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October 28, 2003

Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: 2003Q-0401: Health Claim Petition – Omega-3 Fatty Acids and
Coronary Heart Disease

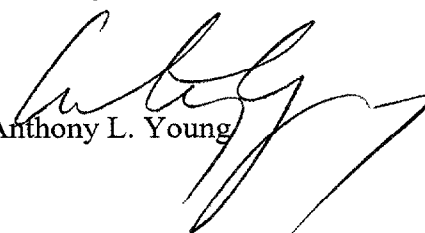
Dear Sir or Madame:

Enclosed are the comments of our client Nu-Mega Ingredients Pty Ltd (“Nu-Mega”), on the pending Health Claim Petition for Omega-3 Fatty Acids and Coronary Heart Disease.

Nu-Mega markets a range of lipid-based products, including Omega-3 DHA in tuna oil. Nu-Mega's tuna oil products are the subject of GRAS Notice 109, to which the Agency has responded that it has no questions, and the subject of a New Dietary Ingredient Notification submitted in 2002 (Rpt. No. 130) and placed on the docket January 27, 2003.

Accordingly, Nu-Mega has a substantial interest in ensuring that marketers of omega-3 fatty acid products, including Nu-Mega's tuna oil products, are permitted to disseminate truthful information about the relationship between omega-3 fatty acid consumption and the risk of coronary heart disease. As reflected in the attached comments, Nu-Mega fully supports the petition submitted by Wellness Lifestyles, Inc. D/B/A American Longevity and Life Extension Foundation Buyers Club, Inc. and urges the Agency to approve the Petition as rapidly as possible.

Sincerely,


Anthony L. Young

Enclosures

2003Q-0401

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A joint venture between
Food Spectrum P/L and
Clover Corporation Ltd

21st October 2003

Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Dear Sir or Madam,

Re: 2003Q-0401: Health Claim Petition – Omega-3 Fatty Acids and
Coronary Heart Disease

These comments are submitted on behalf of Nu-Mega Ingredients Pty Ltd ("Nu-Mega"). Nu-Mega is a joint venture between Food Spectrum Pty Ltd and Clover Corporation Ltd. Nu-Mega markets lipid-based products in powder form (in particular omega-3 and omega-6 fatty acids) to the pharmaceutical, food, infant food and animal health industries.

Core to the Nu-Mega product range is Omega-3 DHA in tuna oil. Nu-Mega's tuna oil products are the subject of GRAS Notice 109, to which the Agency has responded that it has no questions. Nu-Mega's Driphorm range of microencapsulated tuna oils enables the addition of tuna oil to a broad spectrum of products in a convenient and stable dry powder form. As a result of Nu-Mega's microencapsulation technology, Nu-Mega's tuna oil has minimal flavor impact and in many cases does not alter product flavor at all. Nu-Mega markets a range of Driphorm products, each designed to give optimal function to specific food applications.

Nu-Mega fully supports the petition submitted by Wellness Lifestyles, Inc. D/B/A American Longevity and Life Extension Foundation Buyers Club, Inc. ("the Petition"). The Petition seeks to change the existing qualified health claim for Omega-3 Fatty Acids to the unqualified claim, "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease" and to permit use of this claim for both conventional foods and dietary supplements containing omega-3 fatty acids. Nu-Mega supports these changes and believes they are scientifically appropriate.

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In particular, Nu-Mega agrees that the wealth of scientific literature on omega-3 fatty acids conclusively establishes that there is significant scientific agreement among experts in the effect of omega-3 fatty acids on coronary heart disease that consumption of EPA and DHA omega-3 fatty acids reduces the risk of coronary heart disease. We urge the Agency to approve the proposed health claim as soon as possible so that consumers may receive, at the point of sale, truthful information about the important relationship between omega-3 fatty acids and coronary heart disease.

Nu-Mega does, however, wish to clarify the substance that is the subject of the Petition. Footnote 1 of the Petition states, "As used herein, omega-3 fatty acids refers to a group of polyunsaturated fatty acids (LCPUFA) comprised of eicosapentaenoic acid ("EPA"), docosahexaenoic acid ("DHA")." NuMega agrees that this is an appropriate description of the relevant omega-3 fatty acids for purposes of the proposed health claim. Later in the Petition (Section B.6.) the petitioners state, "Omega-3 fatty acids are a group of polyunsaturated fatty acids ("LCPUFA") comprised of eicosapentaenoic acid ("EPA"), docosahexaenoic acid ("DHA"), and linolenic acid ("LNA")." NuMega believes that it is inappropriate to include linolenic acid in the definition of omega-3 fatty acids for purposes of the proposed health claim.

The current qualified health claim is limited to EPA and DHA. In its October 31, 2000 Letter Regarding Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease (Docket No. 91N-0103), the Agency explained the basis for its conclusion that the potential nutrient/disease relationship was appropriately limited to EPA and DHA and their effect on coronary heart disease risk.

In the Agency's words:

In its 1991-1993 review of the scientific evidence for omega-3 fatty acids and reduced risk of CHD, FDA limited its review to two omega-3 fatty acids, eicosapentaenoic acid (EPA) and

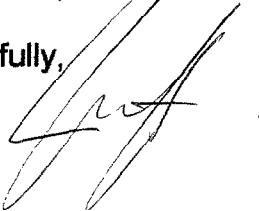
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docosahexaenoic acid (DHA). FDA did not include the omega fatty acid, linolenic acid, in its review. Unlike EPA and DHA which are derived from fish oils and from fish, linolenic acid is derived primarily from plant sources. FDA limited its review to EPA and DHA because the hypothesis for a relationship between omega-3 fatty acids and CHD derived from correlations between low rates of CHD and high consumption of fish oils. In addition, most of the information about the effects of omega-3 fatty acids on CHD was derived from studies of fish oils or fish consumption. Furthermore, only a limited amount of linolenic acid is converted in the body to EPA and DHA. Therefore, FDA concluded that the potential nutrient/disease relationship was appropriately limited to EPA and DHA and their effect on CHD risk. See 58 Fed. Reg. at 2683. FDA's conclusion has not changed. Consequently, the agency is similarly limiting its current review to the relationship between EPA and DHA and reduced risk of CHD. Thus, when the term "omega-3 fatty acids" is used in this letter, FDA means only EPA and DHA omega-3 fatty acids, unless otherwise noted.

NuMega believes that the above-quoted rationale remains valid and urges the Agency to similarly limit any new approved health claim to EPA and DHA omega-3 fatty acids.

NuMega appreciates the opportunity to comment on this important Petition, and respectfully requests that the Agency approve the Petition as rapidly as possible.

Yours faithfully,



Jerry Luff
Executive VP – Business Development