

Dooley - for TGA (15.2.08)

EA# 198 476



Australian Government

Department of Health and Ageing

Minute

② Ms Lee
② copy Mr. Brown

Ms Halton
Secretary

Tony / PIS

cc Ms Mary Murnane, Deputy Secretary

Dr Rohan Hammett, National Manager, Therapeutic Goods Administration (TGA) *[Signature]*

Ms Cath Halbert, First Assistant Secretary, Office of Health Protection

RECEIVED

- 3 MAR 2008

National Manager
TGA

For advice please re actions
to be undertaken by your respective areas

3/310.P.

Subject: REGULATION OF COSMETICS - ADVERTISING

Purpose

To:

- update you on the action which has been taken to resolve a previous complaint from the Advocate for Consumer Cosmetic Hygiene and Specialty Industry Products (ACCORD);

Issue 1 - Status of resolution of complaint by ACCORD

2. In reviewing the claims made in a previous letter from ACCORD (12 November 2007), I advised you that an inconsistent approach has been taken by portfolio regulators for products at the cosmetic / therapeutic interface. I undertook to review the case in consultation with the TGA and NICNAS and subsequently update you on progress in resolving this issue.

Background

3. ACCORD wrote to you claiming that the TGA's Complaint Resolution Panel had exceeded its authority in considering a complaint about the advertising of the product *Nivea DNAge Cell Renewal System Day Care*. You signed an interim response to ACCORD

Comments

4. TGA proposes to amend the *Therapeutic Goods (Excluded Goods) Order* (the Order), to provide that products which meet the Cosmetics Standard are not therapeutic goods. This is consistent with arrangements previously agreed to by TGA and NICNAS and appears to be supported by industry.

5. TGA and NICNAS agree that the Order should also provide for a time limited transitional period to ensure that the labelling and packaging of products manufactured to meet the regulatory requirements for therapeutic goods are not in breach of the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*, under which they will otherwise fall once the Order is in place. TGA Legal Services Unit is currently drafting this amendment and it will be shortly released to NICNAS and RPGD for consultation. This is expected to resolve the regulatory anomaly.

6. In regard to the specific issue raised by ACCORD about the product, *Nivea DNaGe Cell Renewal System Day Care*, the Complaints Resolution Panel has referred the matter to the TGA to pursue appropriate regulatory action, in consultation with NICNAS. TGA has advised that the matter will now be referred to NICNAS, as the cosmetic regulator.

Issue 2 - The latest letter from ACCORD

7. ACCORD has raised further issues concerning the regulation of certain products at the cosmetic / therapeutic goods interface. In seeking to clarify that the Complaints Resolution Panel for therapeutic goods does not have authority to consider matters about the advertising of cosmetics, ACCORD has suggested that the Therapeutic Goods Advertising Code (the Advertising Code) should be changed to exclude cosmetics covered by the Cosmetics Standard from its scope.

8. In the same correspondence, ACCORD is also seeking to formally replace the now defunct Cosmetics, Toiletries and Fragrances Association of Australia (CTFAA) as an official observer to the TGACC.

Background

9. The TGACC is established under Division 2 of the *Therapeutic Goods Regulations 1990*. Regulation 42J (2)(b) establishes the CTFAA as one of the bodies that may nominate a person to attend meetings of the TGACC as an observer. The CTFAA voluntarily cancelled its incorporation in 2006. In 2006, the TGACC recommended that the Therapeutic Goods Regulations be amended to grant ACCORD official observer status. Since then ACCORD has been attending TGACC meetings as an invited guest. Steps to give this arrangement legal effect were held over pending the commencement of the Australia New Zealand Therapeutic Products Authority.

10. One of the functions of the TGACC is to provide recommendations to the Minister on changes required to the Advertising Code.

Comments

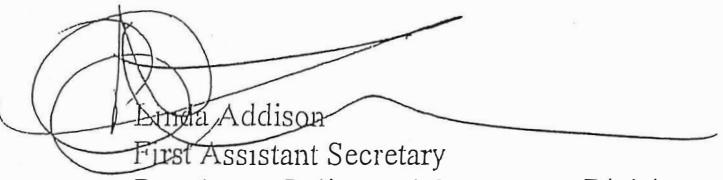
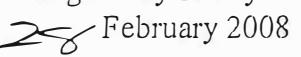
11. Once the Excluded Goods Order is in place, it should not be necessary to repeat this exclusion in the Advertising Code, as the Code applies only to therapeutic goods.

12. The TGA has advised that it is reviewing membership arrangements for a number of external committees established in the Therapeutic Goods Regulations, including the TGACC.

Recommendations

R1. That you **NOTE** that the Regulatory Policy and Governance Division will work with TGA and NICNAS to ensure that the *Therapeutic Goods (Excluded Goods) Order* provides regulatory clarity.




Emma Addison
First Assistant Secretary
Regulatory Policy and Governance Division
 February 2008

R1. NOTED / PLEASE DISCUSS

R2. SIGNED / NOT SIGNED

Jane Halton
2008