ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Mr Terry Slater
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Dear Terry

The Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods

ACCORD Australasia (formerly the Australian Consumer & Specialty Products Association) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

A significant number of ACCORD's members have an important interface with the Therapeutic Goods Administration (TGA) Group of Regulators including the TGA and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

ACCORD welcomes the opportunity to provide the attached Final Submission and response to the recommendations contained in the draft report of the *Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods*.

ACCORD, on behalf of its member companies, has a specific and direct interest in the immediate resolution of the interface issues for this range of low risk, low regulatory concern products. ACCORD will continue to work collaboratively with the TGA Group of Regulators to ensure that implementation of appropriate recommendations is achieved as soon as possible.

Yours sincerely

Bronwyn Capanna
Executive Director

20 May 2005

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Innovative solutions for healthy living and a quality lifestyle

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

The Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods

20 May 2005

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Foreword

ACCORD Australasia (formerly ACSPA) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help us look and feel our best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

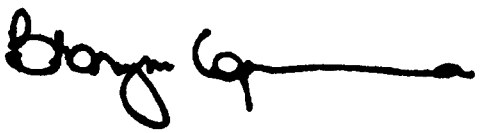
These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With an estimated $3 billion plus in annual product sales (ex factory), the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and through our industrial and institutional sector supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

A list of ACCORD member companies is provided at *Attachment 1.*

ACCORD, on behalf of its member companies, has a specific and direct interest in *The Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods (Draft Report)* and welcomes the opportunity to provide this submission and recommendations for consideration and implementation.



Bronwyn Capanna
Executive Director

20 May 2005

Executive Summary

ACCORD welcomed the release of the Draft Report in March 2005 regarding this as a significant milestone given our involvement with this issue for a number of years.

Reform and appropriate risk resource allocation for the regulation of low regulatory concern chemicals (LRCC) undertaken as part of the Government's response to the Chemicals and Plastics Action Agenda by NICNAS, and endorsed by the Australian Parliament, has not diminished public health and safety, worker safety and/or environmental standards.

ACCORD is disappointed that the same intellectual rigour and approach in the treatment of this group of low risk interface products was not adopted by the independent consultant in undertaking his review. One of the Review's Guiding Principles was that regulatory reform will be undertaken in accordance with the 1997 COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG principles). ACCORD is concerned that the Draft Report and its recommendations did not appear to apply the COAG principles to its analysis and in the framing of its recommendations.

ACCORD will however continue to work with the TGA Group of Regulators to implement the Draft Report's recommendations as well as our additional recommendations. To facilitate this, ACCORD has provided draft additions to the Excluded Goods Order at Attachment 3 identifying the low risk products which should be excluded as soon as possible and preferably by 30 June 2005.

In the establishment of working parties to develop the cosmetic guidance material and explore the theoretical resistance issues for antibacterial products, ACCORD expects that effective stakeholder engagement principles will be put in place by the TGA Group of Regulators to ensure equal representation of government and industry participants.

Timely implementation of ACCORD's recommendations will have significant benefits for our membership, the regulatory agencies and the community and at the same time meet the objectives of the review and all of its guiding principles.

ACCORD Recommendations

ACCORD's Recommendation 1

ACCORD recommends a rewording of the Draft Report Recommendation 1 to reflect the partnership approach and role of industry, as follows:

> *A Cosmetic Regulatory Guidance Note should be established by NICNAS, the ACCC and the TGA in equal partnership with industry and in consultation with stakeholders and other relevant regulators to clarify the distinction between cosmetic and therapeutic products.*

Implementation timetable:

- ACCORD recommends immediate establishment of the government and industry working group to develop the Guidance Note - ESTABLISHED AND MEETING 1 - BY 31 AUGUST 2005.

ACCORD's Recommendation 2

ACCORD supports antiperspirant preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency.

ACCORD does not support that antiperspirants other than those that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium should be regulated as Class II medicines.

Implementation timetable:

- ACCORD recommends immediate implementation of Recommendation 2 by the TGA through an Excluded Goods Order – BY 30 JUNE 2005
- The TGA and NICNAS convene an industry working party to identify a way forward regarding the treatment of additional ingredients for antiperspirant products – ESTABLISHED AND MEETING 1 - BY 31 AUGUST 2005.

ACCORD's Recommendation 3

ACCORD does not support this recommendation.

ACCORD recommends that antidandruff products become 'excluded goods' with improved ingredient control and consumer product information (in Australia and New Zealand).

Implementation timetable:

- ACCORD recommends immediate implementation by the TGA through an Excluded Goods Order – BY 30 JUNE 2005

ACCORD's Recommendation 4

ACCORD notes Draft Report Recommendation 4A

ACCORD supports Draft Report Recommendation 4B

ACCORD supports Draft Report Recommendation 4C

ACCORD recommends that the Joint Agency and/or the relevant regulator adopts the international SPF standards currently accepted by the EU, USA and other comparable countries in addition to the AS/NZS.

Implementation timetable:

- ACCORD seeks immediate implementation of Recommendation 4B through an Excluded Goods Order - BY 30 JUNE 2005.
- ACCORD seeks immediate implementation of Recommendation 4C through an Excluded Goods Order - BY 30 JUNE 2005.

ACCORD's Recommendation 5

ACCORD does not support the maintenance of the status quo for antibacterial products, i.e. that this group of products be registered as Class II medicines.

ACCORD is extremely concerned that our recommendations for a stratified approach were not accepted as the pragmatic solution to the overregulation of this class of products. However, we support the recommendation for the establishment of a review committee to further explore this issue and to make recommendations on the appropriate controls for this group of products in order to finally put to bed the theoretical resistance issues.

ACCORD recommends a revised Draft Report Recommendation 5 as follows:

> An Antibacterial Working Party will be established by the TGA Group of Regulators (including NICNAS) and in equal partnership with industry and in consultation with relevant stakeholders and experts in public health and microbiology to determine whether the routine domestic use of hand washes containing an antibacterial agent (irrespective of the stated purposes of the product) gives rise to the developments of resistant strains of bacteria.
>
> The Antibacterial Working Party in drafting its report will make recommendations to the Department of Health and Ageing on the appropriate classification of these products across the cosmetic/therapeutic interface.

Implementation timetable

- The TGA and NICNAS convene the Antibacterial Working Party immediately with a requirement to provide a Final Report to the Department of Health and Ageing – BY 31 OCTOBER 2005.

ACCORD's Recommendation 6

ACCORD does not support Draft Report Recommendation 6.

ACCORD recommends that anti-acne skin cleaners and anti-acne products that cleanse and/or help control, treat or prevent acne and do not contain any scheduled substances, should be treated as excluded goods.

ACCORD recommends that such products containing scheduled substances should be classified as therapeutic products and described as Class I medicines.

Implementation timetable

- ACCORD seeks immediate implementation through an Excluded Goods Order - BY 30 JUNE 2005

ACCORD's Recommendation 7

ACCORD does not support Draft Report Recommendation 7A and recommends that these products be treated as excluded goods.

ACCORD supports Report Recommendation 7B.

ACCORD supports in-principle Report Recommendation 7C but suggests a minor rewording for clarification:

> *Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion and that contain an antibacterial substance for freshening breath or fighting plaque and where no therapeutic claims are made for the antibacterial substance should not be classified as therapeutic products.*

ACCORD supports Draft Report Recommendation 7D

Implementation timetable

- ACCORD seeks immediate implementation of al elements of Report Recommendation 7 through an Excluded Goods Order - BY 30 JUNE 2005.

ACCORD's Recommendation 8

ACCORD does not support Draft Report Recommendation 8.

ACCORD recommends that personal lubricants without therapeutic claims should become excluded goods.

Implementation timetable:

- ACCORD recommends that the TGA immediately exempt personal lubricants without therapeutic claims through the application of an Excluded Goods Order – BY 30 JUNE 2005.

Hand wipes

ACCORD accepts the Draft Report's recommendation that hand wipes that contain an antibacterial agent and make antibacterial claims should be regulated in the same way as antibacterial skin washes and the same stratified approach as suggested for antibacterial skin washed in Recommendation 6 should be applied. ACCORD notes that this class of product will be addressed by the working group established to implement Recommendation 5.

Medicated soaps

ACCORD considers medicated soaps have been overlooked in the review process. Currently medicated soaps are registered with an exclusion from requiring GMP. Consideration should be given to bringing these low risk products in line with the suggested approach for the other products currently at the cosmetic/therapeutic interface. ACCORD would argue that medicated soaps should be treated as excluded goods. However, ACCORD would support the inclusion of medicated soaps in the review to be conducted by the working party established to implement Recommendation 5.

Blemish sticks

ACCORD supports the Draft Report's findings regarding the treatment of this group of products and supports the status quo for blemish sticks.

Personal Insect Repellents

ACCORD notes that personal insect repellents are also another category of low risk product at the interface of therapeutic and agricultural and veterinary interface. This category of good is currently classified as exempt by the TGA but given the nature of these goods, should also be considered in this Review process. Personal insect repellents are included in the definition of cosmetic in New Zealand.

1. General Comments

ACCORD welcomed the release of the Draft Report in March 2005 regarding this as a significant milestone given our involvement with this issue for a number of years. ACCORD is disappointed that in the release of the Draft Report, the views of the Australian and New Zealand governments regarding their position in respect of each recommendation was unknown, and this continues to be the situation.

The catalyst for the review of products at the cosmetic/therapeutic interface was Recommendation 5.4 from the Low Regulatory Concern Chemicals (LRCC) reform initiative undertaken by NICNAS in collaboration with industry and the community. The original timetable for implementation of Recommendation 5.4 as outlined in NICNAS's LRCC Implementation Strategy in July 2003 was for a report to be provided to the Parliamentary Secretary to the Minister for Health and Ageing by December 2003. While it is heartening to see that many of the recommendations contained in the LRCC report have been implemented for some time, disappointingly, Recommendation 5.4 is still outstanding.

1.1 Identification of 'low regulatory concern' categories

The aim of the LRCC reforms was to identify chemicals which presented a low regulatory concern to the industrial chemicals regulator, and because of certain characteristics, the regulatory response for this category of chemicals would be different to that for high risk chemicals. A risk management process for low regulatory chemicals is consistent with the Council of Australian Government's (COAG) approach to efficient risk resource allocation.

The approach adopted during the reform process involved NICNAS and industry identifying categories where low regulatory concern already existed based on experience over the range of new chemical assessments/applications processed over the past six years. A preliminary review by NICNAS identified a number of circumstances where reduced costs and/or data requirements are supported and/or where reduced assessment requirements may apply. These areas were explored with industry and the community with a view to defining LRCC to provide certainty to industry. A single definition of LRCC was not possible except in the most generic sense:

> *Chemicals could qualify for reduced regulatory input on the basis of a definition of low risk or where regulatory input from elsewhere is sufficient to meet Australian requirements.*

The introduction of new LRCC categories within the existing framework optimises risk-resource allocation in the industrial chemicals assessment process ensuring that NICNAS's important resources are used efficiently and regulatory costs to industry and the community are kept down. The risk resource allocation for the regulation of these low regulatory concern chemicals has not diminished public health, worker safety and/or environmental standards.

ACCORD is disappointed that the same intellectual rigour and approach in the treatment of this group of low risk interface products was not adopted by the independent consultant in undertaking his review. One of the Review's Terms of Reference (TOR) was that regulatory reform will be undertaken in accordance with the 1997 COAG

Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG principles). The Draft Report and its recommendations do not appear to apply the following COAG principles in the analysis, in particular, the following points are relevant:

1. The consultant did not ask the most basic and first question of the COAG principles, *Is the regulation needed – where is the market failure?*(p5);

2. The COAG Principles state that *when asserting the need for regulation, the essential first step is to review the adequacy of existing bodies of law (e.g. trade practices, consumer protection and product liability) which wherever possible should be used instead of industry specific regulation* (p5). The Consultant dismissed existing alternatives such as the Australian Government's industrial chemicals regulator and the Australian Government's consumer protection provisions as inadequate and inferior to the protections offered by the TGA Act indicating a personal bias which ACCORD members regarded as unprofessional for a report of this importance;

3. The consultant ignored the COAG principle which states that *the burden of proof that a regulation is necessary remains with the proponents of regulatory action* (p7);

4. The Consultant chose to ignore the COAG requirement for minimizing the impact of regulation - *working from an initial presumption against new or increased regulation, the overall goal is the effective enforcement of stated objectives – legislation should entail the minimum necessary amount of regulation to achieve the objectives* (p7); and

5. The Consultant failed to take into account the COAG requirement that regulatory action *should not restrict international trade,* and if putting forward a proposal for higher regulatory standards then scientific justification for the higher standard is required.

Despite ACCORD's reservations regarding the consultant's methodology and the fact that the recommendations do not go as far as ACCORD's recommendations to the Review, we believe that this is a good start and look forward to working with the TGA Group of Regulators to further the reform process in the longer term.

In order to strengthen ACCORD's position and final submission, industry wide information seminars were provided which proved very useful in teasing out issues which other associations and/or other companies had identified. In general, these seminars supported ACCORD's position with regard to the treatment of this group of low risk products. The comments provided below indicate the views of ACCORD's members. Where there has not been agreement on an approach, this has been identified. Some of ACCORD's members may also be providing their own submissions on the Draft Report.

1.2 Regulatory principles – efficient risk resource management

ACCORD supports the Australian Government's approach to regulatory best practice and recommends that the COAG principles should be rigorously applied to any regulatory decisions proposed by the TGA Group of Regulators and the future Joint

Agency to the Joint Ministerial Council. ACCORD supports the following as good regulatory practice principles.

Regulatory solutions should:

- be the minimum required to achieve the stated objectives;
- adopt a risk management approach to forming and administering regulation;
- minimize the impact on competition;
- be compatible with international standards and practices;
- cause no restriction to international trade;
- be developed in consultation with the groups most affected and be subject to regular review;
- be flexible, not prescriptive and be compatible with the business operating environment
- standardize the exercise of bureaucratic discretion; and
- have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.

1.3 Effective Controls

It is ACCORD's recommendation that the majority of identified products can and should be treated as excluded goods and regulated through the existing public health and safety and consumer safety and labeling controls as provided by the:

- *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA);
- the *Trade Practices Act 1974* (TPA) and in particular the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991; and
- where relevant, specified performance and/or safety standards such as the AS/NZ standard for sunscreens.

In addition, the management of scheduled substances through the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) provides another level of control which is legislatively unpinned to ensure public health and safety standards are maintained through minimum regulation. These controls would be in addition to complementary legislative amendments and support via the Therapeutic Goods legislation e.g. Excluded Goods Orders, and effective self-regulation through improved guidance on acceptable cosmetic claims and industry benchmarks.

ACCORD's suggested approach is consistent with COAG Principles regarding the utilisation of existing bodies of law rather than industry specific legislation. ACCORD does not support the Draft Report's concern regarding a regulatory vacuum. This is not a possibility in Australia because of the nature of the regulatory controls for chemicals. ACCORD is of the view that the existing bodies of law (such as ICNA and trade practices) provide highly effective and responsive regulatory controls. The recent

examples of the Australian Competition and Consumer Commission's (ACCC) involvement in labeling of children's cosmetic products and food products making therapeutic claims provide excellent examples of the adequacy, timeliness and responsiveness of the ACCC to protect the consumer interest.

1.4 Therapeutic Use/Goods Definition

The current Australian definition of therapeutic use (and therefore a therapeutic good), if interpreted to its extreme, is very broad and indeed potentially infinite. In particular, clauses –

a) preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury in persons or animals; or

b) influencing, inhibiting or modifying a physiological process in persons or animals.

There is however current precedent for goods making therapeutic claims to be regulated as cosmetics in Australia as detailed on the Excluded Goods Order e.g. for improvements to oral hygiene and prevention of tooth decay. ACCORD is not recommending changes to the above definition, but rather agreement of those product categories that can be effectively regulated as Excluded Goods on the basis of their low risk and low regulatory concern.

1.5 Good Manufacturing Practice

A fundamental area of concern and practical regulatory difficulty with the majority of the specified product categories relates to the requirement under the Therapeutic Goods Act for GMP licensing and to the same level as that of internal medicines.

Cosmetic companies generate quality products, most operating locally and overseas with self regulation to ISO 9001 and integrated Total Quality Management (TQM) and /or Total Product Management (TPM) programs.

The capital investment demanded in Australia and/or overseas sites to ensure these products comply with an onerous level of medicinal GMP (one designed for much higher risk products), as well as the additional ongoing compliance costs, provide little value-add to topical products such as cosmetics and sunscreens with moisturisers. It is therefore very difficult to justify on a cost benefit basis, particularly given the relative size of the Australian and New Zealand markets that GMP licensing be required for this group of products. Further, these requirements are not consistent with international requirements and will result in unnecessary barriers to trade for Australian and potentially for New Zealand industries wishing to compete in international markets by adding costs with no benefits in quality, safety or efficacy.

Further, from a risk management perspective, the allocation of precious resources from the TGA to audit and control local and overseas manufacturing facilities for these products seems unjustified and we would argue that the same general principles of quality control and manufacturing as utilized by the cosmetic industry is more appropriate.

1.6 *Safety Standard/Performance Requirements*

Where safety standards and/or performance requirements are deemed necessary in any of the specified product categories, e.g. antibacterial or SPF claims, ACCORD recommends the adoption of existing self-regulatory mechanisms such as the Code of Practice for Household and Commercial Cleaning Products Claiming Antibacterial Action (Antibacterial Code) or the incorporation of recognised standards into the TPA and/or the ICNA regulations and/or guidance material depending on the nature of the final product classification.

ACCORD's recommendation for minimum effective risk based regulation and the adoption of COAG principles has only been met in part by some of the recommendations in the Draft Report as outlined above. However the recommendations do not go far enough, and are therefore inconsistent with the TGA's objective for efficient regulation through appropriate risk resource allocation and the COAG principles. In framing a new regulatory approach to the treatment of these low risk products, the Draft Report does not give due consideration to using the existing alternatives to the TGA legislation such as those outlined above, again a significant oversight of the COAG requirements.

We note that in some areas of regulation the Draft Report proposes to move products previously treated as cosmetic in New Zealand to therapeutic products under the Joint Australian and New Zealand Agency, e.g. personal lubricants, primary sunscreens and antibacterial products. ACCORD is concerned that the proposals seek to widen the regulatory net rather than look at innovative ways to put in place minimum effective regulation. We would argue this is again contrary to minimum effective regulation and the principles of the Trans Tasman Mutual Recognition Agreement (TTMRA) where an equivalent standard in one country is recognised in another. The COAG Principles require the where a higher regulatory action is recommended then this should be justified. The Draft Report does not contain any data to demonstrate that the proposed increased level of regulatory activity for New Zealand is justified and has not demonstrated the market failure in that country which requires a higher degree of intervention. Similarly, the Draft Report has not provided any data or evidence to demonstrate that the current high levels of intervention for a small range of interface products is required in Australia. A quick scan of the TGA's own Adverse Drug Reporting Scheme would indicate that no problems have been identified with this range of products.

1.7 *Cosmetics regulation reform in Australia*

The aim of the recent reforms for cosmetics in Australia was to align the regulatory system with international requirements as a further step towards global harmonization of cosmetics regulation. The cosmetics industry is a highly globalised industry with companies marketing brand products across international boundaries. In recognition of this, and the fact that the Australian market accounts for only 1.2% of this market, the LRCC reforms were aimed at reducing regulatory and other barriers to trade to ensure that Australian consumers were not disadvantaged and that Australian manufacturers were able to be responsive to market innovations without being unduly constrained by outmoded regulatory requirements.

When products are defined as therapeutic goods in Australia contrary to a cosmetic in other countries, the TGA usually requires additional assessment beyond which would be required if the products were regulated as a cosmetic in Australia. In pursuing its specific reform objectives for cosmetic through the LRCC it was hoped that Australia would be able to broadly align with international cosmetic product classifications and permissible international cosmetic ingredient lists to minimize Australia specific data generation and/or assessment. This was seen as a priority by the various industry sectors participating in the LRCC review process. This objective is under threat as a result of the recommendations contained in the Draft Report as they do little to harmonise Australia with the international community and potentially decrease rather than increase trade between Australia and New Zealand for this class of low risk products. This flies in the face of the objective of the TTMRA and Closer Economic Relations (CER) regarding the removal of regulatory barriers for the movement of goods between Australia and New Zealand. The industry had high hopes for reform and a quick resolution to the issues identified at the interface given the then Parliamentary Secretary's commitment to the LRCC reform process in 2003.

2. *Analysis of the Draft Report's Recommendations*

2.1 Recommendation 1. Cosmetics

Cosmetics claims guidelines should be established by the Joint Agency, in consultation with stakeholders and other regulators, to clarify the distinction between cosmetics and therapeutic products. These guidelines should be underpinned by legislation if necessary.

ACCORD's Comments:

ACCORD supports the proposal for a regulatory tool to provide clarity to industry on the distinction between a cosmetic and therapeutic product. ACCORD supports the Draft Report's findings that the regulatory agencies at the interface issues i.e. NICNAS, the ACCC and the TGA should be the decision makers and not the National Coordination Committee on Therapeutic Goods (NCCTG). ACCORD is of the view that this work can commence immediately and it is not necessary to wait for the establishment of the Joint Agency. Both NICNAS and the ACCC have a consistent definition of cosmetic in their respective legislation while the therapeutic goods legislation does not include a definition of cosmetic and has no jurisdiction over this class of products.

ACCORD notes that the current Cosmetic Claims Guidelines developed in May 1997 are out of date and do not reflect current market practices nor meet consumer expectations and are not consistent with international marketing guidelines in comparable countries.

Consistent with ACCORD's approach to regulatory best practice, we are of the view that the guidance material should be developed by the regulators and industry as equal partners to ensure that they do not pose an unnecessary burden on industry. The guidance material can be reviewed and updated as required to accommodate any changes arising from the Joint Agency. While ACCORD is of the view that the Guidance Note does not require legislative underpinning to enable implementation, this issue can be explored during its development.

All advertising standards and complaints are handled by the one body in New Zealand, the Advertising Standards Authority Inc (ASA). The ASA manages a self regulatory system of advertising standards. The ASA has developed a series of codes to cover the entire range of advertising activity; which includes 3 codes related to therapeutic products and services. The Advertising Standards Complaints Board hears complaints about all advertising in New Zealand. There is no specialist therapeutic advertising standards and complaints body in New Zealand as there is in Australia. ACCORD supports this model of self-regulation as it avoids unnecessary duplication of advertising complaints bodies as exists in Australia.

ACCORD members raised the issue of rightful ownership of the Guidance Note, i.e. the ACCC because of its role in cosmetics labeling or NICNAS as the cosmetic's regulator. It was agreed that these issues would be resolved by the working party established to develop the regulatory guidance note.

ACCORD **supports** Recommendation 1 subject to the acceptance that NICNAS, the ACCC, the TGA and industry are equal partners in the development of the Cosmetic Regulatory Guidance Note.

ACCORD's Recommendation 1

ACCORD recommends a rewording of the Draft Report Recommendation 1 to reflect the partnership approach and role of industry, as follows:

> **A Cosmetic Regulatory Guidance Note should be established by NICNAS, the ACCC and the TGA in equal partnership with industry and in consultation with stakeholders and other relevant regulators to clarify the distinction between cosmetic and therapeutic products.**

Implementation timetable:

- **ACCORD recommends immediate establishment of the government and industry working group to develop the Guidance Note - ESTABLISHED AND MEETING 1 - BY 31 AUGUST 2005.**

2.2 Recommendation 2. Antiperspirants

Antiperspirant preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency. Antiperspirants other than these should be regulated as Class II medicines.

ACCORD's Comments

ACCORD has argued that as deodorants are already adequately controlled as cosmetics i.e. excluded goods, antiperspirants could also be effectively managed in the same way i.e. by control and assessment of ingredients via NICNAS and total ingredient disclosure as required by the ACCC's labeling guidelines.

The Draft Report accepts that antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency as they 'unquestionably behave in the marketplace as cosmetics or toiletries' (p49). The Draft report notes that future products which might be formulated as antiperspirants containing ingredients other than those proposed for the classification as cosmetics should be automatically regulated as Class II (i.e. registrable) medicines under the Joint Agency. ACCORD's members do not accept that ingredients other than those listed already nominated automatically makes antiperspirants Class II medicines. The current system of clearance of new chemicals through NICNAS is sufficient to safeguard for consumer safety. Further product efficacy claims made on the product or pack and in advertising can be controlled through the ACCC. ACCORD members have proposed that other acceptable antiperspirant ingredients could include those allowed by the FDA or the EU Cosmetics Directive for the same purpose. ACCORD will continue to work with the TGA and NICNAS on an acceptable way forward for the inclusion of additional ingredients.

ACCORD's Recommendation 2

ACCORD supports antiperspirant preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency.

ACCORD does not support that antiperspirants other than those that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium should be regulated as Class II medicines.

Implementation timetable:

- **ACCORD recommends immediate implementation of Recommendation 2 by the TGA through an Excluded Goods Order – BY 30 JUNE 2005**
- **The TGA and NICNAS convene an industry working party to identify a way forward regarding the treatment of additional ingredients for antiperspirant products – ESTABLISHED AND MEETING 1 - BY 31 AUGUST 2005.**

2.3 Recommendation 3. Antidandruff preparations

Antidandruff shampoos, hairdressings or lotions should be classified as therapeutic products by the Joint Agency.

If the antidandruff product is not included in any Schedule to the SUSDP,

(a) the product should be exempted from licensing; and

(b) the premises where the product is manufactured should be exempt from licensing.

ACCORD's Comments

ACCORD has always argued that all lotions and shampoos used for the prevention or treatment of dandruff should be treated as excluded goods unless they contain a scheduled ingredient. ACCORD has never accepted that any strong argument exists, and the Draft Report also, does not provide any strong arguments as to why these preparations could not become 'excluded goods' with the controls and labeling limitations being exerted by scheduling, NICNAS, the ACCC and the revised cosmetic guidance material. Antidandruff shampoos unquestionably behave in the market place as cosmetic products, they are stocked with other shampoos which are regulated as cosmetics and yet have less consumer information available on them because they are regulated as therapeutic goods. The treatment of antidandruff preparations as cosmetics will address this anomaly. The current system of clearance of chemicals (actives and excipients) through NICNAS is appropriate to safeguard for consumer safety. Scheduling provides and additional of level of public health, safety and labeling when necessary. Further product claims made on the product or pack and in advertising can be controlled through the ACCC and if necessary the proposed Cosmetic Regulatory Guidance Note.

ACCORD's Recommendation 3

ACCORD does not support this recommendation.

ACCORD recommends that antidandruff products become 'excluded goods' with improved ingredient control and consumer product information (in Australia and New Zealand).

Implementation timetable:

- **ACCORD recommends immediate implementation by the TGA through an Excluded Goods Order – BY 30 JUNE 2005**

2.4 Recommendation 4. Sunscreens

A. Primary sunscreens where SPF is≥ 4 *should be classed as therapeutic products and described as Class I medicines.*

As a condition of licensing, the SPF of each product must be determined by the method prescribed by AS/NZS 2604:1998 for the particular product. The Joint Agency should consider moving to an acceptable international standard when one becomes available.

The Joint Agency Rules should specify that all performance statements and markings on the product label (both "mandatory" and "optional") are expressed in the manner prescribed by AS/NZS 2604:1998 and no other.

B. Primary sunscreen products where the SPF is <4 *should not be classified as therapeutic products.*

C. Moisturisers that contain a sunscreen as and for a secondary purpose where the SPF ≥4 *should not be classified as therapeutic products provided:*

(a) *they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and*

(b) *any SPF or equivalent category description is disclosed on the label;*

(c) *the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation; and*

(d) *the SPF as disclosed on the label does not exceed 20; and*

(e) *the formulation is not water-resistant; and*

(f) *there is an expiry date or use by date on the label if the product is not stable for at least 36 months; and*

(g) *no therapeutic claims, including any representation about skin cancer, are made; and*

(h) *any representation about anti-ageing can be made only if the product is defined as a "broad-spectrum product" within the meaning of AS/NZS 2604:1998; and*

(i) *the pack size does not exceed 300 mL or 300 g; and*

(j) *all performance statements and markings (both "mandatory" and "optional") are expressed on the product label in the manner prescribed by AS/NZS 2604:1998 and no other.*

An Australia- or New Zealand- specific disclaimer or advisory statement to the effect that the product is only for use as a cosmetic should not be compulsory on moisturizers that are secondary sunscreens.

ACCORD's Comments

Moisturisers with sunscreens defined as secondary sunscreens

ACCORD strongly supports the view that moisturizers with SPF should be 'excluded goods' with controls exerted by NICNAS, the ACCC and underpinned by the AS/NZS standard or equivalent acceptable international standards. Primary claims on these products relate to moisturizing and secondary claims are limited to identification of SPF.

ACCORD members have not recommended any changes to the regulation of those products defined as primary sunscreens although we note that these are not regulated as therapeutic products in New Zealand and in the European Union.

In previous submissions regarding the treatment of moisturizer with SPF as cosmetics, we brought to the TGA's attention information about market surveys regarding consumer recognition of this class of products as cosmetics. A copy of one such submission is provided at Attachment 2 for your information. In addition, the Skin & Cancer Foundation has made supportive submissions in the past to the TGA on moisturizers with SPF. In particular, Dr Margaret Stewart, former Chief Executive Officer and Medical Director of The Skin & Cancer Foundation Australia stated:

"All dermatologists are supportive of maximum protection sunscreens and other aids to protect individuals from the sun and to reduce skin cancer. Dermatologists also want

labeling of all ingredients on packs for safety reasons. The expansion of the use of sun protective products and an increase in ingredient labeling would be both enhanced if moisturizers with SPF were classified as cosmetics."

The Draft recommendation proposes 10 conditions to improve the regulation of moisturizers containing sunscreens. These regulatory conditions will:

- improve the information available to consumers so they are better able to determine their level of incidental sun protection;
- re-enforce in the market place the important distinction between primary sunscreens and moisturizers with sun screening capability; and
- provide safeguards necessary to ensure that moisturizers meeting these conditions do not need to be considered as therapeutic goods.

The majority of ACCORD members support the recommended approach in the Draft Report for the treatment of primary and secondary sunscreens. A few members have expressed reservations about any changes and support the status quo. These members have expressed their concerns about the effect of the proposed changes on Australian manufacturing and the poor return on the high investment already incurred through the impost of the unique Australian regulatory requirements. In addition, concerns were raised about ensuring that adequate compliance systems are in place.

Some ACCORD members considered that an additional safeguard could be that the labeling provisions of the AS/NZS standard for secondary sunscreens be incorporated into the Trade Practices (Consumer Product Information Standard) (Cosmetics) Regulation 1991. However, on balance this was deemed pre-emptive as the 10 conditions were regarded as more than adequate controls. Additionally, members considered the issue of the specific disclaimer as raised by the Draft report to the effect that the product is only for use as a cosmetic and agreed with the Draft Report that this should not be compulsory.

ACCORD therefore supports Recommendation 4C as a pragmatic compromise between the various sectional interests. We believe that there is no reason for delay in implementing this recommendation as it has been a priority for the majority of ACCORD's members since 2000. We believe that this recommendation will go a long way towards harmonizing Australia with international standards which will benefit Australian industry and consumers alike.

ACCORD supports the Draft Report's finding that sunscreens for lip use or tinted facial makeup should continue to be treated as cosmetics.

International sunscreen standard

We strongly support the recommendation that the Joint Agency move to recognise international standards for testing of sunscreens. We believe that for static SPF testing this situation already exists and has existed for some time. In the USA the FDA method as described in the "Sunscreen Drug Products For over the Counter Use Final Monograph (May 1999)" has been used for many years and is widely accepted as a reproducible and acceptable method for determining static SPF. It is likely that the number of tests done using this method is a magnitude greater than the number done by the method of the AS/NZS 2604:1998. There is also the "International Sun Protection Factor (SPF) Test Method" used in Europe, Japan and South Africa (Feb

2003) which is also recognised as an international standard for static SPF testing. The Canadian position on SPF testing methodology states:

> It should be noted that absolutely no attempt has been made here to describe or establish an official method. The conditions for determining an SPF depend on the product being tested, and any methodology development or modification necessary to validate claims is the manufacturer's responsibility.

It can be therefore argued that there are international test methods already available for Static SPF testing and have been available for many years and these should be recognised and approved as alternatives to the AS/NZS2604:1998. Work on a single world or ISO sunscreen testing standard appears to be some years away and deferral to await such a standard is unwarranted. The AS/NZ standard method has not been updated for over seven years and if the guiding principles of the Draft Report are to recognise international best practice then continued acceptance of only the AS/NZS for static SPF testing appears to be no more than a barrier to trade. ACCORD has a representative on the technical working group considering the revision of the Australian Standard as well as participating in international fora on the development of an internationally acceptable standard.

ACCORD's Recommendation 4

ACCORD notes Draft Report Recommendation 4A

ACCORD supports Draft Report Recommendation 4B

ACCORD supports Draft Report Recommendation 4C

ACCORD recommends that the Joint Agency and/or the relevant regulator adopts the international SPF standards currently accepted by the EU, USA and other comparable countries in addition to the AS/NZS.

Implementation timetable:

- **ACCORD seeks immediate implementation of Recommendation 4B through an Excluded Goods Order - BY 30 JUNE 2005.**
- **ACCORD seeks immediate implementation of Recommendation 4C through an Excluded Goods Order - BY 30 JUNE 2005.**

2.5 Recommendation 5. Antibacterial skin washes

A. Antibacterial skin washes *(including antibacterial hand wipes) should be classified as therapeutic products and described as Class II medicines.*

B. *The Joint Agency, in conjunction with NICNAS, ERMA and other regulators and in consultation with stakeholders and experts in public health and microbiology determine whether the routine domestic use of hand washes containing an antibacterial agent (irrespective of the stated purposes of the product):*

(a) *gives rise to the development of resistant strains of bacteria;*

(b) *has a deleterious effect on micro-organisms that are harmless or whose presence has, in some way, a beneficial effect in humans.*

If the decision is that there is no risk to public health from the routine domestic use of hand washes containing an antibacterial agent, further consideration should be given to the appropriate classification of these products across the therapeutic / cosmetic interface.

ACCORD's Comments:

It is ACCORD's view that the Draft Report has introduced elements into the review which are inappropriate under the terms of reference for the identification and treatment of products at the interface. In the treatment of antibacterial products, the Draft Report inappropriately infers that the presence of antibacterial has no legitimate therapeutic or hygiene role and may be, in public health terms, deleterious. There is no evidence for this statement. This class of product is regulated in the USA and Canada as a cosmetic. The regulatory controls put in place by the TGA are a substantial barrier to trade as the cost imposts makes them uncompetitive in these markets. Australia is the only jurisdiction regulating the entire range of these products as therapeutics.

ACCORD considers that a stratified approach for this broad product category based on the nature of the claim, such that general household/domestic anti-bacterial skin washes, medicated soaps and wipes for use on unbroken skin could become 'excluded goods', those used for commercial food, specialty and occupational areas be regulated as 'listable' and the remainder eg surgical use, remain 'registerable'. ACCORD acknowledges that the Draft Report found merit in this approach but is disappointed that the Draft Report did not put to bed the so called concerns regarding this class of products. Researchers have not shown any link between antibacterial hand washes and antibiotic resistance. In 1997, the USA Food and Drug Administration convened an expert panel to review the scientific knowledge available and concluded that antibacterial washes were not a public health concern. This continues to be the case to the present day.

GMP licensing would still be required for 'listable' and 'registerable' categories, with relevant performance standards being specified in the associated regulations/guidelines for such products.

Relevant controls for excluded skin washes, medicated soaps and wipes can be exerted via scheduling, NICNAS, the ACCC, the revised cosmetic guidance material with relevant performance criteria specified in an expanded industry code such as the Antibacterial Code. Precedent already exists for delineations of this type of product in the therapeutic devices area, drawing the parallel with these products as skin disinfectants i.e. not antiseptics.

ACCORD **does not support** the establishment of a TGA Expert Committee as prescribed under the TGA legislation, but rather the establishment of a representative group of key stakeholders and regulators. ACCORD would argue that the Working Party established to review the issue of antibacterial and taking into account points (a) and (b) of Recommendation 5, should also be able to make recommendations to the appropriate policy body, presumably the Department of Health and Ageing on the appropriate classification for these products for immediate adoption.

ACCORD's Recommendation 5

ACCORD does not support the maintenance of the status quo for antibacterial products, i.e. that this group of products be registered as Class II medicines.

ACCORD is extremely concerned that our recommendations for a stratified approach were not accepted as the pragmatic solution to the overregulation of this class of products. However, we support the recommendation for the establishment of a review committee to further explore this issue and to make recommendations on the appropriate controls for this group of products in order to finally put to bed the theoretical resistance issues.

ACCORD recommends a revised Draft Report Recommendation 5 as follows:

> **An Antibacterial Working Party will be established by the TGA Group of Regulators (including NICNAS) and in equal partnership with industry and in consultation with relevant stakeholders and experts in public health and microbiology to determine whether the routine domestic use of hand washes containing an antibacterial agent (irrespective of the stated purposes of the product) gives rise to the developments of resistant strains of bacteria.**
>
> **The Antibacterial Working Party in drafting its report will make recommendations to the Department of Health and Ageing on the appropriate classification of these products across the cosmetic/therapeutic interface.**

Implementation timetable

- **The TGA and NICNAS convene the Antibacterial Working Party immediately with a requirement to provide a Final Report to the Department of Health and Ageing – BY 31 OCTOBER 2005.**

2.6 Recommendation 6. Antibacterial skin cleansers (anti-acne products)

Antibacterial washes that are represented to prevent or treat acne or pimples should be classified as therapeutic products and described as Class II medicines.

ACCORD's Comments

The Draft Report's sole reason for maintaining the existing level of control on these particular antibacterial skin cleansers appears to be that consumers will be unable to make informed choices about these products because liberalizing these controls would:

> *enable manufacturers of acne washes to make claims that are for frank therapeutic use without any real evidence that the products, and specifically the antibacterial agent in it, does any good.* (p79)

This group of products is currently 'exempt' where claims relate to use as skin cleansers for acne-prone skin. ACCORD's view is that the category could be transferred to

'excluded goods' and further claims such as 'helps control, treat or prevent acne' by virtue of cleansing the skin could be clarified in the revised cosmetic guidance material. The current system of clearance of chemicals (actives and excipients) through NICNAS is appropriate to safeguard for consumer safety. Scheduling provides and additional of level of public health, safety and labeling when necessary. Further product claims made on the product or pack and in advertising can be controlled through the ACCC and if necessary the proposed Cosmetic Regulatory Guidance Note.

ACCORD's Recommendation 6

ACCORD does not support Draft Report Recommendation 6.

ACCORD recommends that anti-acne skin cleaners and anti-acne products that cleanse and/or help control, treat or prevent acne and do not contain any scheduled substances, should be treated as excluded goods.

ACCORD recommends that such products containing scheduled substances should be classified as therapeutic products and described as Class I medicines.

Implementation timetable

- **ACCORD seeks immediate implementation through an Excluded Goods Order - BY 30 JUNE 2005**

2.7 Recommendation 7. Toothpastes and mouthwashes

A. Desensitising toothpastes and gels *should be classified as therapeutic products and described as Class II medicines.*

B. Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion *and that do not make any claim (except cosmetic claims) other than preventing caries or preventing or removing plaque should not be classified as therapeutic products.*

C. Mouthwashes that contain an antibacterial substance *for freshening the breath or for fighting plaque and where no therapeutic claims are made should not be classified as therapeutic products.*

D. Mouthwashes that contain 220 mg/L or less of fluoride ion *and that do not make any claim (except cosmetic claims) other then preventing caries or preventing or removing plaque should not be classified as therapeutic products.*

ACCORD's Comments

ACCORD is of the view that the Draft Report does not demonstrate any justification to increase the level of regulation for oral hygiene products beyond that which is currently applied in Australia.

In considering its recommended approach to this section of the Draft Report, the consultant appears to be making the observation that only the TGA can ensure that manufacturers would have to prove the safety and efficacy of their products. It is

inappropriately suggested that if the controls on desensitizing toothpastes and gels were removed such as through the application of an Excluded Goods Order, then the consumer would be vulnerable. The Draft Report accepts that these products are a low regulatory risk, but the consultant appears unable to develop another model where the public health and safety aspects can be safeguarded through other regulatory controls such as scheduling, the ICNA and TPA Acts.

Desensitizing toothpastes are regulated in Australia as 'registered therapeutic goods'. Given the nature of this claim i.e. the dental profession consider sensitive teeth to be less clinical significance than the prevention of tooth decay, ACCORD's recommendation is that these products which contain (mainly) potassium nitrate or strontium salts could also become 'excluded goods'. ACCORD submits that this is appropriate and consistent with a public health risk approach to the regulation of other toothpastes.

ACCORD is concerned that the Draft Report implies that the public health and safety provisions of the ICNA Act and the consumer protection provision for false and misleading and deceptive conduct and the product safety liability provisions of the TPA are inadequate controls to safeguard consumers against any potential threat of misleading claims on safety and efficacy made by manufacturers. ACCORD rejects these claims. This again goes to the argument of maintaining low risk products which present a low regulatory concern to the TGA but need to ensure that consumer product information is available to provide for informed choice. The treatment of these low risk goods through ICNA and the TPA provisions appears to be an appropriate regulatory solution for this category of low risk products. All relevant and/or necessary controls can be managed the same as for other unscheduled oral hygiene products. As discussed, if necessary, active ingredients utilized in this category could be specified in the relevant regulations.

It was also noted that this product category is regulated as a 'related' product in New Zealand.

ACCORD's Recommendation 7

ACCORD does not support Draft Report Recommendation 7A and recommends that these products be treated as excluded goods.

ACCORD supports Draft Report Recommendation 7B.

ACCORD supports in-principle Draft Report Recommendation 7C but suggests a minor rewording for clarification:

> ***Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion and that contain an antibacterial substance for freshening breath or fighting plaque and where no therapeutic claims are made for the antibacterial substance should not be classified as therapeutic products.***

ACCORD supports Draft Report Recommendation 7D

Implementation timetable

- **ACCORD seeks immediate implementation of al elements of Recommendation 7 through an Excluded Goods Order - BY 30 JUNE 2005.**

2.8 Recommendation 8. Other product categories that may be candidates for reform

Personal lubricants should be classified as therapeutic products, irrespective of any representations that are or are not made.

ACCORD's Comments:

The Draft Report provides little justification for treating personal lubricants as therapeutic products apart from that the public interest *would be best served by bringing all of these products within the ambit of therapeutic appliances.*

In its submission, ACCORD identified that there is considerable confusion within industry as to how such products are currently regulated as therapeutic devices and this was borne out by the Draft Report. The Draft Report notes that personal lubricants can be subject to different sections of the TGA depending on use. However, since the product comes within contact with the mucous membrane and if that membrane is damaged then use of this product might pose a risk to the user. ACCORD does not accept this as a justification for extending existing controls of personal lubricants to a therapeutic product within the Joint Agency regardless of claim.

ACCORD remains of the view that such products should become 'excluded goods' with the controls and labeling limitations being exerted by scheduling, NICNAS, and the ACCC. The proposed cosmetic guidance material could also include reference to personal lubricants and clarify areas of concern identified in the Draft Report.

The majority of ACCORD's members regard personal lubricants as cosmetics with a small number suggesting that personal lubricants with claims should continue to be classified as Class I devices.

ACCORD's Recommendation 8

ACCORD does not support Draft Report Recommendation 8.

ACCORD recommends that personal lubricants without therapeutic claims should become excluded goods.

Implementation timetable:

- **ACCORD recommends that the TGA immediately exempt personal lubricants without therapeutic claims through the application of an Excluded Goods Order – BY 30 JUNE 2005.**

Hand wipes

ACCORD accepts the Draft Report's recommendation that hand wipes that contain an antibacterial agent and make antibacterial claims should be regulated in the same way as antibacterial skin washes and the same stratified approach as suggested for antibacterial skin washed in Recommendation 6 should be applied. ACCORD notes that

this class of product will be addressed by the working group established to implement Recommendation 5.

Medicated soaps

ACCORD considers medicated soaps have been overlooked in the review process. Currently medicated soaps are registered with an exclusion from requiring GMP. Consideration should be given to bringing these low risk products in line with the suggested approach for the other products currently at the cosmetic/therapeutic interface. ACCORD would argue that medicated soaps should be treated as excluded goods. However, ACCORD would support the inclusion of medicated soaps in the review to be conducted by the working party established to implement Recommendation 5.

Blemish sticks

ACCORD supports the Draft Report's findings regarding the treatment of this group of products and supports the status quo for blemish sticks.

Personal Insect Repellents

ACCORD notes that personal insect repellents are also another category of low risk product at the interface of therapeutic and agricultural and veterinary interface. This category of good is currently classified as exempt by the TGA but given the nature of these goods, should also be considered in this Review process. Personal insect repellents are included in the definition of cosmetic in New Zealand.

3. *Concluding Comments*

ACCORD has welcomed the opportunity to respond to the Draft Report and will continue to work with the TGA Group of Regulators to implement the Draft Report's recommendations. ACCORD believes that the immediate implementation of an Excluded Goods Order for this class of products will have significant beneficial outcomes for ACCORD's members. To facilitate the implementation of the Excluded Goods Order, ACCORD has provided a draft Order at Attachment 3 containing the low risk products which should be excluded as soon as possible and preferably by 30 June 2005.

Attachment 1

List of ACCORD Member Companies

May 2005

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

ACCORD Australasia Membership

Advance Chemicals Pty Ltd
Albright & Wilson (Aust) Ltd
Amway of Australia Pty Ltd
Applied Chemicals Pty Ltd
Archem Australia Pty Ltd
Auto Klene Solutions Pty Ltd
Beiersdorf Australia Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Canpoint International Pty Ltd
Castle Chemicals Pty Ltd
Castrol Australia Pty Ltd
Chemetall (Australasia) Pty Ltd
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Clorox Australia Pty Ltd
Creative Brands Pty Ltd
Colgate Palmolive Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
DuPont Chemical Solutions Enterprise
Ecolab Pty Limited
GlaxoSmithKline Consumer Healthcare
G S B Chemical Co Pty Ltd
Healthcare Manufacturing Group
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Jasol Australia
Johnson & Johnson Pacific Pty Ltd
Kao (Australia) Marketing Pty Ltd
Lab 6 Pty Ltd
L'Oreal Australia Pty Ltd
Milestone Chemicals Pty Ltd
Northern Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Recochem Inc
Rohm and Haas Australia Pty Ltd
Scental Pacific Pty Ltd
Selkirk Laboratories Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Unilever Australasia
Whiteley Industries Pty Ltd

Associate Members:

AMS Laboratories Pty Ltd
Cintox Pty Ltd
Competitive Advantage
Dermatest Pty Ltd
DSL Packaging
E-Three & Associates Pty Ltd
Hydro Nova Controls
Middletons Lawyers
Silliker Microtech Laboratories Pty Ltd
Sue Akeroyd & Associates
Tonic Creative
Visy Industrial Packaging

Innovative solutions for healthy living and a quality lifestyle

Attachment 2

ACSPA/CTFA Submission to TGA on Moisturisers with SPF as Cosmetics. 8 April 2003

ACSPA
Australian
Consumer & Specialty
Products Association
ABN 83 205 141 267

C T F A
THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION OF AUSTRALIA INC.
ABN 90 187 366 173

8 April 2003

Mr. Pio Cesarin,
Director, Chemicals and Non Prescription Medicines
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Copies: Mr. Terry Slater, National Manager, TGA
Dr Margaret Hartley, Director, NICNAS
Mr Paul Archer, Head of OTC Medicines Evaluation Section, TGA

Dear Pio,

Re: Moisturisers with SPF as Cosmetics

Firstly we would like to thank you, Paul and Craig for a very constructive meeting on the 20th March 2003.

Our earlier submission dated 7 November 2002 detailed our recommendations for changes to the regulatory responsibility for these products without diminishing public confidence, nor public health and safety standards.

We undertook to get back to you to confirm that moisturisers with SPF are identified and regarded as cosmetics in the market place. Further, to suggest a mechanism to ensure that the change would maintain the distinction between sunscreens and moisturisers with SPF.

Market Research

Industry market research data from a 1999 Perceptor Study identifies the attributes of moisturisers with SPF:

- There were 7 dimensions to explain consumers' preferences and their relative importance were ranked:
  - i. Moisturises 27%
  - ii. Pleasant to use 25%
  - iii. Gentle to Skin 16%
  - iv. Anti Aging 10%
  - v. For Mature Skin 10%
  - vi. UV Protection 6%
  - vii. Other <6%

- The dimension "moisturises" was 4.5 time more important than "UV protection"

- 75% of consumers believed a moisturiser with SPF could help protect against sun damage, but indicated, "they would use a sunscreen in direct sunlight".

In a Habits and Attitude study conducted by industry in 2000, consumers were asked to rate a large number of product attributes for skin products in order of importance to them. Attributes "protects from the sun" and "protects the skin from the environment" both rated less than average for moisturiser attributes such as "cares for the skin" and "leaves skin soft and smooth" – the latter were rated far more important.

We note that a recent Choice magazine article on moisturisers (April 2003, www.choice.com.au) differentiated moisturising products with SPF easily and without question. This is in line with consumer perceptions as detailed above. An earlier Choice article (March 2003) on Hopes, Dreams and $100 Creams complained about the lack of ingredient labelling on some moisturising products with SPF. Choice did not mention however that the reason for this is due to these products not being classified as cosmetics and not requiring ingredient labelling.

Market Data

We have taken 2002 national market data in grocery and pharmacy and graphed the results in Attachment 1. We believe this demonstrates that moisturisers with SPF are not being substituted for sunscreens. These data also support the difference in seasonal buying patterns ie

- sunscreens sell best in summer,
- moisturisers, including those with SPF, sell year round
- moisturisers with SPF tend to grow in the market place at the expense of moisturisers only.

In reviewing the national market data, we note that the relative share of moisturisers with SPF as a percentage of total moisturisers is under 15% (we think about 10%), which appears to be low by international comparison. Although the evidence is anecdotal, we suggest that this low proportion is related to the current classification and licensing as sunscreens in Australia, i.e. companies do not offer full moisturiser ranges in Australia or alternatively sell them as moisturisers without labelling the SPF.

These data confirm that

> *"consumers understand that moisturisers with SPF provide a valuable additional benefit to help protect against intermittent sun exposure and damage but know they are not a substitute for a sunscreen".*

Moisturisers with SPF are considered first and foremost by consumers to be cosmetics.

Therefore, if moisturisers with SPF were treated as cosmetics in the manner and with the regulatory controls we've suggested in our submission date 7 November 2002, we believe such moisturisers would be more available and/or transparently labelled to add

to the important protection available to Australian consumers from casual and intermittent sun exposure.

Safety, quality and efficacy

At our meeting we agreed to review again the points raised by ASMI in their 15 January 2002 letter. Their points are, we believe, addressed in our subsequent submission dated 7 November 2002 as it contained assurances on safety, efficacy and quality that we recommend be mandated as conditions in making moisturisers with SPF excluded therapeutic goods. The key points are summarised in Attachment 2.

Importantly, these issues, such as compliance with the Australian Standard for SPF performance, TGA maintenance of a positive list of approved UV filters, and no other therapeutic claims being made by the products, we agree should be legislatively underpinned by amendment to the Excluded Goods Order.

Maintaining the positioning of moisturisers with SPF as cosmetics

Also during our meeting it was emphasised and agreed by all parties, the importance to clearly maintaining the distinction of these products as cosmetics. It was suggested that a disclaimer may be useful. We have considered this approach and make the following comments.

Given the consumers' ease of differentiation, and the lack of substitution between the products, we have reviewed and identified the fundamental differences between moisturisers with SPF and sunscreens – these are summarised in Attachment 3.

We would recommend that a preferable and more comprehensive way of defining and testing subsequent products in the market place is by the nomination of five delineating attributes that could be used to categorise for the regulatory authorities the two different product types:

- product name – moisturisers with SPF are not called sunscreens
- claims (on label and in advertising) – sun screening claims are always subsidiary to the cosmetic attributes of the product
- usage instructions – instructions are as part of a daily regimen, independent of sun exposure
- package design – packaging is generally not designed for ease of portability or outdoor use
- ingredient disclosure – all ingredients are fully disclosed

We have demonstrated that moisturisers with SPF are perceived by the consumer as cosmetics and with our recommendations for change, we believe we will retain the positioning of moisturisers with SPF as cosmetics, as well as maintaining the current safety, quality and efficacy standards that are particularly expected by the Australian consumer.

Further the Associations believe we can jointly provide additional assistance by establishing a self-regulatory industry control mechanism utilising these attributes to ensure clear delineation of these products, should the regulatory agencies have inquiries and/or require such industry/commercial input and experience.

Both Associations stand ready to meet with you to assist in explaining the approach and recommendations to other stakeholders.

Yours Sincerely

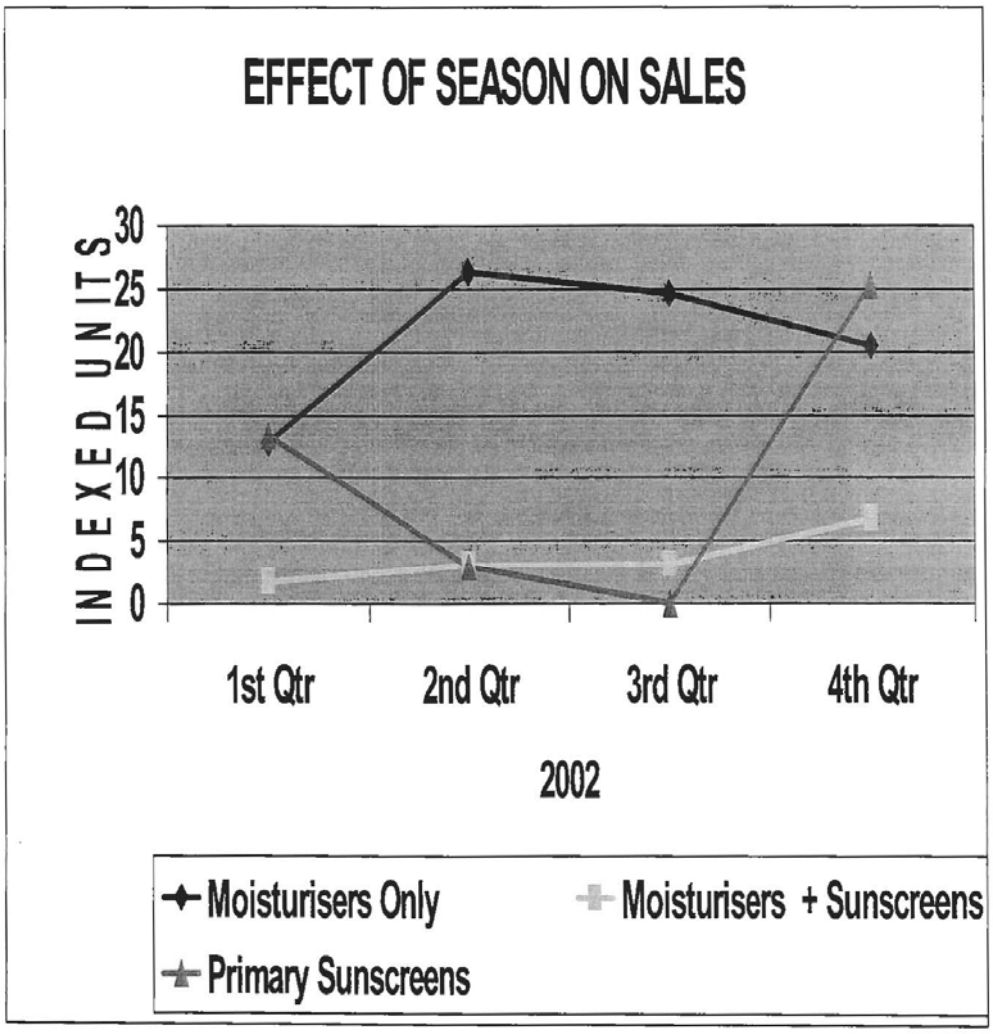
J M Woods
Executive Director
CTFA

Yours Sincerely

Bronwyn Capanna
Executive Director
ACSPA

Attachment 1

SALES OF MOISTURISERS WITH & WITHOUT SPF AND SUNSCREEN PRODUCTS



Attachment 2

Support for Moisturisers with SPF as Cosmetics from ACSPA/CTFA submission of 7 November 2002*

AREA	POINT (*)	DETAILS
Claims	1	In skin care products with sun protection, the sun protection claim must be subsidiary to moisturising and other cosmetic claims. This will be achieved through the adoption of the definition of secondary sunscreens as per the AS/NZS 2604:1998.
	2	Sun protection related claims will only be made in line with AS/NZS 2604:1998 i.e. claims for "Sun Protection Factor (SPF)", "protects against UV light", "protects the skin from certain harmful effects of the suns rays", "broad spectrum", "helps protect against skin ageing caused by the sun" and "helps prevent the signs of premature ageing, fine lines and wrinkles".
	4	No therapeutic claims will be made such as "helps prevent or reduce skin cancer", "helps repair DNA", or any other "unqualified" anti-ageing claims.
Safety	5	Only UV filters already included in products on the ATRG will be used i.e. those commonly used now An efficient process for the addition of new UV filters will need to be agreed separately with TGA, NICNAS and industry.
	6	All ingredients must be or have been notified to NICNAS and comply with NICNAS requirements for permit applications and AICS listing.
	7	No ingredient will be used that is on the EU Cosmetic Directive Annex II "List of substances which must not form part of the composition of cosmetic products". –
	10	All products will have a full list of ingredients included in their labelling as per the ACCC requirements thus giving consumers greater information for purchase decisions and avoidance of irritation problems.
Efficacy	3	All products must be tested in accordance with AS/NZS 2604:1998 and its revisions and test results must be held supporting the SPF or broad spectrum claims being made.
	5	Only UV filters already included in products on the ATRG will be used i.e. those commonly used now An efficient process for the addition of new UV filters will need to be agreed separately with TGA, NICNAS and industry.
	9	Expiry dating of products will occur where products are not stable to at least 36 months.
Quality	8	Manufacturing Plants will comply with the existing cosmetic GMP Codes and requirements.
	9	Expiry dating of products will occur where products are not stable to at least 36 months.

Attachment 3

Differences between Moisturisers with SPF and Sunscreens

There are a number of fundamental differences between Moisturisers with SPF and Sunscreens and example are summarized below.

Attributes	Moisturisers + SPF	Primary Sunscreen
DELINEATORS		
1.Product Name	Moisturiser (Not a Sunscreen)	Sunscreen (Not a Moisturiser)
2. Claims/ Advertising/ Labels	Primary claim - Use to moisturize and protect, Makes skin look good, feel good.	Primary claim - use when in sun to protect from sunburn
3. Usage Instructions	Use daily, morning and/or night. Instructions are to use as part of a daily regimen, indoors or outdoors, in all weather conditions. Instructions are to apply sparingly.	Use when going out into the sun. Instructions are to use liberally and reapply frequently and after prolonged swimming, exercise and towelling dry. Used outdoors.
4. Package Design	Mainly for indoor use. Packs are a fashion statement. Often in opaque glass jars. Packs usually 100ml or less.	For outside use. Larger packs, portable plastic bottles and tubes for easy dispensing. Sizes greater than 100 ml.
5. Ingredient Disclosure	Ingredients fully disclosed.	Excipients not disclosed.

Attributes	Moisturisers + SPF	Primary Sunscreen
OTHER DIFFERENCES		
a) In Store - Display	Sold mainly in Department Stores and Supermarkets and some pharmacy.	Sold mainly in Pharmacies, in Supermarkets and some Department Stores.
b) Store Placement	Separate shelves	Separate shelves
b) Advertising	No other therapeutic claims	Designated therapeutic claims
c) Target Part of Body	Separate products for face and for body and hands.	Generally same product for body and face.

d) Sensory Properties	Face- thicker, but rub in for feel good benefit. Body- thinner, fast rub-in.	Face / Body- compromise on viscosity, slightly greasy feel.
e) Seasonality (see attachment 1)	Face- Use increases when cold Body- Large increase when cold and skin is dry	Face/ Body- Large increase in sales when hot, almost no sales when cold
f) Market Positioning	Multipurpose products to suit type of skin, age of consumer and area- face, body & hands Purchased throughout the year.	Products for sun protection with ranges to cover some niche areas Purchased in Summer.
g) SPF Levels	If with SPF, usually SPF mid range 15-20. Focused on Broad Spectrum.	SPF predominately SPF 30+, with Broad Spectrum, and with water resistance.
h) Pricing	Economical to Premium Pricing.	Generic to Economical Pricing.
i) Substitution	Consumers brand loyalty. Sales figures show consumers do not use these products for sun protection.	Consumers use Sunscreens for sun protection only.
k) GST Exemption	Not qualified for GST Exemption	Can claim GST but must be SPF 15 or 15+, marketed principally a sunscreen, for dermal application and a listed or registered product.
l) Cost per mL	Price average 20c/mL range 6- 100 c/mL	Price average 6c/mL range 4-30 c/mL

Attachment 3

Proposed Additions to Therapeutic Goods (Excluded Goods) Order

ACCORD

Proposed Additions to Therapeutic Goods (Excluded Goods) Order

DRAFT

Commencement
This Order commences on 30 June 2005

DRAFT TABLE ADDITIONS

Col 1 **Item**	**Col 2** **Goods**	**Col 3** **Specified use, advertisement, or presentation for supply**
xx	Deodorant **and antiperspirant** preparations	Use for dermal application or with therapeutic devices. **Only antiperspirant products deriving their properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium are acceptable**. (*Other acceptable antiperspirants ingredients may also include those accepted by the USA Food and Drug Administration and/or the European Union's Cosmetics Directive for the same purpose*)
xx	Oral hygiene preparations, devices or products (including dentifrices, mouthwashes, breath fresheners, brushes and flosses that are not included in a Schedule to the Poisons Standard	If the benefits claimed to result from the use of the goods: (a) are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay; **and/or** **(b) containing desensitising agents that are accepted by the USA Food and Drug Administration and/or the European Union's Cosmetics Directive.** .
xx	**Primary sunscreen products**	**Where the SPF is <4**
xx	**Preparations defined in the Australian/New Zealand Standard for Secondary sunscreen preparations which are primarily for the purpose of moisturizing the skin**	**If the specified use is the primary purpose to moisturize the skin, and:** **(a) they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and** **(b) any SPF or equivalent category description is disclosed on the label;**

		(c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation; and **(d) the SPF as disclosed on the label does not exceed 20; and** **(e) the formulation is not water-resistant; and** **(f) there is an expiry date or use by date on the label if the product is not stable for at least 36 months; and** **(g) no therapeutic claims, including any representation about skin cancer, are made; and** **(h) any representation about anti-ageing can be made only if the product is defined as a "broad-spectrum product" within the meaning of AS/NZS 2604:1998; and** **(i) the pack size does not exceed 300 mL or 300 g; and** **(j) all performance statements and markings (both "mandatory" and "optional") are expressed on the product label in the manner prescribed by AS/NZS 2604:1998 and no other.**
xx	**Antidandruff preparations**	**All lotions, shampoos and hairdressings used in the prevention or treatment of dandruff that do not include any ingredients in a Schedule to the Poisons Standard.**
xx	**Antibacterial products**	**Anti-bacterial skin washes, medicated soaps and skin wipes for use on unbroken skin not making any other therapeutic claims.**
xx	**Anti Acne Skin Cleansers and Anti- Acne Products**	**For the purpose of cleansing and/or helping to control, treat or prevent acne that do not include any ingredients in a Schedule to the Poisons Standard.**
xx	**Personal lubricants**	**Personal lubricants without therapeutic claims that do not include any ingredients in a Schedule to the Poisons Standard.**