

May 28, 1998

Mr. Finn Dyrby Hermansen
President, Danish Association
Navervel 28 D
4000 Roskilde
Denmark

RE: Naturally derived hydroxycitric acid for use in food supplements.

BY FAX: 011 45 46 75 66 08; TOTAL PAGES: 15

Dear Sir,

Only yesterday we have received a letter from the IADSA from the office of Mr. Loren Israelsen, Esq, alerting us to an unfavorable position of the Danish Food Control Agency against food supplement use of natural hydroxycitric acid from *Garcinia cambogia*. In response to your request to submit data in support of the *Garcinia cambogia* derived natural hydroxycitric acid (HCA) use in food supplements, we hereby send you this letter with attachments.

Sabinsa is a nutraceutical company which has been prominently involved in research, development and marketing of the brand of natural hydroxycitric acid, Citrin®, in various countries all over the world, for close to a decade now. Let me from the position of history on the research and development of natural hydroxycitric (HCA) acid, and its market introduction in this country, Europe and Japan, share with you some of the information that may help to convince the critics as to the safety of nutritional use of the natural HCA.

As you may see from the enclosed references, natural HCA has been derived from the rind of a fruit of *Garcinia Gambogia*, a tree indigenous to the southern part of India. *Gracinia* fruits, containing approximately 30% of HCA, have a long standing history of culinary use in India as a food acidifier and also as an addition to curry together with turmeric root. This fruit has also been eaten in its raw form.

During the 1970's, scientists at Brandeis University and at Hoffman LaRoche demonstrated that HCA, when blended with the diet, had a marked suppressive effect on appetite and weight gain in rats. The mechanism behind that weight-loss effect was discovered, i.e. inhibition by HCA of a specific enzyme, citrate lyase, which is responsible for the synthesis and storage of fat in our body.

The LD50 value established by Hoffman LaRoche scientists for HCA is 4000 mg/kg (comparable to the value for a known GRAS [Generally Recommended As Safe] item, citric acid). You may also compare this value with a daily recommended dose of HCA established through our clinical studies to be 750 mg/person/day.

Our company sponsored, between 1993 and 1997, six clinical studies of our brand of HCA Citrin ®, i.e. three open field, and three double-blind designs. A chronological list of this research is provided for your convenience:

1. Conte AA (1993 Summer) A Non-Prescription Alternative in Weight Reduction Therapy. *The Bariatrician*: 17-19.
2. Conte AA (October 1994) The effects of (-) - Hydroxycitrate And Chromium (GTF) On Obesity. *J Amer Coll Nutr.* 13 (5): 535 [Abstract 60].
3. Katts GR, Pullin D, Parker LK, Keith PL, Keith S (March 1995) Reduction Of Body Fat As A Function Of Taking A Dietary Supplement Containing Garcinia Cambogia Extract, Chromium Picolinate And L-Carnitine - A Double Blind Placebo Controlled Study. Abstract/Poster presented at a symposium on obesity organized by the Mexican Sociedad Medical del Sureste para el Estudio de la Obesidad, March 4, 1995, Merida, Yucatan, Mexico.
4. Conte AA (June/July 1995) Effective Natural Weight Loss Techniques. *Alternative Complementary Therapies.* I (4): 212-215.
5. Badmaev V, Majeed M (July 1995) Open Field, Physician Controlled, Clinical Evaluation Of Botanical Weight Loss Formula Citrin ®. *Nutracon 95: Nutraceuticals, Dietary Supplements And Functional Foods.* Day One (Sponsored by Global Business Research LTD). Published in the symposium book.
6. Thom E (May 1996) Hydroxycitrate (HCA) In The Treatment Of Obesity. *Int J Obesity.* 20 (4): 75 [Abstract /Poster 08-193-WP1 at 7th European Congress on Obesity in Barcelona, Spain 14-17 May, 1996].

Based on our 8 weeks and up to 36 months clinical study of Citrin ® in overweight patients, some of which had poor glucose tolerance, we can report that Citrin ® in a dose of 1500 mg [calculated as 750 mg of pure HCA] did not affect the overall clinical status of the patients and did not alter blood biochemistry in a detrimental way.

The blood levels of triglycerides, often elevated in patients with poor glucose tolerance, assessed for the entire population studied with Citrin ® decreased significantly ($p < 0.05$). The mean value of triglyceride levels before Citrin ® intake was 166.5 mg/dl and after the 8 weeks was 154.8 mg/dl. On the other hand the HDL ("good cholesterol") levels

were significantly ($p < 0.01$) increased after 8 weeks of Citrin® from a mean value of 47.4 mg/dl to a mean value of 50.4 mg/dl.

The 8 week Citrin® intake lowered the risk of coronary heart disease [CHD] (as assessed from the blood lipid profile) significantly ($p < 0.01$) for the entire population studied. The risk index decreased from a mean value of 0.998 to a mean value of 0.90. This finding is particularly important in view of increased risk of CHD in patients with poor glucose tolerance.

In addition, the blood chemistry parameters like blood electrolytes, in particular sodium, potassium, chloride, calcium and phosphorus, blood urea nitrogen [BUN], creatinine, plasma proteins and liver enzymes were not altered even after several months administration of Citrin®.

We enjoy now several years of success in providing Citrin® to the nutritional market world-wide, with a solid safety record of using this product in supplements, foods and beverages. Based on our extensive experience with our brand of Garcinia cambogia derived HCA we recommend use of this product in the USA as a category of Food for Special Dietary Use (FSDU), or as a Dietary Supplement under the new Dietary Supplement Health and Education Act of 1994 (DSHEA).

For additional information on the nutritional use of the Citrin® brand of HCA you may contact Sabinsa's exclusive representative in the Scandinavian countries, Superfos Health Care Inc. of Copenhagen. The person to contact there is Ms. Birgit Laursen at tel. 43 29 28 88.

Sincerely,

Vladimir Badmaev, MD, PhD
VP Medical & Scientific Affairs
Sabinsa Corporation

CC: Ms. Birgit Laursen, Mr. Loren Israelsen, Esq.