Food & Drug Administration's recent acceptance of omega-3 content claims for food products and dietary supplements

Saskatoon, SK Canada—Bioriginal Food & Science Corp., the world’s leading supplier of essential fatty acids (EFAs), welcomed the Food & Drug Administration’s (FDA’s) recent acceptance of omega-3 content claims for food products and dietary supplements.

As a result of the FDA’s decision, content levels for omega-3s such as alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) content levels can be claimed by food and supplement manufacturers. As a strong incentive for the industry to use meaningful amounts of EPA/DHA and ALA, the FDA and the Institute of Medicine (IOM) are defining products as “high in” when they contain at least 130 mg per serving of EPA/DHA or contain 260 g or more of ALA. Additional guidelines are in place for products labeled a “good source” and “more.”

“As a company that actively promotes consumer education on the benefits of omega-3s, including flax in particular, we are pleased to have the FDA confirm flaxseed’s status as a high source of ALA,” commented Barry Skorobohach, Bioriginal’s quality manager. Every lot of Bioriginal’s flax oils are third-party tested, using stringent procedures to ensure their products’ omega-3 contents are as high as possible. The company’s 1000 mg flax oil capsule contains 430 g of ALA, qualifying as “high in ALA,” according to the new guidelines.

The FDA’s approach of having predetermined levels of EPA/DHA and ALA will prohibit food and supplement marketers from calling attention to these nutrients in labeling claims if they only contain smaller, inconsequential amounts. Consumers will benefit from knowing exactly how much of these omega-3s a product contains, allowing them to make more informed decisions when purchasing.

FDA acceptance of omega-3 claims occurred when the 120-day time period had passed without contest on May 16, 2004. The original petition submitted to the FDA can be found at http://www.fda.gov/ohrms/dockets/dailys/04/may04/051904/04n-0217-cp00001-01-001.pdf.

Review on Vitamin E and Mortality

A recent report based on an analysis of 19 clinical trials stated that dosages of vitamin E 400 IU and higher used by patients with chronic diseases showed a higher all-cause mortality rate than found in healthy adults. It should be pointed out that this was not a clinical study, but a summarization of 11 high dose and eight low dose selected studies that involved various types and forms of vitamin E, which were sometimes given in combination with other vitamins. Also note, a study was not considered for inclusion in the report unless 10 deaths or more had been reported, which eliminated many studies from being included and which could have greatly affected results.

The study authors note that their data from these selected studies show longer life span when lower dosage of vitamin E is taken. Also, that their analysis has limitations, but that “... use of any high-dosage vitamin supplements should be discouraged until evidence of efficacy is documented...” To apply one meta-analysis of one vitamin to all supplements is a stretch of conclusions.

Source: John Carlson, president, J.R. Carlson Laboratories, Inc. 847.255.1600.

Aqueous Extract of Cinnamon Increases Insulin Sensitivity

Cinnulin PF® is the patented aqueous extract of cinnamon. The aqueous extract of cinnamon was discovered more than 20 years ago by USDA researchers. The foremost expert in this field is Dr. Richard A. Anderson, who is also recognized for his research on chromium.

Numerous studies have been conducted showing the effects of cinnamon and the aqueous extract on glucose uptake. For example, a study by Broadhurst et al. has demonstrated that the aqueous extract of cinnamon is a strong potentiator of insulin (J. Agric. Food Chem. Vol. 48 pp. 849-52, 2000). Additionally, a purified compound from the aqueous extract of cinnamon is an effective mimetic of insulin and may be useful in the treatment of insulin resistance. (Jarvill-Taylor, K.J., et al. J. Am. College Nutr. Vol. 20 pp. 327-36, 2001).

Furthermore, bioactive compound(s) extracted from cinnamon were shown to potentiate insulin activity. Wortmannin, a potent PI 3'-kinase inhibitor, decreased the biological response to insulin and bioactive compound(s) from cinnamon similarly, indicating that cinnamon is affecting an element(s) upstream of PI 3'-kinase. Enzyme studies conducted in vitro show that the bioactive compound(s) can stimulate autophosphorylation of a truncated form of the insulin receptor and can inhibit PTP-1, a rat homolog of a tyrosine phosphatase (PTP-1B) that inactivates the insulin receptor. No inhibition was found with...
alkaline phosphate or calcineurin suggesting that the active material is not a general phosphatase inhibitor. It is suggested, then, that a cinnamon compound(s), like insulin, affects protein phosphorylation-dephosphorylation reactions in the intact adipocyte (Imparl-Radoselvich, J., et al. Horm Res. Vol. 50 pp. 177-82, 1998).

A study released in Diabetes Care recently shows tremendous promise for the treatment of type II diabetes. Those treated with cinnamon for a period of 40 days showed decreases in fasting glucose levels of 18-29 percent, cholesterol decreases of 12-26 percent and decreases in triglycerides of 23-30 percent (Khan, A., et al. Diabetes Care Vol. 26 pp. 3215-18, 2003). The researchers added, however, that they do not yet have sufficient data on the safety or potential toxic build-up from consistently ingesting table cinnamon and that the aqueous extract which contains the active compounds is less likely to be toxic (Anderson, R., et al. J. Agric. Food Chem. Vol. 52 pp. 65-70, 2004).

Yet another study suggests that the aqueous extract of cinnamon would improve insulin action via increasing glucose uptake in vivo, at least in part through enhancing the insulin-signaling pathway in skeletal muscle (Qin B., et al. Diabetes Research and Clinical Practice Vol. 62 pp. 139-48, 2003).

The USDA has just recently reidentified the active components found in Cinnulin PF as type-A polymers and not MHCP. According to the USDA, there was a misidentification of the compound MHCP in an earlier study, but the NMR and Mass Spec results confirmed the identification as doubly-linked procyanidin type-A polymers (Anderson, R.A., J. Agric. Food Chem. Vol. 52 pp. 65-70, 2004).

Cinnulin PF is being used in several clinical studies by the USDA, and results are expected to be available in mid-2005. Cinnulin PF is currently available in a variety of dietary supplements including Cinnabetic™ from Hero Nutritionals.

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