CORNUCOPIA
INSTITUTE

Ms. Lisa Ahramjian
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave., SW.,
Room 2640 -S
Washington, DC 20250

April 10, 2011

Dear members of the National Organic Standards Board,

The Cornucopia Institute is a non-profit farm policy research organization, representing more than 4,000 members, with organic farmers as our primary constituency.

The growth of the organic industry depends on consumers' trust that the organic label signifies a safe refuge from chemicals, synthetics and non-organically produced ingredients, including untested, novel ingredients used as "nutrient" marketing tools. If accepted, the Handling Committee's (HC) recommendation regarding nutrients would irreparably weaken this trust in the integrity of the organic label.

As written, the Handling Committee's proposed annotation for "vitamins and minerals" would allow <u>any</u> nutrient ingredient allowed by the FDA, including those that have <u>never been tested for safety or efficacy</u>.

We urge the Board to reject the Handling Committee's recommendation.

We agree with Joan Gussow's comment and Richard Theuer's proposed annotation. Both Dr. Gussow and Dr. Theuer were members of the 1995 NOSB, and both have advanced degrees in nutrition science**. Since there was no minority opinion published, we suggest using Dr. Theuer's suggested annotation**, which would clarify that the current rule is limited to vitamins and minerals and would **continue the current system of requiring petition, review and approval of "accessory nutrient" materials** before they can be added to organic foods.

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Theuer suggests: "Vitamins and Essential Minerals, restricted to Vitamins identified in 21 CFR 107.100 and Essential Mineral elements identified in 21 CFR 101.9(c)(8)(iv), regulated according to 21 CFR 101.9."

We would suggest adding, "and nutrients that are required in infant formula, limited to those listed under 21 CFR 107.100(a)." This will ensure that organic infant formula contains the necessary nutrients, without the unnecessary/scientifically unproven ones, like DHA, that serve mainly as marketing tools.

Why the Board should reject the HC proposal: preventing a "slippery slope"

The HC recommends the following annotation:

> "Materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods, including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies."

Grouping "nutrients" for "enrichment, supplementation and fortification" together in one category is in **conflict with definitions provided by FDA law and regulations**.

The FDA does not have a list of materials or ingredients that can be classified as "nutrients." It therefore appears that the HC has come up with its own definition of "supplementation" of foods, in an effort to open the door to any material that supplies any nutritional value, and that could therefore be considered a "nutrient."

Fortification and 21 CRF 104.20

Fortification policy by the FDA can be found in 21 CFR 104.20, to which the current annotation for "nutrient vitamins and minerals" in the organic standards refers.

The FDA rule clearly states, under 21 CFR 104.20(a) that it is concerned with "random fortification" of foods:

> "Random fortification of foods could result in over- or under-fortification in consumer diets and create nutrient imbalances in the food supply."[i]

In the same section of the fortification rule, the FDA also states that fortification could lead to false advertising:

> "It could also result in deceptive or misleading claims for certain foods."[ii]

As a result, the FDA states:

> "The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods."[iii]

Moreover, in an FDA Compliance Manual, the agency has expressed concern with fortification and misleading advertising associated with fortification:

> "In addition, the agency is concerned that the declaration of the fortification may be accompanied by deceptive or misleading claims for the fortified food that lead the consumer to believe that there is some special benefit from eating the food, which may not be the case."[iv]

The FDA rule also states, under 21 CFR 104.20(f), that "Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter."

Former National Organic Program (NOP) director, Barbara Robinson, at the urging of industry lobbyist/lawyer Jay Friedman, at the time with the Washington law firm of Covington and Burlington, overruled her staff's decision to enforce the law by using 104.20(f) as a loophole to justify the legality of any "nutrient" ingredient, such as Martek's DHA, in organic foods. The NOP, under its new leadership, has since declared that it considers this interpretation to be "incorrect," a very generous description in light of the documented corruption that went into a number of Dr. Robinson's decisions (see July 3, 2009 *Washington Post* article).[v]

Yet, despite this declaration by the current NOP, it appears that the HC is referencing this rule (21 CFR 104.20(f)) when stating that any "material allowed by law" should be allowed in organics. In that case, any material that is considered Generally Recognized as Safe (GRAS) by the FDA would be allowed in organics, which is highly problematic.

The FDA does not adequately ensure safety of novel "nutrient" ingredients

The HC incorrectly assumes that the FDA expends great resources in ensuring the safety of the conventional food supply, including the safety of "nutrient" ingredients, under its GRAS system. The HC, in its recommendation, states:

> "The committee sees great value in the FDA's expenditure of resources implementing its role in regulating the safety and efficacy of nutrients, vitamins and minerals and little value in a separate nutrient supplementation regime for food products that contain organic agricultural ingredients."

What is the HC referring to when it claims that the FDA adequately regulates the safety and efficacy of nutrients? Substantial evidence points to the contrary—many independent observers believe the FDA is currently severely failing in its responsibility of ensuring the safety of novel nutrient ingredients and protecting the public.

Safety

According to the Government Accountability Office, which conducted an investigation of the FDA's GRAS system, published in February 2010,[vi] "FDA's oversight process does not help ensure the safety of all new GRAS determinations."

The GAO report points out that the FDA does not test all nutrient ingredients for safety. Under the current GRAS system, a corporation that markets a nutrient ingredient is not required to even notify the agency of its intention to market the material. The FDA does not perform its own safety testing, but rather relies on a statement of a panel of scientists put together by the corporation.

GRAS status is therefore a self-determination by the corporation marketing the nutrient, not a statement by the FDA that the agency has tested the nutrient and deemed it safe for consumption. The FDA does not even make its own determination regarding the GRAS status of any new materials.

Other problems with the FDA's GRAS system exist, as pointed out in the GAO report: "FDA has not issued guidance to companies on how to document their GRAS determinations or monitored companies to ensure that they have conducted GRAS determinations appropriately."

Moreover, the GAO report is highly critical of the FDA's failure to conduct post-market surveillance. While the agency, when issuing letters of notification regarding GRAS status, often recommends rigorous post-market surveillance of new nutrients, the agency has not followed up to ensure that this post-market surveillance was performed.

For Martek Biosciences Corporation/DSM's algal oil (Martek was recently acquired by the Dutch corporation DSM), FDA officials specifically requested "rigorous post-market surveillance"[vii] of infants consuming formula with these oils, and requested regular reports submitted to the FDA. No such post-market surveillance or additional safety reports have ever been submitted to the FDA, according to the agency (a legal complaint filed by Cornucopia pertaining to this serious deficiency is pending).

(Note: we will use Martek's DHA oil as an example of an unreviewed ingredient in organics throughout this letter, since it provides a poignant, real world case study. For more information, please refer to our report, *Replacing Mother*, and materials posted on our website. The report was originally published in 2008 and an update was also posted, based on additional published research, in 2010: http://www.cornucopia.org/2008/01/replacing-mother-infant-formula-report/ As stated, Martek's DHA is currently added to some organic foods, due to an incorrect interpretation of the rule. Approving the HC's proposal would make hundreds of potential ingredients legal in organics, including Martek's DHA oil).

The GAO report also pointed out that some materials, which had been deemed GRAS by the FDA, were later found to be harmful (such as cyclamate salts).

The FDA is also failing in its responsibility to ensure that GRAS status is reviewed and updated when new safety data comes to light. In the case of Martek's DHA, more than a hundred reports[viii] had been filed with the FDA, as of 2009, that indicate that some infants experience serious gastrointestinal problems when consuming Martek's DHA oil in infant formula (a current FOIA for subsequent adverse reaction reports is pending at the FDA). Yet the FDA has not reviewed Martek's oils' GRAS status in light of this important information, which has only come to light after the materials were brought to market.

Moreover, opening the organic door to <u>any</u> GRAS substance with nutritional value could potentially also open the door to nanotechnology in organics. The GAO report states: "Because GRAS notification is voluntary and companies are not required to identify nanomaterials in their GRAS substances, FDA has no way of knowing the full extent to which engineered nanomaterials have entered the U.S. food supply as part of GRAS substances." Without the required petition, review and approval process for novel ingredients in organics, it would not be unreasonable to predict that companies could add nanotechnology ingredients to organics without the NOP's knowledge.

Moreover, Michael Hansen, Senior Scientist at Consumers Union, recently wrote to the FDA: "At present, the FDA does not have statutory authority to require that companies even inform them of any GRAS determinations that they make. Consequently, companies can make their own determination that a substance is GRAS, not tell the FDA of that decision, and then start adding that substance into food and selling it to consumers. We believe that this system allows for potentially dangerous substances to enter the food supply, without FDA's knowledge or supervision."

These defects in the FDA's protocol are exactly what drive some consumers to trust the organic label and depend on organic foods as an alternative.

Finally, regarding the safety of supplements (which the FDA defines separately from "nutrients" used to fortify foods), **the FDA states[ix] that no safety testing is required before supplements are brought to the market**:

> "Dietary supplements do not need approval from FDA before they are marketed."

The FDA further states that supplements need not be proven safe or effective before they can legally be marketed:

> "By law (DSHEA), the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer."

Furthermore, **FDA does not require that manufacturers limit the serving size of a dietary ingredient in a supplement**:

> "Other than the manufacturer's responsibility to ensure safety, there are no rules that limit a serving size or the amount of a nutrient in any form of dietary supplements."

The FDA also admits it has limited resources to ensure the safety and efficacy of dietary supplements:

> "In that ***FDA has limited resources*** to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. The remaining funds are used for routine monitoring of products pulled from store shelves or collected during inspections of manufacturing firms.
>
> "***The agency does not analyze dietary supplements before they are sold to consumers.*** The manufacturer is responsible for ensuring that the "Supplement Facts" label and ingredient list are accurate, that the dietary ingredients are safe, and that the content matches the amount declared on the label."[x]

We therefore disagree entirely with the HC's contention that the FDA's system for ensuring the safety of "nutrients" is adequate. On the contrary, we would argue, based on the Government Accountability Office's report, that **the FDA is currently lacking an adequate framework for ensuring the safety of novel substances in our food supply**.

Therefore, it would be irresponsible for the NOSB to support a rule change relinquishing its statutory authority to preserve the safety and integrity of organic food.

Organic consumers, who are generally wary of novel inputs created by corporations (this is why they pay a price premium for foods grown without chemical, synthetic and novel inputs), should be able to trust that the National Organic Program serves as a buffer between the FDA's laxness toward novel ingredients, and the organic foods they eat.

Efficacy

The FDA allows novel "nutrient" ingredients even when they are not shown to benefit human health. Taking DHA as an example, numerous organizations, including the World Health Organization and the U.S. Institute of Medicine, encourage a certain level of DHA, EPA and other omega-3's in the diet.

DHA is one of several naturally occurring omega-3 fatty acids that have been found to play a role in health. However, with **the exception of corporate-funded organizations and scientists, no independent group has endorsed the addition of manufactured DHA, such as Martek's algal DHA oil**, to foods, including infant formula.

The FDA, per the Infant Formula Act of 1980 and regulations found under 21 CFR 107, requires certain nutrients in infant formula—it does not require DHA/ARA. The agency also does not state that the addition of DHA to formula is beneficial.[xi] The American Academy of Pediatrics does not recommend the addition of DHA in infant formula. As recently as April 6, 2011, the World Health Organization stated explicitly that it "does not have a recommendation regarding the addition of DHA to formula milk."[xii] UNICEF also recently strongly objected to the use of claims that DHA in formula promotes infant brain and eye development, and stated: "there would appear to be no consensus in the scientific community about the effects of supplementing DHA."

In the scientific community, independent scientists (i.e. those that do not disclose financial support from corporations involved in manufacturing DHA oils and infant formula) repeatedly state that there is weak or no evidence that adding DHA to infant formula benefits infant development. In fact, three leading scientists in this field recently published a letter[xiii] in the *Archives of Disease in Childhood,* of the *British Medical Journal*, stating the following:

> "Although the vast majority of infant formulas now contain LCPUFA [DHA and ARA], the scientific evidence base for their addition is recognised by most investigators and Key Opinion Leaders in the field to be weak.
>
> We contend this field of research has been driven to an extent by enthusiasm and vested interest. Our experience of publishing in this field has consistently been that publications supporting the addition of LCPUFA to infant formula are more readily accepted and less criticised than those which do not support the intervention, or which raise potential concerns."

Numerous review studies and meta-analysis studies, which review *all* data on the subject, conclude there are no benefits to infant development from supplementing formula with DHA and ARA. A partial list of such studies, with references to the peer-reviewed academic journals in which they are published, is available in Appendix A.

Finally, the Federal Trade Commission has cautioned Martek regarding claims that its DHA in infant formula benefits development: "We would encourage Martek to exercise caution in characterizing the extent or permanence of any benefits and in describing the certainty of the supporting science in any future advertising."[xiv]

The consumption of omega-3 fatty acids, including but not limited to DHA, is beneficial when consumed as part of a varied diet of wholesome, natural (real) foods. However, the creation of individual nutrient additives such as DHA, in

laboratories and factories, to add to foods in order to make marketing claims and make profit, is not supported by science (certain vitamins and minerals, like folic acid in the early weeks of pregnancy, have been proven scientifically to be crucial in the prevention of serious public health problems—these vitamins and minerals are already allowed in organics under the current "vitamins and minerals" rule).

The organic label should provide a refuge from such novel ingredients that serve primarily as marketing tools for corporate profit.

Cornucopia's response to HC justifications

Furthermore, Cornucopia disagrees with the four statements in the HC recommendation that serve as justification for the proposed annotation.

1. **The Handling Committee states: "First, it would honor and implement the authorization proposed by the NOSB in 1995 by restoring the meaning of the listing and eliminating the annotation erroneously added during rulemaking."**

Cornucopia response: As pointed out by Jim Riddle, Organic Outreach Coordinator at the University of Minnesota and former NOSB chair, in his comment, "The language referenced above was offered as an addendum, and was never acted upon by the full NOSB – no record exists to verify that there was a motion to accept or that the language was voted in affirmative by a 2/3 majority of the NOSB."

In addition, the 1995 addendum stated that "vitamins, minerals and/or accessory nutrients … must be limited to that which is required by regulation or recommended for enrichment by independent professional associations."

Even if this 1995 addendum were a valid recommendation, the current HC recommendation does not honor its intent, which clearly aimed to *restrict* the use of vitamins, minerals and nutrients to those that are required or recommended by independent professional associations. The HC recommendation would allow any and all nutrients, regardless of whether they are required by FDA regulation or recommended by independent professional associations.

Comments submitted by Richard Theuer and Joan Dye Gussow, who were on the 1995 NOSB, clarify the intent of this addendum. We urge the Board to seriously consider these expert opinions and reject the HC's proposal.

2. **The Handling Committee states: "Second, it would annotate the listing during the sunset process in a manner that recognizes and embraces both the development of the organic marketplace since the time of the adoption of the original National List and the NOP rulings and Guidance issued since the inception of the National List by the NOP."**

Cornucopia response: NOP rulings and Guidance issued since the inception of the National List offer conflicting viewpoints and interpretations. The HC's

recommendation "recognizes and embraces" one particular ruling—the one that has been determined by the current NOP to be "incorrect" (see the NOP's April 26 memo to the NOSB).

This "incorrect" interpretation, which the HC now apparently embraces, was the result of a corrupt backroom deal between the former NOP director and a corporate lobbyist representing the industry. An investigative article in the *Washington Post* exposed this deal to intentionally misinterpret the organic standards. It is absolutely baffling that four members of the HC would embrace this incorrect interpretation, despite their knowledge of the corruption involved.

3. **The Handling Committee states: "Third, it would harmonize the rules on fortification, supplementation and enrichment of organic food products with the rules governing other foods in a manner that avoids unnecessary conflict with other statutes and governmental agencies."**

Cornucopia response: This is a nonsensical statement. There has never been a need to "harmonize" organic standards with other agency rules.

The very nature of the organic law (the Organic Foods Production Act of 1990) requires that NOP standards be <u>stricter</u> than those of other government agencies.

Where the EPA allows certain pesticides, the organic standards prohibit them. Where the USDA allows genetically engineered seed, the organic standards prohibit them. Imagine the absurdity if the Crops Committee suggested that organic standards should be "harmonized" with EPA rules governing pesticides, or that organic standards should be "harmonized" with USDA rules governing genetically engineered organisms.

Moreover, we disagree with the suggestion that there is currently an "unnecessary conflict with other statutes and government agencies." Fortification of nutrients required by law is allowed in organics. All required nutrients in infant formula are currently included in organic infant formula. However, no federal agency requires unnecessary fortification and supplementation for marketing reasons, such as Martek's DHA. In fact, the FDA cautions against random fortification of foods.

4. **The Handling Committee states: "Lastly, it ensures the maximum freedom of choice for organic consumers"**

Cornucopia response: This is another nonsensical statement, for two reasons. First, nobody is suggesting that organic consumers be prohibited from supplementing their organic diets with non-organic nutrient supplements (pills, powders, oils, etc.).

Second, organic consumers pay a price premium precisely because they desire products that have been strictly regulated. They want to be able to trust that the

green seal signifies a refuge from unapproved novel ingredients, whether they be non-organically produced agricultural products or synthetics.

We are suggesting that organic consumers should have the freedom to buy foods—organic foods—that are produced in accordance to strict standards that put consumer safety before corporate profit. The HC's proposal would take away this freedom.

Request for enforcement of the law

The HC recommendation also requests that the NOP "delay publishing any guidance regarding this listing, … until after the publication of the proposed amended annotation in the Federal Register."

Although this is the "age of enforcement," it appears that the HC is requesting the NOP to delay enforcing the current law.

Instead, we urge the NOSB to recommend that the NOP immediately publish its guidance, enforce the law, and ensure that companies are in compliance with the organic standards. Consumers, and ethical industry participants, expect no less.

Possible Consequences of the HC proposal

The HC's recommendation, if accepted, would allow the use of any nutrient "supported by the FDA," meaning, any nutrient regardless of whether it has been tested for safety or considered beneficial.

Cornucopia believes this would have the following consequences for the organic industry:

Erosion of Consumer Trust in the Organic Label

If there are novel "nutrient" materials that should be included in organic foods, consumers trust that the open and transparent process of individual petitioning works in favor of organic integrity. Blanket approval is troubling.

Chipping away at the meaning of organics

Consumers pay a price premium for strict standards. Any material that can be considered a "nutrient" and is "allowed by law" would be like saying any pesticide allowed by law. The whole point of organics is stricter standards than those governing conventional foods. That's why people pay more for organics.

Obstructing innovation in the organic market

Any conventional ingredient with theoretical nutrient value would be allowed.

Clarkson Grain worked hard to develop organic soy lecithin, but that will be moot if this proposal passes. Lecithin has nutritional value, and any

corporation wishing to use the cheaper non-organic version will be allowed to do so under the "nutrient" allowance.

Another example is soy protein isolate. If a company wants to make an organic milk shake, but wants to boost the protein level, for competitive reasons, they would be allowed to add conventional, hexane-extracted soy protein isolate under the "nutrient" allowance, instead of adding certified organic soy protein.

By allowing any conventional nutrient in organics, innovation in organics will come to a halt. We are aware of several companies that are developing a certified organic alternative to Martek's DHA oils. These companies' efforts to grow the organic market will surely come to a dead stop if this proposal passes—and future innovators will have no reason to even consider developing organic nutrient materials.

Conclusion

What has happened to the organic label that processors feel they need the help of chemical companies and biosciences corporations with their marketing? Organic companies should pride themselves on being free of non-organically produced ingredients and synthetics—providing pure foods produced in harmony with natural farming processes and offered to consumers the way nature intended.

Organic, grass-fed milk provides a poignant example—produced in a way that nature intended and therefore supplying superior nutrition, including higher levels of omega-3 fatty acids. This is real food rather than, as Michael Pollan describes, "food-like substances," and is exactly what organic consumers expect.

We urge the National Organic Standards Board to reject the split decision of the Handling Committee, and vote down this proposal.

Sincerely,

Charlotte Vallaeys
Director, Farm and Food Policy
The Cornucopia Institute

Attached: Appendix A

Appendix A

Peer-reviewed, published review studies and meta-analysis studies conclude that there are no proven benefits to infant development from adding DHA and ARA to infant formula.

2005 Review Article—American Journal of Clinical Nutrition

"[Randomized clinical] trials have often not shown an effect of long-chain polyunsaturated fatty acid supplementation on cognitive or behavioral performance, and some reviewers have considered that, overall, the evidence was insufficient to conclude that long-chain polyunsaturated fatty acid supplementation benefited development."

- McCann, J.C., Ames, B.N. (2005) Is docosahexaenoic acid, an n-3 long-chain polyunsaturated fatty acid, required for development of normal brain function? An overview of evidence from cognitive and behavioral tests in humans and animals. *American Journal of Clinical Nutrition* 82, 2: 281–295

2006 Review Article—Journal of Specialists in Pediatric Nursing

"The majority of studies found the addition of DHA and ARA to have no significant effect on infant development. … More expensive formula with endogenous DHA and ARA is not necessary."

- Wright, K., Coverston, C., Tiedman, M., Abegglen, J.A. (2006) Formula supplemented with docosahexaenoic acid (DHA) and arachidonic acid (ARA): a critical review of the research. *Journal for Specialists in Pediatric Nursing* 11: 100–112

2007 Review Article—Journal of Perinatology

"*Studies in both preterm and term infants have not consistently demonstrated efficacy with long-chain polyunsaturated fatty acids supplementation of infant formulas."*

- Adamkin, D.H. (2007) Controversies in neonatal nutrition: docosahexanoic acid (DHA) and nucleotides. Journal of Perinatology 27, Suppl 1: S79–82

2008 Meta-Analysis—Cochrane Database of Systematic Reviews

"The results of most of the well conducted randomized clinical trials have not shown beneficial effects of long-chain polyunsaturated fatty acid supplementation of formula milk on the physical, visual and neurodevelopmental outcomes of infants born at term."

- Simmer, K., Patole, S. and Rao, S. (2008) Longchain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database Systems Review. Jan 23;(1):CD000376.

2009 European Health Safety Authority—Rejection of a Health Claim

"On the basis of the data presented, the Panel concludes that the data presented are insufficient to establish a cause an effect relationship between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of the fatty acids and a ratio ARA:DHA between 1.4:1 and 2:1 and the contribution to normal brain development in infants and young children from birth to three years of age."

- European Food Safety Authority. Scientific substantiation of a health claim related to DHA and ARA and brain development pursuant to Article 14 or Regulation (EC) No 1924/2006. EFSA Question # 2008-212

2010 Meta-Analysis—Journal of Pediatric Gastroenterology and Nutrition

"The absence of any detectable benefit or disadvantage in Neurodevelopment assessed with BSID at the age of 18 months for all of the children or in any subgroup therefore provides evidence against beneficial effects of LCPUFA [DHA and ARA] supplementation on BSID at 18 months under the conditions of the trials included here."

- Beyerlein, A, Hadders-Algra M, Kennedy K, Fewtrell M, Singhal A, Rosenfeld E, Lucas A, Bouwstra H, Koletzko B, von Kries R (2010) Infant Formula Supplementation With Long-chain Polyunsaturated Fatty Acids Has No Effect on Bayley Developmental Scores at 18 Months of Age-IPD Meta-analysis of 4 Large Clinical Trials. *Journal of Pediatric Gastroenterology and Nutrition* 50(1): 79-84.

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[i] 21 CFR 104.20(a)
[ii] ibid
[iii] ibid
[iv] http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074434.htm
[v] http://www.washingtonpost.com/wp-dyn/content/article/2009/07/02/AR2009070203365.html?nav=emailpage
[vi] http://www.gao.gov/products/GAO-10-246
[vii] GRAS Notice 000041
[viii] http://cornucopia.org/DHA/AdverseReactionReports.pdf
[ix] http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what
[x] http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what
[xi] www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/ConsumerInformationAboutInfantFormula/ucm108079.htm
[xii] World Health Organization letter by Francesco Branca, MD, PhD, Director, Department of Nutrition for Health and Development. April 6, 2011. Letter to Glenis Willmott, Member of the European Parliament, UK.
[xiii] http://adc.bmj.com/content/95/8/588/reply
[xiv] http://www.ftc.gov/os/closings/staff/050711martek.pdf