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Unilever South Africa
(Pty) Ltd.

16 July 2008

The Chairman
Parliamentary Committee on Health
CAPE TOWN

Attention: Mr Lincoln Vumile James Ngcuku

Email: vmaialamba@parliament.gov.za

Dear Sir

SUBMISSION ON THE PROPOSED MEDICINES AND RELATED SUBSTANCES
AMENDMENT BILL, Notice 475 of 2008 (the " Bill")

INTRODUCTION

Unilever South Africa (Pty) Ltd is a fast moving consumer goods manufacturer in a wide variety of categories in the Home, Personal Care and Food Industry and forms part of the global Unilever Group of Companies which is one of the largest grocery manufacturing companies in the World.

Unilever has been established in South Africa for over 100 years. Some of our more prominent brands include LUX, DOVE, OMO, SKIP, SURF, SUNLIGHT, DOMESTOS, HANDY ANDY, RAMA, FLORA, and KNORR. We have identified that our portfolio of brands and the categories within which we operate, give us a unique ability to add vitality to life of our consumers: inside and outside the body, at home and in the everyday environment. Internationally Unilever has set up programmes to assess, formulate and develop our food and cosmetic products at state-of-the-art laboratories located in Europe, the United Kingdom and the United States. With this in mind, we are open and transparent in our product information and brand communication, using our expertise in consumer marketing to promote a healthy lifestyle. In this context we trust that our submission will be seriously considered.



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AMENDMENT OF SECTION 1 of the MEDICINES and RELATED SUBSTANCES ACT 101 of 1965 ("the Act")

It is our submission, in brief, that the drafters of the legislation have not properly understood the natural distinction between foodstuffs, cosmetics and medicines and have almost disregarded the Foodstuffs, Cosmetics & Disinfectants Act #54 of 1972 as amended and tried to "lump" foodstuffs and cosmetics into Act 101, where it has no natural home and thereby unnaturally burdening foodstuffs and cosmetics with legal constraints normally accorded to pharmaceutical medicines which are alleged by some to have been over-regulated and thereby constrained the development of the pharmaceutical industry in South Africa, for years. This is not in line with what is done in other Western countries and for this reason there is a need to prevent this form of over regulation to now stifle the food and cosmetic industry in South Africa, as well.

The Bill accordingly seeks to expand the applicability of the Act 101 to "products" (as opposed to medicines). In terms of section 1(f), a product would include "a medicine, cosmetic, medical device, and foodstuff" One could not ask for a more disparate collection! Thus a "cosmetic" and "foodstuff" is as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972, in respect of which medicinal claims are made (our underlining). It is this section of the Bill that we wish to take issue with.

* While an argument can be made out for Act 101 being extended to foodstuffs and cosmetics where medicinal claims are being made, it is our view that the Bill fatally fails to clarify what exactly a "medicinal claim" comprises.*

- This implies that foodstuffs and cosmetics that carry "health claim" will have to be registered with the South African Health Products Regulatory Authority and may only be sold through registered agencies such as pharmacies? The drafters of the legislation cannot be serious if this is their intention as it will completely disrupt the presence of foodstuffs and cosmetics in our supermarkets and fast moving consumer good outlets. For instance our product Flora Pro-Activ which contains plant sterols which reduce cholesterol (and this has been proven in our internationally accredited laboratories and independent tests over countless years of study), could only be sold in pharmacies



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which cannot be the intention of the draftsmen of the legislation! This could mean that retail outlets (supermarkets) would have to be licensed to sell foodstuffs with health claims.

- Provision has been made for health claims on foodstuffs in the draft regulations of the Foodstuffs, Cosmetics & Disinfectants Act which is the right home for such products and claims. It does not make sense for Act 101 to set up a new regime where legislation is already on the Statute Book
- Unintended consequences to consumers will be the higher cost and availability of foodstuffs if stores have to be licensed to sell such products with health claims.
- No draft guidelines have been published for comment, to date.
- Health claims on Foodstuffs offer important information to consumers in helping them to make the best purchases in order to improve their health and determine the nutritional status of such products which is international best-practice in any event. The Bill will change the manner in which these foodstuffs can be advertised to the public.
- If a foodstuff health claim is regulated under the same Act as a medicinal claim, then this could pose a barrier to trade for imported foodstuffs to enter the South African market.
- The prohibitions currently applicable to the supply of medicines in terms of incentive schemes, rebates, discounts &c (sections 18a and B) will become applicable to foodstuffs and cosmetics. The application of a discount to a foodstuff or cosmetic, in the supply of the product will no longer be allowed in terms of this Act. This is ridiculous as it would prevent normal healthy trade competition in the market-place
- The Bill would allow the Authority to publish information relating to any product under its jurisdiction, to the public. This may include confidential intellectual property and commercial information which may interfere with the competitive value of the foodstuff or cosmetic.

Advertisers in South Africa conform to the self-regulatory Code of Advertising Practice laid down by the Advertising Standards Authority ("the Code") . In terms of Appendix C, section 3.3 of the Code it may be a cosmetic as defined by its primary purpose, it may have a secondary function contributing to general health and well-being, for example an *anti-fungal body wash*. Surely it is not the intention of the draftsmen of the Bill to include within the realm of Act 101 products which are in fact cosmetics, but make claims which promote healthy skin? Without clarification of what exactly the legislature construes as a "*medicinal claim*" it is our view that the Bill is fatally flawed. Moreover there is no clarity given with regard to the definition of the word "claim" It is imperative that any legislation have direction on whether this is intended to mean advertising claims, direct marketing claims, claims made by product names, on packaging and/or labels etc.



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The Advertising Code of the Advertising Standards Authority could give useful guidance to the draftsmen of the Bill as what a more sensible definition of *medicinal claim* could be. For instance, Section 4 of Appendix C of the Code states:

4. THE USE OF WORDS IN A COSMETIC CONTEXT AND IN A MEDICINAL CONTEXT

4.1 The cosmetic context has the typical characteristics of:

- temporary action;
- improvement of the appearance of the skin;
- to be used regularly to maintain the effect;
- the effect is aimed at grooming and enhancing the appearance of the skin texture.

4.2 The medicinal context has the typical characteristics of:

- permanent or drastic effects after completion of a treatment;
- healing or curative aspects;
- to be used restrictively because of the potency of the treatment;
- the effect is aimed at treatment of, or relieving, a disease or condition.

4.3 Examples

4.3.1 REVITALISE, in the cosmetic sense. *The moisturising and toning properties of this product will leave your skin feeling revitalised, refreshed and will look years younger.*

4.3.2 TREATMENT, in the cosmetic sense. *This Winter Skin Treatment Pack provides you with all the products to nourish, moisturise and tone your skin in the dry climate of winter and will leave your skin looking at its best.*

CONCLUSION

We wish to thank you for the opportunity to participate in this process. Should you have any queries relating to the issues raised above, please do not hesitate to contact the writer on 031 570 2643/082 454-6935.

We formally request to be able to attend the Parliamentary Portfolio Committee on Health Public hearing on the 5th and 6th August 2008 in order to further engage and verbally submit to the Committee members on the issues highlighted in this submission.

Yours faithfully



RAY LÉCOLLE-BROWN
GROUP LEGAL DIRECTOR



ASSOCIATION FOR DIETETICS IN SOUTH AFRICA



NUTRITION SOCIETY OF SOUTH AFRICA

Minister of Health
Attention: Chief Director: Medicines Regulatory Affairs
Private Bag X828
PRETORIA
0001

8th October 2004

Dear Sir / Madam

**RE: COMMENTS – PROPOSED DRAFT AMENDMENTS TO THE
GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND
RELATED SUBSTANCES ACT (ACT 101 OF 1965)**

The Nutrition Society of South Africa is a scientific organisation representing nutrition scientists in South Africa and the Association for Dietetics in South Africa (ADSA), is the professional association for registered dietitians in South Africa. Jointly our members work in all areas of the field of nutrition and dietetics and for have nutrition science is their specialist area.

The vision of ADSA is to represent and develop the dietetic profession to contribute towards achieving optimal nutrition for all South Africans. Amongst our primary aims are:

- To act as spokesperson in negotiations affecting all matters of the dietetic profession.
- To have input on draft legislation on food, nutrition and related matters.
- To build up and maintain contact with organisations and associations which provide nutrition information to communities and individuals in South Africa.

In line with this, ADSA and the Nutrition Society support South African consumers being provided with truthful, evidence-based information on the packaging of foods that might assist them in making more informed and healthful choices from amongst the products available.

To this end, both ADSA and the Nutrition Society have over the years been an active member of the Food Legislation Advisory Group (FLAG) set up by the Directorate of Food Control of the Department of Health, where we believe that we contribute to promoting an evidence based approach to health related food issues and regulations. In addition, both groupings, fully support the Department of Health's Mandatory Food Fortification Programme, that makes fortified staple foods a reality and in so doing, we hope will address the real public health problem of micronutrient malnutrition. At the same time we support any initiative to prevent South African consumers from being misled through the messages carried on food and supplements.

The Nutrition Society and ADSA would like, therefore, to jointly submit their comments on the proposed amendment to Act 101 of 1965, published in Government Gazette R844 No 26572 of 19 July 2004.

We believe that the Food and Agriculture Organisation (FAO), World Health Organisation (WHO) Food Standards Programme, namely the Codex Alimentarius Commission, is a highly credible body. We also believe that the recent WHO Global Strategy for Diet, Physical Activity and Health is a laudable document that requires the attention of all interested in the health of the world's population. We therefore believe that South Africa, as an active member of the United Nations, should ensure that they align themselves with the guidelines developed and being developed by Codex and the recommendations made in the Strategy for Diet, Physical Activity and Health.

We therefore feel strongly that foods should be excluded from the proposed amendment to Act 101 of 1965, published in Government Gazette R844 No 26572 of 19 July 2004 as all health claims on foods, fortification of certain foods and functional foods are being dealt with at a global level by Codex and locally, following Codex, by the Directorate of Food Control in the draft regulations relating to labelling and advertising of foodstuffs, Act 54 of 1972, published in the Government Gazette R7431 No 23714 of 8th August 2002 and the regulations relating to the fortification of certain foodstuffs, Act 54 of 1972, published in the Government Gazette R7634 of 7th April 2003. We believe that re-defining certain categories of foods as medicines, will not only have a negative impact on food security in South Africa, but also will be seen as an unfair barrier to trade in terms of the World Trade Organisation agreements, and we are sure that these were not the intention of the proposed amendments.

In terms of definitions, we note that Codex defines a food as, "*any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.*" Similarly, the Foodstuffs Cosmetics and Disinfectants Act, defines a foodstuff as "*any article or substance (except a drug as defined in the Drugs Control Act 1965 [Act no.101 of 1965]) ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance*".

The Medicines Act defines a medicine as "*any substance or mixture of substances in the use or proportion to be suitable for use or manufacture or sale for use in (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine*". ADSA and the Nutrition Society therefore believe that it is possible to differentiate between drugs and foods and that the two should clearly remain separated.

We acknowledge that the group of products termed supplements and slimming aids, fall somewhere along the continuum between foods and medicines, and that this sector is currently under-regulated. As a result, a wide range of misleading and even blatantly untrue claims are being made, with little regard for the evidence-based approach accepted by medical science, nutritional science and food science.

We believe however, that due to their very nature of being between foods and medicines, these products should constitute a separate category and that all interested stakeholders should be consulted in a transparent process in order to develop an acceptable solution to the current unacceptable situation.

In conclusion, it is the recommendation of both the Nutrition Society and ADSA, that foods be specifically excluded from the proposed amendments to the General Regulations made in Terms of the Medicines and Related Substances Act (Act 101 of 1965) published in Government Gazette R844 No 26572 of 19 July 2004 and that a task force representing all interested stakeholders be convened to resolve the issue of definitions and regulations pertaining to supplements, complimentary medicines and slimming products and aids. We believe that this will ensure that the matter is addressed and resolved in a satisfactory manner without negatively impacting on the health or food security status of South Africans in line with the Department of Health's vision of creating a caring and humane society in which all South Africans have access to affordable, good quality health care.

Yours sincerely

Megan Pentz-Kluyts

ADSA: President

Johann Jerling (Prof)
Nutrition Society of South Africa