



VIA HAND DELIVERY

January 8, 2004

Food and Drug Administration  
Office of Nutritional Products, Labeling  
And Dietary Supplements (HFS-800)  
5100 Paint Branch Parkway  
College Park, Maryland 20740



7361 Calhoun Place,  
Suite 500  
Rockville, Maryland 20855-2765  
301.838.3120  
fax: 301.838.3182

RE: Petition for Qualified Health Claim for Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids

Dear Sir/Madame:

Enclosed please find an original and one copy of a petition for a Qualified Health Claim for Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids.

AAC Consulting Group is submitting this petition pursuant to Section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act on behalf of Belovo, Inc., Pinehurst, NC 28374 with respect to Belovo Columbus<sup>®</sup> or Christopher<sup>®</sup> eggs with enhanced levels of omega-3 fatty acids that are balanced in approximately a 1:1 ratio with omega-6 fatty acids. Petitioner respectfully proposes that the qualified health claim be approved for labeling of the Belovo Columbus<sup>®</sup> or Christopher<sup>®</sup> eggs with increased levels of omega-3 fatty acids as follows:

**Consumption of one egg per day containing 660 mg of omega-3 fatty acids with a balanced ratio of omega-3 to omega-6 fatty acids (1:1) may reduce the risk of heart disease and sudden, fatal heart attack. FDA has determined that the scientific evidence is supportive, but not conclusive, for this claim. See nutrition information for cholesterol content.**

We are waiving the right to a review under the Significant Scientific Agreement standard and request that the petition be reviewed under the interim procedures for a qualified health claim.

2004Q-0072

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We believe that the FDA's qualified health claim program is a positive step, which can greatly benefit the health of consumers in making informed decisions regarding their diet.

An independent panel of recognized experts reviewed the information in the enclosed petition and concluded that the scientific information presented here supports the proposed qualified health claim and the document is a reasonable and representative interpretation of the scientific literature in support of the potential health benefits of omega-3 fatty acids in the diet.

As presented in the scientific summary, both the emerging scientific consensus of experts in nutrition and cardiovascular disease and authoritative bodies such as the American Heart Association, the USDA and the Office of Management and Budget of the White House have recognized the consistent and convincing scientific evidence for omega-3 fatty acid's role in reducing the risk of coronary heart disease and mitigation of sudden, fatal heart attacks by recommending increases in dietary omega-3 fatty acid intake. As consumed in a conventional food, omega-3 enhanced egg products offer the general public a means to better nutritional and health status toward achieving this goal without noticeable alteration in current eating habits and preferences.

If you have any questions, please contact Stanley M. Tarka, Jr., Ph.D. at AAC Consulting Group, Inc. Thank you.

Sincerely,



Edward A. Steele  
Vice President  
Food, Dietary Supplement & Cosmetic Consulting

Enclosure

**QUALIFIED HEALTH CLAIM PETITION FOR EGGS WITH  
ENHANCED OMEGA-3 FATTY ACID CONTENT  
AND A BALANCED 1:1 RATIO  
OF OMEGA-3/OMEGA-6 FATTY ACIDS**

**SUBMITTED TO THE FOOD AND DRUG ADMINISTRATION**

**DECEMBER 23, 2003**

**PETITIONER:**

**BELOVO, Inc.,  
Pinehurst, N.C. 28374**

**On behalf of:  
BELOVO, S.A., Z.I. 1, Bldg 31,  
6600 Bastogne, Belgium**