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GOVERNMENT NOTICES

COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Sections 14 and 14A Notice

On 1 December 2015, a delegate of the Secretary of the Department of Health, on the application of Regulatory Concepts, consented under sections 14 and 14A of the *Therapeutic Goods Act 1989* (the Act) to the supply of

- ALUSTAL BERMUDA GRASS EXTRACT cynodon dactylon 10 IR/mL injection suspension vial [AUST R 132834]
- ALUSTAL BERMUDA GRASS EXTRACT cynodon dactylon injection suspension vial composite pack [AUST R 132835]

that do not conform with the requirements of paragraph 3(2)(c), (j), (k), (h), 3(5)b(i),(ii), 3(10)(a) and 7(1)(a)(iv) of the *Therapeutic Goods order No 69 – General requirements for labels for medicines*, in that

(i) generic outer box with affixed over labels provided do not include the following;

- Strength in terms of IR/mL or IC/mL (although this is included on the vial labels inside the box)
- Direction for use
- The statement "Single patient use only" although there is a statement that states: NPP: NAMED Patient Product
- Quantities of Excipients and
- The word 'Refrigerate' as part of the storage condition
- The batch number prefix

(ii) generic vial labels do not include the following

- Sponsor's name or logo
- Dosage form (suspension)

The consent is effective from1 December 2015 until 31 March 2016.

The consent is subject to the following conditions:

1. An assurance that sponsor will add an additional over label to the front main panel label on the box as contained in the application letter dated 3 November 2015. These extra over labels will include the following information:
    - SUSMP signal headings: PRESCRIPTION ONLY MEDICINES and KEEP OUT OF REACH OF CHILDREN in sans serif, bold capital letters not less than 1.5 mm in height
    - The AUST R number for the specific product
    - Sponsor's name and address

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au Website: http://www.tga.gov.au

- Stallergens product code such as 3I51 or 3I5M. The numbers relate to the specific allergen while the I and the M identify the initiation or maintenance packs.

2. An assurance that the outer box will also include the Australian product information included which does include other important information such as the quantity of excipient, active ingredients as per the Australia Approved Name and Directions for use.
3. An assurance to mitigate the risks posed by the use of these generic labels by providing with the product a "Dear Doctor " letter advising about the situation with regards to the use of these interim labels.
4. An assurance that the manufacturer's product codes are also included in the order forms and so provide a second check point for the doctor as part of the risk mitigation procedure.