manufacture, or any advertisement for the goods, contains a false representation with respect to, among other things:
    (a) the formulation of the goods or of any ingredient or component;
    (b) the presence or absence of any ingredient or component of the goods; and
    (c) the strength or size of any ingredient or component of the goods.

Conduct of concern

12. Aussie Gelatin understands that the TGA is concerned that Aussie Gelatin has contravened subsections 19D(1)(a)(iii) and (iv) of the Act, subsection 42DLB(1) where subsection 42DLB(9) applies and section 42EA of the Act, by the conduct detailed in **paragraphs 3-6** above.

Acknowledgement of breach

13. Aussie Gelatin acknowledges that its conduct detailed in **paragraphs 3-6** above is likely to have contravened section 19D of the Act, subsection 42DLB(1) where subsection 42DLB(9) applies, and section 42EA of the Act.

14. Aussie Gelatin has taken actions to address the non-compliance with the Act, including by:

    (a) removing the Products from the Website;

    (b) stopping supply of the Products;

    (c) ceasing the manufacture of Products; and

    (d) engaging with the TGA recalls branch to conduct a recall of the Products (the Products currently being publicly listed on the TGA Recall Database).

Period of Undertaking

15. This undertaking comes into effect on the day that both of the following are satisfied:

    (a) The undertaking is executed by Aussie Gelatin; and

    (b) The delegate of the Secretary signs the executed undertaking.

16. This undertaking terminates on the third anniversary of the day on which it comes into effect.

Undertakings

17. On commencement of this undertaking, Aussie Gelatin undertakes to assume the obligations set out in **paragraphs 18-23**.

Conduct of Aussie Gelatin

18. Aussie Gelatin undertakes not to, whether itself or through its employees, servants or agents or bodies corporate under its control:

    (a) import, export, manufacture, or supply or advertise to persons in Australia any Bone and Joint formula or derivatives in contravention of the Act

    (b) aid, abet, counsel or procure, or otherwise authorise, assist or encourage in any way, any conduct by another person of a kind which Aussie Gelatin has undertaken not to engage in under **paragraph 18(a).**

Recall of unregistered therapeutic goods

19. Aussie Gelatin commits to complying with all requirements of the TGA recall process, including the submission of the interim report and the final close out report by the dates specified by the TGA.

Root Cause and Risk Assessment

20. Within 30 calendar days of the undertaking coming into effect, Aussie Gelatin will conduct a comprehensive analysis of the non-compliances the subject of this undertaking and submit a complete root cause analysis to the TGA.
21. Within 30 calendar days of the undertaking coming into effect, Aussie Gelatin will perform a risk assessment and develop a prevention strategy to mitigate any further risk of this kind. The risk assessment report (and risk prevention / mitigation strategy) are to be provided to the TGA within 30 calendar days of this undertaking coming into effect.

22. Additionally, within 12 months of the undertaking coming into effect, Aussie Gelatin will deliver to the TGA an annual report detailing Aussie Gelatin's compliance with the TG Act, outlining how it has addressed the findings of the risk assessment and implement the prevention strategy as mentioned in **paragraph 21**.

Costs of compliance

23. Aussie Gelatin acknowledges and agrees to bear all its costs of compliance with this undertaking.

Acknowledgements

24. Aussie Gelatin acknowledges that:

    (a) This undertaking was given voluntarily by The Aussie Gelatin Company Pty Ltd (ABN 34 616 264 950) trading as Nutra Viva;

    (b) Pursuant to s 42YL(3) of the Act, the Secretary must make this undertaking and information about this undertaking publicly available including by publishing it on the TGA's website;

    (c) The Secretary may, from time to time, make public reference to this undertaking including in news media statements and in publications by the TGA or the Department including on various forms of social media;

    (d) 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 Nutra Viva;

    (e) the Secretary's acceptance of this enforceable undertaking does not affect the power of the Secretary to investigate or pursue a criminal prosecution, to seek a pecuniary civil penalty or use any other power available to the Secretary under the Act in relation to

any contravention or breach, or possible contravention or possible breach of the Act, arising from future conduct (not referred to in the Background section of this enforceable undertaking); and

(f) This undertaking has no operative force until accepted by the Secretary.

Executed by:

[redacted]

The Aussie Gelatin Company Pty Ltd (**ABN 34 616 264 950**) trading as Nutra Viva

This 26 **day of** MARCH **2025**

ACCEPTED BY A DELEGATE OF THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGED CARE UNDER SECTION 42YL OF THE *THERAPEUTIC GOODS ACT 1989*

[redacted]

Delegate of the Secretary

This 24 **day of** June **2025**