

1. Is the product intended for consumption by an animal and not intended for direct application by a person to an animal's digestive tract?

YES

### INGREDIENT REQUIREMENTS

2. Does the product contain any ingredients that are:

- (a) a hormone
- (b) material from a vertebrate (if the product is to be consumed by ruminants)
- (c) an antibiotic listed in schedule 2, 3, 4, 7, 8 or 9 of the Poisons Standard
- (d) an antibiotic listed in schedule 6 of the Poisons Standard, other than a preservative in the product, or
- (e) an ingredient listed in an APVMA legislative instrument for the purpose of Part 3 Division 3.2 Section 5(7)(e)?

NO

3. Is each ingredient of the product:

- A. a substance of plant or animal origin that is edible by an animal, including:
  - (a) an edible grain and a processing by-product of an edible grain; and
  - (b) whey powder and any other milk by-product
- OR**
- B. listed in at least one of the following, for the purpose and in accordance with any other restrictions specified on the list:
  - (a) The following ingredients authorised by the Food Standards Code, as existing at the time of the supply:
    - (a) permitted flavouring substances; (b) generally permitted processing aids; (c) food additives (including colourings) specified in Schedule 16 to the Food Standards Code
  - (b) A determination under section 8B of the Agricultural Compounds and Veterinary Medicines Act 1997 of New Zealand (substances generally recognised as safe for use as or in an agricultural compound), as existing on 5 March 2015
  - (c) Annex I (list of additives) of the European Union Register of Feed Additives established in accordance with Article 17 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, as existing at the time of the supply, only authorised by or in accordance with this Annex if (i) the ingredient is not referred to as a category 5 substance and (ii) the Annex specifies an expiry date for authorisations of the ingredient
  - (d) Parts 573, 582 and 584 of Title 21 of the Code of Federal Regulations of the United States of America, as existing at the time of the supply
  - (e) Chapter 6 (Feed Terms and Ingredient Definitions) of the Official Publication of the Association of American Feed Control Officials, as existing at the time of the supply, only if the ingredient is not specified as a tentative listing in that Chapter
  - (f) Handbook of Pharmaceutical Excipients published by the Royal Pharmaceutical Society, as existing at the time of the supply, only if the substance or mixture in which the ingredient is used is for canine or equine consumption
  - (g) An ingredient determination at Division 3.5 of the Agvet Regulations
  - (h) Part 1 of Schedule IV and V to the Feeds Regulation 1983 of Canada, as existing at the time of the supply

YES

### MANUFACTURING REQUIREMENTS

4. Is the product manufactured under one of the following QA systems, noting the QA system must be appropriate for the product:

- (a) Australian GMP Code
- (b) an applicable Australian industry code of practice
- (c) An animal feed quality standard of the United States of America or the European Union?

YES

### LABEL REQUIREMENTS

5. Is the following information included on a label for a container of the product, or accompany the product at the time it is supplied?

- (a) Name of product
- (b) Instructions for use including, application or dosage rate and length of period during which it may be used for each species
- (c) Instructions for safe handling
- (d) Analysis of key ingredients to support claims
- (e) List of ingredients ordered by decreasing mass
- (f) Name, address and phone number for person responsible for marketing the product
- (g) Batch number
- (h) Expiry date (or equivalent)
- (i) That the product is for veterinary supply only if the product can make claims about treating a disease or injury on that basis
- (j) Information required by EU Commission directive 2008/38/EC about treating or alleviating a disease or condition or modifying the physiology of an animal.
- (k) Signal words required by Poisons Standard, including first aid instructions and poisons information centre contact details

### CLAIM REQUIREMENTS

6. Does the product claim to cure?

YES

7. Is the product supplied by or in accordance with the instructions of a vet?

YES

NO

8. Does the product claim to alleviate or prevent a disease or condition? or Does the product claim to modify the physiology?

YES

9. Is the product supplied by or in accordance with the instructions of a vet?

NO

NO

Product does not require registration

10. Are the claims of the product supported by:

- (a) Scientific studies that are published in a reputable journal, refereed scientific journal, or that are of a standard publishable in such a journal, or
- (b) Compliance with EU Commission Directive 2008/38/EC?

YES

Veterinary Chemical Product  
Product **requires** registration

NO

NO

NO

Veterinary Chemical Product  
Product **requires** registration

NO

Veterinary Chemical Product  
Product **requires** registration

NO

Product is an Excluded Nutritional or  
Digestive (END) Product  
Registration is **NOT** required.

YES

YES

NO