

OMB 0651-0066 Approved for use through 8/31/15.
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Humanitarian Use Application

Application Title: **Pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients.**



Application Date: November 8, 2015

Category: Nutrition

Organization Applying:



Primary Location of the applicants:

City: Palo Alto State: CA Country: USA

Public Contact Info:

Name: Asha Nutrition Sciences, Inc.
Address: PO Box 1000, Palo Alto, CA 94302
Email: admin@asha-nutrition.com
Phone Number: 650-322-7861
Preferred contact method: admin@asha-nutrition.com
Press contact: admin@asha-nutrition.com

If you wish to provide private contact info to be notified about your application status, please email it to patentsforhumanity@uspto.gov. Otherwise we will use any contact info associated with your submission.

It is estimated that the Humanitarian Award Application will take 4 hours to complete. Applying for the Award is voluntary; however, if you apply you must provide the information requested. Failure to provide this information may delay or prevent processing of your application. Please send any comments on the amount of time required to complete this form and/or suggestions for reducing the time burden to the Chief Information Officer, USPTO, PO Box 1450, Alexandria, VA 22313-1450. DO NOT SEND APPLICATIONS TO THIS ADDRESS

Qualifying Patents

- List the relevant U.S. utility patents or patent applications you own or license that you wish to apply under. These patents must relate to the technology described in this submission. Add more rows if needed. Only one patent or patent application is required for eligibility. If any patents or applications are found ineligible, the remaining items will be considered. If no eligible items remain, the PTO may contact the applicants to determine if eligible material can be identified.

U.S. Patent Application Number (PCT Number) (PCT Publication number)	Title	Filing Date
12/426,034 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof	April 17, 2009
13/332,251 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof Allowed as of 17 December 2018	December 20, 2011
13/877,847 (PCT/US2011/056463) (WO 2012/051591 A2)	Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof	April 4, 2013

- Are any of these patents or patent applications licensed from an entity not listed as an applicant on this form?

NO

In no more than five pages, please address the following questions.

Eligibility Questions

3. What humanitarian issue(s) does this application cover? If not widely recognized, provide enough information to determine whether the issues significantly affect the health or quality of life of an impoverished population.

This application covers, pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients, a game-changing solution for protecting and advancing public health at foundational level, whereby millions of people worldwide can benefit particularly the impoverished populations.

The foundation to health is nutrition. The most important and difficult to manage nutrients consumed are lipids, which include omega-6, omega-3, and several antioxidants and phytochemicals. Micronutrients include antioxidants, phytochemicals, and minerals, which affect metabolism of omega-6, omega-3, and other fatty acids. Most of the chronic diseases are associated with mismanaged lipid consumption, further immunity and daily well being is affected by lipid consumption, furthermore lipid requirements are different for different members of the family (by body size, hormones...)(See *Bhagat et al. 2015, Arch Med Sci 2015; 11, 4: 807–818*). In 2012, in the US chronic diseases affected 117 million people costing ~\$2 trillion (<http://www.cdc.gov/chronicdisease/overview/index.htm>); worldwide chronic and infectious diseases affected ~2 billion people (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html).

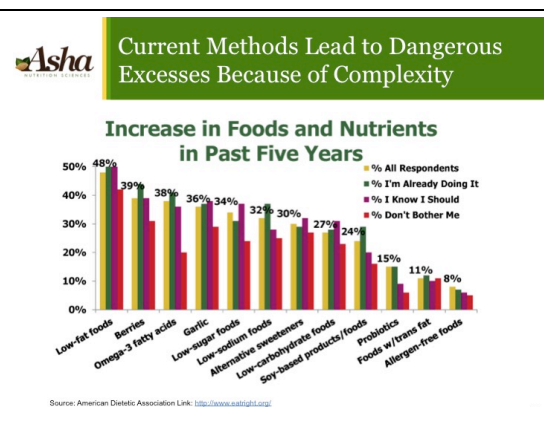
Natural lipid sources, oils, nuts and seeds etc, are variable and unreliable in lipid content and composition, and they contain many components that materially affect lipid metabolism. Important lipids such as polyphenols and several phytochemicals are poorly understood and absent from available dietary guidance, see Dietary Guidelines for Americans (http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf). Adding to the complexity is mass confusion in the field with many spins on what is desirable and what is not. For example, many bodies and publications have disparaged omega-6 or taught low amounts of omega-6 and low omega-6 to omega-3 ratios (*Lands, Nutrition Reviews 1986:44-6:189-95; Lands, Ann. N.Y. Acad. Sci. 1055: 179–192 (2005); Simopoulos, Ann Nutr Metab 1999;43:127–130; Hamazaki et al. World Rev Nutr Diet. Basel, Karger, 2003:92:109–132*), even though omega-6 is the most critical fatty acid for health. Further, too many supplements are sold without regard for interactions. For example, it is a misconception that omega-3, antioxidants, and phytochemicals are always good for health. Such issues have increased the risk of some diseases. It is extremely complex for public to solve this problem. For example, **less than 1%** of Americans can correctly name types of fats (see surveys at <http://www.foodinsight.org>), let alone lipids. Unless corrected, the chaotic out-of-context touting of nutrients will create further problems in the field of nutrition and consequently health.

Fatty acid composition of some common edible fats and oils.

Percent by weight of total fatty acids.

Oil or Fat	Unsat./Sat ratio	Saturated						Mono unsaturated		Poly unsaturated	
		Capric Acid C12:0	Lauric Acid C14:0	Myristic Acid C14:0	Palmitic Acid C16:0	Stearic Acid C18:0	Oleic Acid C18:1	Linoleic Acid (ω6) C18:2	Alpha Linolenic Acid (ω3) C18:3		
Almond Oil	9.7	-	-	-	7	2	69	17	-		
Beef Tallow	0.9	-	-	3	24	19	43	3	1		
Butterfat (cow)	0.5	3	3	11	27	12	29	2	1		
Butterfat (goat)	0.5	7	3	9	25	12	27	3	1		
Butterfat (human)	1.0	2	5	8	25	8	35	9	1		
Canola Oil	15.7	-	-	-	4	2	62	22	10		
Cocoa Butter	0.6	-	-	-	25	36	32	3	-		
Cod Liver Oil	2.9	-	-	8	17	-	22	5	-		
Coconut Oil	0.1	6	47	18	9	3	6	2	-		
Corn Oil (Maize Oil)	6.7	-	-	-	11	2	28	58	1		
Cottonseed Oil	2.8	-	-	1	22	3	19	54	1		
Flaxseed Oil	9.0	-	-	-	3	7	21	16	53		
Grape seed Oil	7.3	-	-	-	8	4	15	73	-		

Also see <http://www.ars-grin.gov/duke/> for other lipid content.



Pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient delivery to public, can prevent or at least reduce the suffering from many chronic diseases. Such pre-formulated lipids are particularly indispensable for impoverished populations who have inadequate access to medical care, are subjected to poor living conditions, and have poor knowledge to choose lipids making them disproportionately susceptible to infections and diseases. Thus, delivering pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient to public, especially to impoverished populations, can significantly reduce incidence and/or severity of disease.

4. What technologies does this application cover? Provide a brief description of each and indicate how they relate to the patents or patent applications in question 1.

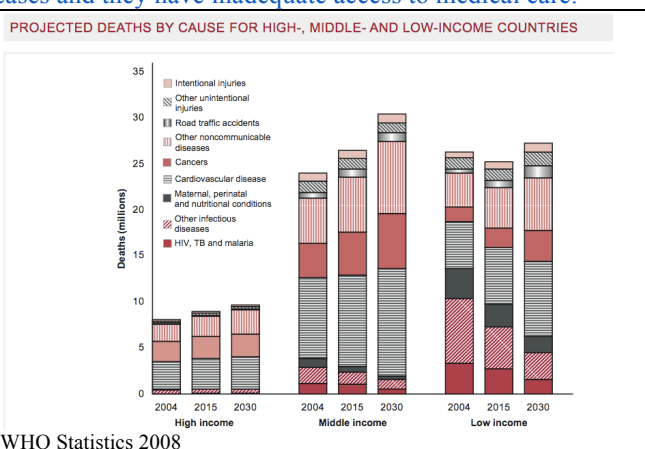
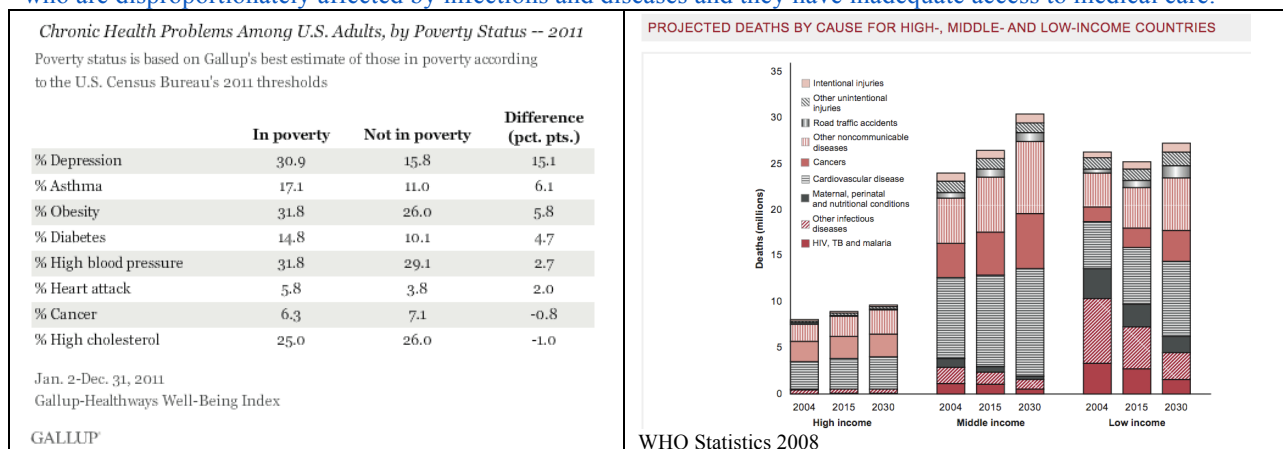
Technologies covered; product name: **LIPILIFE** (subject to change):

- US 12/426,034 and 13/332,251 cover **pre-formulated lipids** containing omega-6 and omega-3 with omega-6 to omega-3 ratios greater than 4:1 or omega-6 greater than 20% of total lipids, wherein their dosages are controlled and/or content of other lipids in controlled. These applications also cover **tailored lipids** delivery wherein ratios and/or amounts of omega-6 and omega-3 are controlled by age, gender, and diet type, and lipid-free or low-lipid foods are designed to complement the tailored lipids.
- US 13/877,847, covers **nutritional managements systems**, which include multi-component nutritional formulations and methods of providing nutrition by demographic cohorts, designed to control the delivery of lipids including omega-6 and micronutrients, including antioxidants and phytochemicals. It also covers computer systems by means of which public can be remotely guided to managing sensitive lipid and phytochemical consumption.
- It is important to manage the dosage of omega-6 and omega-3, and lipids that affect their metabolism, as discussed above. Many variables modulate the metabolism of various fatty acids. It is difficult for consumers to calibrate on a daily basis the demands of the body for various fatty acids, since the requirements of various biologically active unsaturated fatty acids change depending on age, gender, and various life style factors. It is possible that there could exist differences in the requirements of various fatty acids and their co-factors even among members of the same family. (*Bhagat et al. 2 015 Supra, page 808*)

5. What populations are your actions described in this application targeting? Please describe how these populations are impoverished, and how they are affected by the humanitarian issues described in question 4.

The patent applications (see appendices) describe that technologies covered have prophylactic and therapeutic effect on almost all medical conditions, such as menopause, musculoskeletal disorders, mood, cognitive function, neural disorders, mental disorders, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, infectious diseases, inflammatory diseases, and cardiovascular disease. Further, the described technologies improve quality of life by stabilizing hormones, mood, and sleep for example.

The actions described in this application are beneficial to all populations, particularly to impoverished populations who are disproportionately affected by infections and diseases and they have inadequate access to medical care.






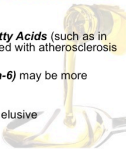

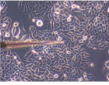




Thus, the disclosed solutions can especially reduce the burden of disease for impoverished populations. Applicant is targeting to provide the disclosed solutions in all economies with large share of impoverished populations.

Scoring Questions

6. Effectiveness – How do the applicants' technologies effectively address the humanitarian issues in question 5? Are any products or services that employ these technologies being used to benefit the target population?

Applicant's technologies effectively address almost all chronic and infectious diseases, which lead to ill health in 117 million people (133 million by some estimates) in US, and in ~2 billion people worldwide (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html). In fact, suffering is more than accounted here. For example, ~80% of females above the age of 13 (not counted in 2 billion) suffer from hormonal fluctuations, which can be debilitating and can be abated with controlled lipid delivery (*Filho et al., Reproductive Health 2011, 8:2*).

 <p>Tailored Lipids are the Most Sensible, Effective, and Sustainable Solution to Chronic Diseases...</p>  <p>133M People in US!</p>	 <p>Tailored And Steady Lipid Consumption Can Optimize Hormones</p>  <p>Very large percentage of teenage girls and women, 80% according to some reports, suffer from hormonal fluctuations and associated symptoms, which can be debilitating with consequences on school, education, work, and family.</p> <p>The instability costs them further in access to education, jobs, and economic and social standing.</p> <p>Hormonal fluctuations and associated symptoms can be abated to a large extent with correct and steady lipid delivery.</p> <p>Lipids affect hormone levels therefore erratic lipid consumption can lead to erratic hormone levels.</p> <p>Lipid requirements for girls and women are different from boys and men. Thus tailored lipids can help prevent health issues associated with hormones.</p>	
 <p>Scientific Evidence – MUFA & PUFA</p> <p>Conclusions from Fatty Acids Symposium by National Lipid Association:</p> <p>Monounsaturated Fatty Acids (such as in olive oils) are associated with atherosclerosis</p> <p>Dietary PUFA (omega-6) may be more protective than MUFA</p> <p>Omega-3 benefits are elusive</p>  <p><small>Burns et al. "Fatty Acids in cardiovascular health and disease: A comprehensive update." <i>Journal of Clinical Lipidology</i> (2012) 6: 216–234</small></p>	 <p>Scientific Evidence – PUFA & Cancer</p> <p>An Omega-6 PUFA (LA) inhibited colorectal cancer cell growth</p> <p>Results suggested that this PUFA is toxic to colorectal tumor cells but not normal cells</p>  <p><small>Lu et al. "Linoleic acid suppressed colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction." <i>Lipids in Health and Disease</i> 2010, 9:156</small></p>	 <p>Scientific Evidence – PUFA & Learning Disorders, e.g. ADHD</p> <p>Certain types of Omega-6 and Omega-3 PUFAs are significantly below normal in people with learning disorders</p> <p>This was particularly true for children. Authors theorized, "Children in Westernized countries may be eating a diet containing suboptimal AA to satisfy their dietary requirements during growth." Antioxidants and phytochemicals can inhibit AA (long-chain omega-6) activity.</p>  <p><small>N.L. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid." <i>Prostaglandins, Leukotrienes and Essential Fatty Acids</i> 91 (2009) 375–389</small></p>

Most tissue contains ~10 times omega-6 as compared omega-3 and utilization of omega-6 is higher than omega-3. Omega-6 and other lipids are critical for optimal functioning of the cells and organisms (see *Bhagat et al, 2015* and *Morse 2009*). Further, immunity is materially enhanced by controlled lipid delivery. Therefore, health effects of the technology are at a broad level. Consumer feedback to LipiLife from preliminary market research has been positive (see table below). Several scientific publications published after the patent applications were filed, also report similar benefits from higher omega-6 consumption. See Appendices.


Thus, significant reduction in the cost of chronic diseases and human suffering can be achieved by implementation of the solutions disclosed in the patent applications. Some of the suffering and cost estimates are as follows:

<p>United States Estimates (http://www.cdc.gov/chronicdisease/overview/)</p> <ul style="list-style-type: none"> 86% percent of all health care spending, ~\$2 trillion annual healthcare spending (2010) ~117 million people affected by chronic diseases (2012) 	<p>Worldwide 2012 Estimates (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html)</p> <ul style="list-style-type: none"> ~2 billion people suffer from chronic and infectious diseases Heart disease and stroke ~393 million people Cancer ~223 million people
---	--

<ul style="list-style-type: none"> • Costs of heart disease and stroke \$315.4 billion (2010) • Costs of cancer care \$157 billion (2010) • Costs of diagnosed diabetes \$245 billion (2012) • Costs of arthritis and related conditions \$128 billion (2003) • Costs linked to obesity \$147 billion (2008) 	<ul style="list-style-type: none"> • Diabetes ~60 million people • Musculoskeletal disorders ~111 million people • Infectious diseases ~432 million people • Neurological conditions ~80 million people
---	---

Additionally, LipiLife solves 100-year old problem of spoilage of unsaturated fats. In the 1900s, hydrogenated fats were introduced to solve the problem that unsaturated fats form toxic compounds sitting on shelf. However, we now know that hydrogenated fats are deleterious. We also know that unsaturated fats are critical for health, but cannot be added to food meant sit on shelf. The most effective solution is to pre-formulate and tailor lipids and deliver separately from the rest of the food, such that they are not made to sit on shelf for long durations, as LipiLife does. LipiLife is prepared separately from rest of the food and delivered in containers that are meant to last 1-4 weeks, i.e. not designed to sit on shelf for months.


Consumer Feedback to LipiLife*

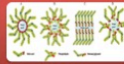


- **LipiLife is a Game Changer**
- **It makes so easy to keep track of fat intake, specifically Omega-3 and Omega-6**
- **It makes eating healthy easy**
- **It reduces the probability of overeating**
- **It makes me think and concentrate better, and I feel more grounded**
- **I sleep better and wake up rested**
- **I haven't had a cold since I started this**
- **I reduced my cholesterol and improved diabetes symptoms**


* Preliminary Market Research

LipiLife Solves 100-Year Old Problem Toxicity of Lipids and Correct Dosage







Lipids form toxic compounds sitting on shelf over time




Hydrogenated fats were introduced in early 1900s to solve this problem



Hydrogenated fats cause diseases - stopped in early 2000s



Polyunsaturated fats good for health but most vulnerable to forming toxic compounds



LipiLife best solution - replacement bottle/box delivered to consumers every 7 days and used with foods prepared without fat

The product, LipiLife, is in limited supply at present due to limited capital. Significant capital is necessary to effectively solve this problem, which includes public education in addition to product implementation. It is important for the patents to be granted for the Applicant to raise sufficient capital. All of the three applications are currently pending. Faster advancement of these applications is necessary for the applicant to secure sufficient capital and implement the solutions with public education to benefit the target populations.

7. Contribution – What meaningful actions did the applicants take to make the technology more available for addressing humanitarian issues?

Applicant is a small entity with very limited resources. Proprietors of the company have invested their personal intellectual and material resources for 10 years with dedication, without remuneration, to advance and implement the technology. Applicant needs sufficient capital to effectively solve this problem and patents need be granted to raise sufficient capital and effectively implement the solutions.

Applicant has committed to providing subsidized/free products to impoverished populations from part of the income generated from for-profit segments. Applicant plans to direct 10-25% of profits generated for providing subsidized/free products to impoverished populations. Such plans will be opportunistically reevaluated based on Applicant's financial strength. Partnerships will be developed with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. For example, Applicant has had

discussions for establishing such relationships with the following organizations: The HSC Foundation, The California Endowment, and California Wellness Foundation.

Applicant has invested very significant resources in building worldwide intellectual property portfolio in order to successfully make technology available to impoverished populations in economies with a disproportionate share of impoverished populations, such as Nigeria, Mexico, South Africa, Ukraine, Indonesia, Sri Lanka, China, and India.

8. **Impact** – How has deployment of the technology to benefit the target populations been significantly advanced as a result of the applicants' contributions? Are the target populations using the technology or products and services based on it? Are they benefitting in other ways? Include downstream actions by third parties stemming from the applicants' contributions.

As stated above, Applicant is a small entity. The products are currently in limited supply due to scarce resources. Applicant has put all resources available to deployment of the technology to benefit the target populations. Applicant has committed to providing subsidized/free products to impoverished populations from part of the for-profit segments returns, and to developing partnerships with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. As evidenced throughout this application unprecedented humanitarian benefits can be realized through this technology.

In the enclosed declarations from Drs. Rustagi, Rucker, and Das, the scientists declared:

“Thus, the art recognized in 1929 that the problem existed as noted in paragraph [0019]. However, the art has failed to solve the long-felt, critical and unmet need until the April 2008 priority date of the subject patent application, i.e. for ~80 years. There have been many persistent attempts as evidenced by the references cited above (e.g. Mark et al., whfoods.com, Lands 1986 and 2005; Simopoulos 1999; Hamazaki et al., 2003 supra), but the problem has not been solved. Lipid art has been struggling to find what are the right combinations of omega-6 and omega-3 and other lipids for consumption, how to keep the fatty acids stable on shelf (without formation of toxic compounds) but bio-available in-vivo (Chen and Chaiyasit supra). Inventions of instant claims 65, 91, 98, 122, 129, and 130 have devised the solutions. Thus, the invention of the subject patent application solves a long-felt critical persistent unmet need, and has great potential to protect and improve public health.” See para [0019]-[0023].

“[The technologies] ... are well-reasoned and directed at much needed lipid solutions, particularly in light of mass erroneous teachings and confusion in the lipid art.” See para [0026].”

Thus, the technology has many immediate and long-term benefits.

- The immediate benefits are reduction in global disease burden and public suffering.
- Long-term benefits include solution to the problem of toxicity from spoilage of unsaturated fatty acids, which has plagued the society for over 100 years.
- Long-term benefits also include that tailored delivery of lipids and micronutrients can prevent diseases from acculturation because of tailoring to demographics.
- The disclosed approach will largely re-align the currently dysfunctional nutrition system.
- The technology has additional long-term benefits, such as when tailored lipids and micronutrients solve the large part of the disease burden, resources and research are focused on solving deeper causes of diseases in populations free of the confounding effects of mismanaged lipid consumption.

Thus, there are numerous immediate and downstream beneficial actions by third parties stemming from the applicants' contributions, which will advance humanitarian causes and make a lasting impact on humanity.

Additional Information

If there's any additional information you would like the judges to consider, include it here. Judges are not required to read more than five pages of material, not counting the pages of this form.

Appendices:

1. Bhagat et al. 2015, "Potential role of dietary lipids in the prophylaxis of some clinical conditions" Arch Med Sci 2015; 11, 4: 807–818
2. Lands, "Renewed Questions about Polyunsaturated Fatty Acids" Nutrition Reviews 1986:44-6:189-95
3. Lands, "Dietary Fat and Health: The Evidence and the Politics of Prevention" Ann. N.Y. Acad. Sci. 1055: 179–192 (2005)
4. Simopoulos, "Essentiality of and Recommended Dietary Intakes for Omega-6 and Omega-3 Fatty Acids" Ann Nutr Metab 1999;43:127–130
5. Calder PC, "Polyunsaturated fatty acids and inflammatory processes: New twists in an old tale" Biochimie 91 (2009) 791–795
6. Johnson et al., "Effect of Dietary Linoleic Acid on Markers of Inflammation in Healthy Persons: A Systematic Review of Randomized Controlled Trials" J Acad Nutr Diet. 2012;112:1029-1041.
7. Baum et al., Journal of Clinical Lipidology 2012:6:216–234 "Fatty acids in cardiovascular health and disease: A comprehensive update"
8. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid" Prostaglandins, Leukotrienes and Essential Fatty Acids 2009:81:373–389
9. Lu et al. "Linoleic acid suppresses colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction" Lipids in Health and Disease 2010, 9:106.
10. Brasky et al., "Plasma Phospholipid Fatty Acids and Prostate Cancer Risk in the SELECT Trial" July 2010
11. Yip et al., "The Omega-3 Fatty Acid Eicosapentaenoic Acid Accelerates Disease Progression in a Model of Amyotrophic Lateral Sclerosis" PLoS ONE 8(4)
12. Declaration from Dr. Pradeep K. Rustagi dated September 29, 2014.
13. Declaration from Dr. Undurti N. Das dated September 30, 2014.
14. Declaration from Dr. Robert B. Rucker dated September 29, 2014.
15. Lipid-Containing Compositions And Methods Of Use Thereof
16. Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof
17. Filho et al. "Essential fatty acids for premenstrual syndrome and their effect on prolactin and total cholesterol levels: a randomized, double blind, placebo-controlled study" Reproductive Health 2011, 8:2