

Professor M. Roy Jobson
M.B.,Ch.B.(UCT); M.Prax.Med.(Medunsa); MFGP(SA)
HDipEdAd(Rand)

Faculty of Pharmacy
Rhodes University
GRAHAMSTOWN
6140
email: R.Jobson@ru.ac.za

046-603-8070/8381 W
046-603-7506 Fax

BY EMAIL

The CEO
Cancer Association of South Africa (CANSA)
JOHANNESBURG

19 February 2013

Dear Ms Janse van Rensburg,

**URGENT: MISREPRESENTATION OF A MEDICINE AS A NUTRITIONAL SUPPLEMENT
BY THE CANCER ASSOCIATION OF SOUTH AFRICA (CANSA)**

I was yesterday sent a copy of an email which was an invitation to announce the awarding of the “Cansa Seal of Recognition” to a *nutritional supplement* “Omega Caro-E” on Thursday 28 February 2013.

The invitation states that the product “can assist with reducing the risk of cancer and other non-communicable diseases like diabetes and heart disease.”(emphases added) [See Annexure 1, underlining added.] These claims mean that, by definition, according to the Medicines and Related Substances Act 1965 (Act 101 of 1965), the product is a *medicine* and not a nutritional supplement. Any promotion of the product as a nutritional supplement would therefore in my view be misleading (and in contravention of the Medicines Act).

To the best of my knowledge the product has not had any definitive human clinical studies done to prove that the exact combination of ingredients in the recommended dosages will in fact reduce the risks of cancer, diabetes and heart disease.

I furthermore believe that CANSA is exceeding and violating the authority granted to it by the Director-General of the Department of Health in a letter dated 3 August 2011, by awarding the CANSA Seal of Recognition to a medicine. (Annexure 2 – 3 pages)

To the best of my knowledge the only claim that could legitimately be made for this product as a nutritional supplement is that the concentrations of the individual ingredients are what they claim to be on the label.

I will be notifying the Registrar of Medicines, Mrs Mandisa Hela, and other members of the MCC and the Food Directorate of my concerns.

Yours sincerely,



M.R. JOBSON

Annexure 1 – Copy of invitation from CANSA (underlining added)

Cancer Association of South Africa - Omega Caro-E Supplement Invitation

Inbox x



From: Alice Victor [mailto:avictor@cansa.org.za]

Sent: 18 February 2013 04:03 PM

Subject: Cancer Association of South Africa - Omega Caro-E Supplement Invitation

The Cancer Association of South Africa (CANSA)'s CEO, Sue Janse van Rensburg invites you to a media breakfast to announce the awarding of the CANSA Seal of Recognition for a new product, **Omega Caro-E** supplement, recognising it as a **CANSA Smart Choice**. This is the first time ever that the Seal will be associated with a nutritional supplement.

Developed by the Cape Peninsula University of Technology (CPUT), Omega Caro-E is a unique combination of fish oil containing 11 different carotenes and 5 different forms of Vitamin E and can assist with reducing the risk of cancer and other non-communicable diseases like diabetes and heart disease. It's an excellent supplement that contains no artificial preservatives, flavourants or colourants as well as being affordable.

Date: Thursday 28 February 2013
Time: 9:45 for 10:00 ending at 11:00
Venue: CANSA Science & Resource Centre
37A Main Road, Mowbray, Cape Town
RSVP: Alice Victor on avictor@cansa.org.za or 021 689 5381

Opportunities for possible interviews will be made after the event at the venue.

Programme speakers include:

- CANSA CEO, Sue Janse van Rensburg (programme director)
- Prof Chris Nhlapo (Deputy Vice Chancellor: Research, CPUT)
- Prof Gary Atkinson-Hope (Director Technical Transfer Office, CPUT)
- Prof Spinner Benadé (Head: Functional Foods Research Unit) & Dr Maretha Opperman (Researcher Function Foods Research Unit) at CPUT
- Dr Carl Albrecht, Head of Research - CANSA

Looking forward to having you join us.

OMEGA CARO-E

It's an excellent supplement that contains no artificial preservatives, flavourants or colourants as well as being affordable

CANSA
SMART CHOICE SUPPLEMENT



Toll-free 0800 22 66 22 www.cansa.org.za





**DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA**

PRETORIA
Private Bag X326, PRETORIA, 0001, 12th Floor, House of Trade and Industry 266 (HTI) Building, Cnr Frenshich and Pretorius Street, PRETORIA, 0002 Tel (012) 312 3100 Fax: (012) 329 6063
CAPE TOWN
P.O. Box 3679, CAPE TOWN, 8000, Room 464, 120 Plain Street, CAPE TOWN, 8000 Tel (021) 461 2040, Fax (021) 461 6864

Ms Sue Janse van Rensburg
Chief Executive Officer
CANSA
P O Box 2121
**BEDFORDVIEW
2008**

Dear Ms Janse van Rensburg

**REQUEST FOR APPROVAL TO ACT AS AN 'ENDORSEMENT ENTITY' IN TERMS OF THE
REGULATIONS RELATING TO THE LABELLING AND ADVERTISING OF FOODSTUFFS
(R.146 OF MARCH 2010)**

Your request for approval for the Cancer Association of South Africa (CANSA) to act as an 'endorsement entity' in terms of the new Regulations Relating to the Labelling and Advertising of Foodstuffs (R.146 of March 2010 as amended), which were published by the Minister of Health under Section 15 of the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), refers.

The request in question relates to Regulation 13(a)(ii), which provides for the prohibition of certain information or declarations to be reflected on a label or advertisement of a foodstuffs, including words, pictorial representations, marks, logos or descriptions which create an impression that such a foodstuff is supported, endorsed, complies with or has been manufactured in accordance with recommendations by organizations, associations, foundations and other entities. The Regulation also requires that the use of such information or declarations be considered by the Department of Health and approved by the Director-General, based on the evidence provided as verification that your organization is involved in generic health promotion, supported by evidence-based nutrition, as well as that the aims of your organization do not contradict the requirements of these Regulations related to nutritional claims, based on the criteria thereof.

The dossier with relevant documented evidence that accompanied the request received from CANSA for the approval of the use of your logos on labels and advertisements of foodstuffs was evaluated by a Committee comprising officials from the Directorates: Food Control, Nutrition and Non-communicable Diseases of the Department. The following criteria were applied by the Committee to evaluate the relevant information related to applications received by the Department in terms of Regulation 13(a)(ii):

- (i) Evaluation of the evidence submitted in support of projects aimed at promoting evidence-based nutrition; and
- (ii) Assessment to ensure that the activities of the organization do not contradict the requirements of the mentioned Regulations related to nutritional claims and the criteria thereof.

You are hereby informed that, based on the outcome of the evaluation of the information that accompanied your request, the Department is of the opinion that sufficient evidence was provided to support the approval of the CANSA to act as an 'endorsement entity' in terms of Regulation 13(a)(ii) and that the logos of the Foundation can therefore be included on the labels and advertisements of foodstuffs, as provided for under the Regulations Relating to the Labelling and Advertising of Foodstuffs (R.146 of March 2010), subject to the following conditions:

1. This approval is considered to be valid until such time as phase 2 of the Food Labelling and Advertising Regulations have been finalized in future, which will include, among others, requirements for the evaluation of categories of foodstuffs to allow for the approval of nutrient and/or health claims on the labels and advertising of such foodstuffs. Logos such as that of CANSA may not be appropriate for use on those categories of foodstuffs, which, after evaluation may not bear a nutrient or health claim on the label. Such a situation could provide confusing messages to the consumer.
2. The approval by the Director-General of the use of the CANSA logo on the labels and advertising of foodstuffs does not necessarily constitute an approval of the criteria used by CANSA. The Department reserves a final opinion on the criteria in question until such time as phase 2 of the Food Labelling and Advertising Regulations has been finalized.
3. Logos such as that of CANSA may only be used on foodstuffs of which the labels are fully compliant to the new Food Labelling and Advertising Regulations, R.146/2010, as well as the new Trans Fat Regulations, R.127/2011.

It should be noted that the relevant Regulations of the Department related to the labelling and advertising of foodstuffs stipulates that no label or advertisement of any nature of a foodstuff shall refer to the Act or food-related Regulations; the Department of Health, Provincial or Local Government; or an official of the said Department, Provincial or Local Government.

Yours faithfully



MS MP MATSOSO
DIRECTOR GENERAL: HEALTH
DATE: 3/8/2011