AIBMR Life Sciences, Inc.
Natural and Medicinal Products Research

EXPERT PANEL REPORT

The
Generally Recognized as Safe (GRAS) Status
of

Cranberry Seed Oil

For:

Sojitz Corporation of America

March 19, 2008

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I. Introduction

The subject of this GRAS determination is Cranberry Seed Oil (CSO), manufactured using a cold press process by Sojitz Corporation of America (Three Riverway, Suite 800, Houston TX 77056) for use in food. Cranberry Seed Oil is an excellent source of essential fatty acids and can be used to improve the ratio of omega-6 to omega-3 fatty acid in the diet. Additionally, CSO contains a significant level of natural antioxidants including tocopherols, tocotrienols and other phenolic constituents (Shahidi, 2006, **Appendix 5**).

This GRAS Self-affirmation review was conducted by a panel of experts qualified by training and experience to evaluate the safety of food ingredients. Members of the expert panel were Theodore Farber, PhD, Alexander G. Schauss, PhD, FACN, and John R. Endres, ND. The curricula vitae for these experts are at the end of this report.

Sojitz Corporation of America has provided proprietary, and unpublished information regarding the safety of the ingredient and these were made available to the expert panel. In addition to information based upon a long history of usage and consumption, a safety evaluation based on the composition of this product was performed and is discussed below.

II. Manufacturing and Production

A. Manufacturing Process

Sojitz Cranberry Seed Oil is manufactured according to GMP by Sojitz Corporation of America located at Three Riverway Suite 800, Houston TX, 77056. It is produced by a patented cold-press extrusion process from the seeds of the American Cranberry, or *Vaccinium macrocarpon* (see **Appendix 2**). The US Patent number for this process is 6,391,345 (see **Appendix 7**). The process does not utilize oxygen, enzymes, irradiation or solvents, and the temperature during processing does not exceed 100° F. Sojitz Cranberry Seed Oil has been designated as CAS Chemical Registry number 381718-27-0. The material safety data sheet (MSDS) for the product is provided in **Appendix 2**.

An overview of the manufacturing process is described as follows:

1. The seeds are acquired from the waste pulp of a juice extraction process.
2. The dry seeds are mechanically cold expelled with a cold pressing device.
3. Batch tank mixing and mechanical extraction for removal of any solids is performed.
4. The material is then placed in a clarification tank for lotting, and is packaged and stored (see **Appendix 2**).

The resulting cranberry seed oil is greenish-gold in appearance, with a pH of 4.8 and a specific gravity of 0.923. It has a shelf life of 24 months from the date of manufacturing. The seeds and processing used for oil manufacturing are free

from genetic modification and genetically modified organisms. The oil is produced in a manner free of protein derived from milk, eggs, fish, crustaceans, shellfish, tree nuts, peanuts, wheat or soybeans and is thus warranted to be free of these allergens. The process does not use any artificial or synthetic additives, and is hence considered by the company to be 100% natural (see **Appendix 2**).

B. Raw Materials

The cranberry seeds that are used in the production of Cranberry Seed Oil come from waste pulp (seed and fiber) formed from the production of cranberry juice.

C. Historical Use

Sojitz Cranberry Seed Oil is made from the seeds of the American Cranberry, *Vaccinium macrocarpon,* a member of the Ericaceae family. The cranberry plant yields pink flowers followed by reddish-black berries that ripen in June and July (Siciliano, 1996, **Appendix 5**). Cranberry grows in North America, and is cultivated mainly in Wisconsin, Massachusetts, New Jersey, Oregon and Washington (www.library.wisc.edu/guides/agnic/cranberry/faq.htm) (Siciliano, 1996, **Appendix 5**). In 2002, the total US cranberry harvest was 5.6 million barrels (Shahidi, 2006, **Appendix 5**). Cranberry was ranked fifth in total sales for a single herbal dietary supplement in 2005 (Engels, 2007, Appendix 5).

The word *cranberry* was reportedly first used in 1647 in a letter from a Cape Cod missionary named John Eliot (Siciliano, 1996, **Appendix 5**) (www.library.wisc.edu/guides/agnic/cranberry/faq.htm). A very early description of the plant is found in the 1578 book "Lytes' History of Plants".

American cranberries have a long history of use in the United States and their use as an ingredient or component of food is Generally Recognized as Safe (GRAS), indicating that cranberry's safety as a food is well established (see **Appendix 2** page 7). They are often consumed as whole berries, which include the seeds as well as the juice.

North American Natives used cranberries for centuries either as an ingredient in pemmican, which is a combination of crushed berries, dried meat and fat, or as boiled berries sweetened with maple syrup. In the 17th century cranberries were used medicinally for the "relief of blood disorders, stomach ailments, liver problems, vomiting, appetite loss, scurvy, and cancer" (Siciliano, 1996, **Appendix 5**) (Engels, 2007, **Appendix 5**). Additionally, New England folk medicine practitioners used boiled cranberries and seal oil to reduce the severity of gall bladder attacks. Currently, and in the past, cranberries have been consumed for their beneficial effect on urinary tract disorders; especially urinary tract infections (Engels, 2007, **Appendix 5**).

Commercial availability

Cranberry seed oil is produced by several companies and is currently commercially available from companies such as PL Thomas and others.

III. Description of the Product

A. Constituents

Sojitz Cranberry Seed Oil is a very stable and unsaturated triglyceride oil that is uniquely balanced with Omega-3, 6, and 9 fatty acids, tocopherols, tocotrienols, phosphatidylcholine and beta-sitosterol. Cranberry Seed Oil typically consists of the following constituents:

Constituent	Amount
Unsaponifiables	1.18%
Saturated Plant Fat:	6.86%
Monounsaturated Fat:	23.51%
Oleic Acid (18:1) (omega 9)	23.12%
Polyunsaturated Fat:	69.5%
Linoleic Acid (18:2) (omega 6)	35.13%
Linolenic Acid (18:3) (omega 3)	34.26%
Phosphatidylinositol:	9.9 mg/kg
Phosphatidylcholine:	202.0 mg/kg
Stigmasterol:	68 mg/kg
Campesterol:	66 mg/kg
Beta-sitosterol:	1319 mg/kg
Alpha Tocopherol:	508.09 IU/kg
Gamma Tocopherol:	163.9 IU/kg
Gamma Tocotrienol:	1700 mg/kg
Vitamin A (as ß-carotene):	390 IU/kg

All of these compounds are ubiquitous in the human diet and are widely recognized as safe in amounts that are consumed in the typical diet.

Unsaponifiables

Unsaponifiables are by definition the constituents in oils that do not saponify. A small percent of unsaponifiables are present in oils such as soybean, cottonseed, coconut, olive, and avocado oils.

Fat

Cranberry Seed Oil is composed of approximately 35% linoleic acid (omega 6 fatty acid), 34% linolenic acid (omega 3 fatty acid), 23% oleic acid (omega 9), and 7% saturated plant fat. The total percentage of fatty acids in Cranberry Seed Oil is: 99%. These plant-based fats are ubiquitous in the human diet. Omega 3 and omega 6 fatty acids are essential for human health)

Linoleic Acid

Linoleic acid is an essential omega-6 fatty acid. It is affirmed as GRAS by the FDA for use in food and is listed as such in 21CFR 184.1065 with no limitation other than current good manufacturing practice. Cranberry Seed Oil is composed

of approximately 35% linoleic acid. It is also found in many natural food sources such as corn, soybeans, sunflower seeds, canola oil, and olive oil. Sunflower oil from standard cultivars can be has high as 70% linoleic acid (Sobrino et al, 2003).

Linolenic Acid

Linolenic acid is also an essential omega-3 fatty acid and is a constituent of numerous oils that are commonly consumed. Cranberry Seed Oil is a rich source of linolenic acid containing approximately 34 percent. In contrast, flax seed oil contains 50.8% linolenic acid and canola oil contains 9.3% linolenic acid by weight (Conner, 1999).

Oleic Acid

Oleic Acid is a common omega-9 dietary fatty acid that is present at a level of 23% in Cranberry Seed Oil. Oleic acid is a monounsaturated fatty acid that makes up between 55 and 85% of the composition of olive oil. Oleic acid is also present in grape seed oil and sea buckthorn oil at a concentration of 15–20%.

Saturated Plant Fat

Cranberry Seed Oil contains nearly 7% saturated plant fat. Saturated fattys acids are commonly consumed by humans. Some common plant-derived food sources of saturated fats include: cottonseed oil (26% saturated fat), palm oil (45% saturated fat), coconut oil (85% saturated fat), and cocoa butter. (http://encarta.msn.com/media_461524427/Fat_Content_of_Oils_and_Shortenings.html). Sunflower oil from standard cultivars contains less than 15% of the saturated palmitic and stearic fatty acids (Sobrino, 2003, **Appendix 5**).

Phosphatidylinositol

Phosphotidylinositol is a phospholipid that is especially abundant in brain tissue, where it can amount to 10% of the total phospholipids. It is present in all tissues and cell types in the human body and is essential for health. Phosphatidylinositol is present at 9.9 mg/kg in Cranberry Seed Oil.

Phosphatidylcholine

Phosphotidylcholine is found at a very high concentration in lecithin derived from soy and egg yolks. Most commercially available lecithin (used as an emulsifying agent) is 98% phosphotidylcholine. According to CFR 21 184.1400, lecithin is allowed for use in food with no limitation other than current good manufacturing practice. Phosphotidylcholine is found in most plasma membranes of most high organisms.

Phytosterols

Cranberry Seed Oil contains small quantities of stigmasterol (68 ppm), campestrol (66 ppm), and beta-sitosterol (1,319 ppm), with the most significant contribution being from beta-sitosterol. Phytosterols are present in numerous plant foods and are ubiquitous in the human diet. FDA has reviewed a number

of GRAS notifications regarding various phytosterols including the ones listed here, and has not objected (http://www.cfsan.fda.gov/~dms/ds-ltr30.html, http://www.cfsan.fda.gov/~rdb/opa-g177.html). In addition, an FDA approved qualified health claim exists for phytosterols when added to foods with regard to a reduced risk of heart disease.

Vitamin E (alpha-tocopherol and gamma-tocopherol)

Cranberry Seed Oil contains vitamin E as gamma-tocopherol (163.9 IU/kg) and alpha-tocopherol (508.09 IU/kg). Vitamin E is a nutrient that is required for human health and is, of course, ubiquitous in the diet. Vitamin E is one of the most important phytonutrients in edible oils. It consists of eight naturally occuring isomers, a family of four tocopherols (alpha, beta, gamma and delta) and four tocotrienols (alpha, beta, gamma and delta) homologues. Tocopherols are GRAS per 21 CFR 182.8890 and 184.1890 when used in accordance with good manufacturing practice.

Tocotrienols

Cranberry Seed Oil contains gamma-tocotrienol (1,700 mg/kg). Tocotrienols are also found in oil derived from rice bran, barley, wheat germ and rye. Crude palm oil contains a high amount of tocotrienols (up to 800 mg/kg), mainly consisting of gamma-tocotrienol and alpha-tocotrienol (http://www.tocotrienol.org/en/index/sources.html).

Tocotrienols are ubiquitous in the human diet. Alpha-tocotrienol is the predominant vitamin E found in whole coconut at a level of 7.9mg/kg. Gamma-tocotrienol is present at a level of 3.2 and 3.3 mg/kg in cabbage and whole cranberries respectively (Chun, 2006, **Appendix 5**).

Vitamin A (as ß-carotene)

Cranberry Seed Oil contains vitamin A as ß-carotene. ß-carotene is ubiquitous in the human diet and is found in significant concentration in dark leafy greens, carrots, and winter squash.

ß-carotene is also affirmed as GRAS by the FDA for use in food and is listed as such in 21CFR 184.1245 with no limitation other than current good manufacturing practice. It is present in Cranberry Seed Oil at 390 IU/kg.

B. Microbial Assay

A microbial assay of a lot of Cranberry Seed Oil is included in **Appendix 1** (lot #CSO010706). It shows that there were no detectable amounts of yeast, mold or pathogens in the product.

C. Heavy Metal Analysis

Three separate batches of Cranberry Seed Oil were analyzed for heavy metal contamination (Sample ID #s 06322A, 06332E, 06332I). Mercury and lead were not detectable at a minimum detection limit of 0.02 ppm and 0.1 ppm

respectively, utilizing a cold vapor and ICP-MS methods of analysis respectively. Cadmium was detected at 0.11 ppm in all three samples at a minimum detection level of 0.05 ppm, utilizing an ICP-MS method of analysis (see **Appendix 3**).

D. Pesticide Assay

A USP Pesticide Screen was performed on three separate lots of Cranberry Seed Oil (Lot #s 061406, 020606, 082306) using ICP Mass Spectrometry. The results were negative for all pesticides tested in all batches (see **Appendix 4**)

E. Shelf-life and Stability Testing

The Cranberry Seed Oil project data sheet suggests a shelf life stability of 24 months from the manufacture date. Sojitz Corporation did not provide specific data from the shelf-life analysis study.

IV. Intended Uses and Exposure as a Food Ingredient

A. Target Foods

Sojitz Cranberry Seed Oil is intended for use in foods. For the sake of this GRAS report we have listed only the potential target foods and ingested products. Target applications suggested by the Sojitz Corporation are as follows (see **Appendix 2**, page 13):

- Nutritional Bars
- Functional (fortified) Foods

Sojitz Cranberry Seed Oil may be used as a substitute for other oils, or as a blend with oils and other ingredients. It may be used to increase omega-3 and antioxidant levels, while adding a unique (nutty) flavor to foods. The anti-oxidant properties of its vitamin E content may help stabilize other oils, and it may help provide product stability and extended shelf life. The daily serving of Cranberry Seed Oil will not be substantially greater than 10 g.

B. Estimated Daily Exposure Levels

Sojitz Cranberry Seed Oil is 99% fatty acids. The daily value of fat for a 2,000 kcal diet is 65 grams. However, subgroups of Americans consume up to a mean of 108 grams of fat per day according to the WWEIA-NHANES study data from 2003-2004 (http://ars.usda.gov/Services/docs.htm?docid=15044). Below are the amounts of the constituents that would be obtained from Cranberry Seed Oil if it were the only fat consumed in the daily:

Constituent	per 108 grams	per 65 grams
Unsaponifiables	1.27 g	0.767 g
Saturated Plant Fat:	7.4 g	4.46 g
Monounsaturated Fat:	25.39 g	15.28 g
Oleic Acid (18:1) (omega 9)	24.97 g	15.03 g

Polyunsaturated Fat:	75.06 g	45.18 g
Linoleic Acid (18:2) (omega 6)	37.94 g	22.83 g
Linolenic Acid (18:3) (omega 3)	37.00 g	22.27 g
Phosphatidylinositol:	1.07 mg	0.65 mg
Phosphatidylcholine:	21.8 mg	13.13 mg
Stigmasterol:	7.34 mg	4.42 mg
Campesterol:	7.13 mg	4.29 mg
Beta-sitosterol:	142.5 mg	85.74 mg
Alpha Tocopherol:	54.9 IU	33.03 IU
Gamma Tocopherol:	17.7 IU	10.65 IU
Gamma Tocotrienol:	183.6 mg	110.5 mg
Vitamin A (as ß-carotene):	42.12 IU	25.35 IU

V. Experimental Studies

A. Acute Oral Toxicity Study in Rats – Limit Test

An acute oral toxicity study with a 14-day post-treatment observation period in rats (limit test) was performed by Product Safety Laboratories (2394 Route 130, Dayton, NJ 08810) using 100% Cranberry Oil from lot number 10029. The study was conducted in compliance with good laboratory practices and in accordance with OECD Guidelines (OECD 401). A single oral dose of 5,000 mg/kg bodyweight of Cranberry Oil was administered to a treatment group consisting of five male and five female Sprague-Dawley albino rats by gavage. The animals were observed for clinical signs including signs of gross toxicity, behavioral changes, and mortality at 1 and 3 hours post-dosing, and at least once daily thereafter, for each of 14 days. Bodyweights were taken prior to initial administration of the test substance and on Days 7 and 14. Rats were euthanized on Day 14 and gross examination of tissues and organs from the thoracic and abdominal cavity was performed. Histopathological examination was not performed.

No mortality occurred, nor were signs of gross toxicity, adverse pharmacologic effects or abnormal behavior noted. All animals gained weight and appeared active and healthy. Examined organs and tissues of the male and female rats were free from gross changes related to the single oral administration of 5,000 mg/kg Cranberry Oil.

The results of the study show that the single dose acute oral LD_{50} of Cranberry Oil is greater that 5,000 mg/kg bodyweight in rats (see **Appendix 6**).

VI. Conclusions

Based on its independent and collective critical evaluation of the available information on Sojitz Cranberry Seed Oil, the Expert Panel concludes that Sojitz Cranberry Seed Oil, produced in accordance with current Good Manufacturing Practice, and meeting the specifications presented in the document that is the basis for the GRAS determination, is safe for its intended use. The Expert Panel further concludes that this use is GRAS based on scientific procedures and corroborated by a safe composition of sub-ingredients as well as a history of safe use (exposure). The Expert Panel also believes that other qualified experts (qualified by training and/or experience to evaluate the safety of food ingredients) would concur with this GRAS conclusion.

Panel Members:

Theodore M. Farber

Theodore Farber, PhD
Chairman of Expert Panel

Alexander G. Schauss, PhD, FACN
AIBMR Life Sciences, Inc

John R. Endres

John R. Endres, ND
AIBMR Life Sciences, Inc.

A. Dr. Theodore Farber, PhD—Panel Chair

Dr. Farber has a Ph.D., DABT in Pharmacology from the Medical College of Virginia, Richmond, Virginia, 1962, and a B.S. in Pharmacy, Brooklyn College of Pharmacy, Long Island University, New York, 1957 (With Honors). He is a Diplomate, American Board of Toxicology since 1980, and a Licensed Pharmacist, New York and Maryland. He is currently Principal/President of ToxaChemica, International, Inc., where he provides expert consultation to government and private clients on chemical toxicology assessment and toxicity testing, prepares hazard evaluations and risk assessments of environmental chemicals, pharmaceuticals, and food additives, and provides critical evaluation of laboratory reports, assessments, literature compilations, regulatory advice, and litigation services.

He has over 45 years of experience in toxicology, including laboratory testing, and risk assessment of food additives, feed additives, pesticides, industrial chemicals, and pharmaceuticals. He has conducted pharmacologic and toxicologic research and participated in national and international activities as an expert in regulatory requirements of EPA and FDA. Extensive experience in the preparation of state-of-the art reports on toxicity, testing and assessment, especially toxic substances and pesticides. Provides litigation services including expert witness testimony.

Author of over 75 journal articles, chapters, or books on toxicity testing and assessment, and over 50 assessment reports on food and feed ingredients, industrial chemicals and human and veterinary pharmaceuticals.

Past President and Vice President National Capital Chapter of the Society of Toxicology (SOT), Past President of the Carcinogenesis Specialty Section of the SOT, Co-Founder of the Association of Government Toxicologists, Councilor—Regulatory Affairs Specialty Section of the SOT.

Previous positions included Chief, Toxicology Branch, Office of Pesticide Programs and Director, Health Effects Division, EPA, Office of Pesticide Programs (1984–1988), and served as official EPA spokesperson in discussions on pesticides at meetings of the EPA Pesticide Science Advisory Panel.

Dr. Farber served with the Food and Drug Administration from 1965–1984, where he served as Director, Division of Drug and Environmental Toxicology, Human Food Safety Program, Center of Veterinary Medicine (1982 -1984), Acting Associate Director for Regulatory Evaluation, Division of Toxicology, Bureau of Foods (1980–1982), and Chief, Food Animal Additives Evaluation Branch, Bureau of Foods (1978–1982). He was also Group Leader and Acting Chief, 1976 - 1978, Food Animal Additive Evaluation Branch, and Chief, Biochemical Pharmacology Section, Bureau of Foods, Animal Laboratory, Special Pharmacology Animal Laboratory (1973–1976).

In addition to the specific FDA activities, also served on interagency and international committees, including, U.S. delegation to Organization for Economic Cooperation and Development (OECD) which developed international

testing and assessment procedures for food ingredients, toxic substances and pesticides.

He is the recipient of the Dr. Joseph Seifter Memorial Award in Toxicology, EPA, 1986, EPA Bronze Medal For Effort on API Verification Committee, 1986, and EPA Bronze Medal for Efforts in Risk Assessment, 1987. He also received Food and Drug Administration Commendable Service Award, 1979, and Outstanding Performance Award, US FDA, US EPA, 1983, 1984, 1985, 1986.

Societies and organizations that Dr. Farber is or has been a member are the:

American College of Toxicology
American Society for Pharmacology and Experimental Therapeutics
Association of Government Toxicologists.
Genetic Toxicology Association
New York Academy of Science
Academy of Pharmaceutical Sciences
Research Society of America - FDA Chapter
American Association for the Advancement of Science
Rho Chi (Honorary Pharmaceutical Society)
Sigma Xi
Society for Experimental Biology and Medicine
Society for Risk Analysis
Society of Toxicology
Toxicology Forum
Roundtable of Toxicology Consultants

As an educator Dr. Farber has been a:

Faculty Member, Evening Graduate School of the Department of Agriculture (Pharmacology and Toxicology Courses)

Lecturer, Pharmacology, Evening School of the National Institute of Health.

Lecturer in Pharmacology and Toxicology at Howard University Medical School.

Lecturer in Toxicology - American Chemical Society's Toxicology Course for Chemists 1980-1986.

Adjunct Professor - American University - Responsible for teaching a toxicology course in the Department of Chemistry.

Lecturer in Toxicology, University of Maryland.

Lecturer for the Center for Professional Advancement.

Dr. Farber has approximately 75 publications and abstracts in journals and books, and has presented approximately 100 presentations by special invitation in the areas of pharmacology, toxicology, regulatory affairs, risk assessment and science policy at national and international meetings.

B. Dr. Alexander G. Schauss—Panel Member

Alexander G. Schauss, PhD, FACN, is the Director of Natural and Medicinal Products Research, AIBMR Life Sciences, in Puyallup, Washington. He is a former Adjunct Research Professor of Botanical Medicine at the National College of Naturopathic Medicine in Portland, Oregon, and Clinical Professor of Natural Products Research at the same institution. He has held academic appointments at other institutions, including: Senior Director of the Southwest College Research Institute in Scottsdale, Arizona; Associate Professor of Research at the Southwest College of Naturopathic Medicine and Health Sciences, in Tempe, Arizona; Research Director, Institute for Biosocial Research, City University, Seattle; and, Lecturer in Biostatistics and Epidemiology at Bastyr University in Seattle. Dr. Schauss has been a member of the National Institutes of Health (NIH) Office of Alternative Medicine (OAM) Advisory Council (AMPAC); a member of the Ad Hoc Developmental Planning Committee of the NIH Office of Dietary Supplements (ODS), a reviewer of botanical standards and information monographs for the U.S. Pharmacopoeia Convention (USP), and reviewer for the International Bibliographic Information on Dietary Supplements (IBIDS) database, maintained through an interagency partnership with the Food and Nutrition Information Center, National Agricultural Library, and U.S. Department of Agriculture (USDA), which provides access to bibliographic citations and abstracts from published, international, scientific literature on dietary supplements. In 1985, Dr. Schauss was appointed by the US government to represent the United States as a voting member to the WHO Study Group on Health Promotion after being personally selected by Director General, Dr. Hafdan Mahler, of the World Health Organization (WHO), and confirmed by the Secretary of the U.S. Department of Health and Human Services. Dr. Schauss has studied nutrition and botanical medicine for over 30 years. He is a Fellow of the American College of Nutrition (FACN), an Emeritus Member of the New York Academy of Sciences, former Chairman of the Food Policy Council of the National Council for Public Health Policy, an Honorary Founding Member of the British Society of Nutritional Medicine, and Emeritus Executive Director of the American Preventive Medical Association. He is a member of the American Public Health Association, the American Chemical Society, the International Association of Eating Disorders Professionals, the Society for Food Science and Technology, and an Associate Member of the Society of Toxicology. Dr. Schauss received the Linus Pauling Lecture Award for contributions in the medical sciences in 2005 from the American College for the Advancement of Medicine. He earned his undergraduate, graduate (*summa cum laude*), and doctoral degrees at the University of New Mexico at Albuquerque and, California Coast University in Santa Ana, respectively. He completed post-graduate studies at the University of New Mexico, the University of Washington at Seattle, University of Washington at Tacoma, the University of Puget Sound, in addition to continuing education studies at the University of Texas Medical Branch at Galveston and California State University – Fullerton. Since 1992, Dr. Schauss has chaired the Safety Subcommittee of the Compliance and Labeling Integrity Committee (ComPLI) of the National Nutritional Foods Association (NNFA), the nation's

leading natural products trade association, founded in 1935. ComPLI oversees the NNFA's GMP certification program and TruLabel Program and makes recommendations to the Board of Directors regarding quality and purity standards for products sold by the 5,000 members of the association. He is also a member of the joint American Herbal Product Association and NNFA International Committee and chairs the Asian Affairs subcommittee and is a member of the Latin American Affairs and CODEX subcommittees. In 1996 he was an NGO member of the US FDA delegation to the Codex Meeting on Special Nutritionals held in Bonn, Germany. He is the author/co-author of more than 125 papers or works that have appeared in a diverse range of scientific journals, including: *Food and Chemical Toxicology, Renal Failure,* the *International Journal of Neurology, Journal of Applied Nutrition, Biological Trace Element Research,* the *International Journal of Integrative Medicine,* the *Journal of Alternative and Complementary Medicine,* the *Journal of the American Nutraceutical Association, Natural Products Industry Insider, Health Counselor,* the *American Journal of Natural Medicine,* the *Journal for the Advancement of Medicine,* the *Quarterly Review of Natural Medicine, Nature's Impact, Nutraceuticals World, Natural Medicine Journal,* in addition to numerous contributing chapters in the *Textbook of Natural Medicine* (Elsevier Science). He has also presented numerous posters and oral presentations before annual meetings of the Federation of American Societies for Experimental Biology that have appeared as abstracts in the *FASEB Journal.* From 1979 through 1992 he served as Editor-in-Chief of the *International Journal of Biosocial and Medical Research.* He continues to serve on numerous editorial boards or as an editorial review board member for a number of peer review journals. He is the author or a co-author of the following books: *Obesity: Why Are Men Getting Pregnant? (Basic Health, summer, 2006); Minerals, Trace Elements and Human Health, 4th Edition* (Life Sciences Press); *Acai (Euterpe oleracea): An Extraordinary Antioxidant-rich Palm Fruit* (Biosocial Publications); Cat's Claw (*Uncaria tomentosa)* (McGraw Hill); *Nutrition and Behavior* (McGraw Hill); *Anorexia and Bulimia* (McGraw Hill); *Feed My Brain* (Biosocial Publications); *Zinc and Eating Disorders* (Keats); *Eating for A's* (Simon & Schuster); *Nutrition and Criminal Behavior* (Brain Shuppan, Tokyo); *Diet, Crime and Delinquency* (Life Sciences Press). Dr. Schauss has been a part of the AIBMR Life Sciences team for over 28 years, where he brings a wealth of experience and expertise to the wide-range of services provided by this internationally respected consulting and R&D firm that in the period of 2003-2007 worked on projects in over 42 countries.

C. Dr. John R. Endres—Panel Member

Dr. Endres is the Chief Scientific Officer for the Natural and Medicinal Products Division of AIBMR Life Sciences, in Puyallup, Washington. Dr. Endres earned a board certified doctorate degree in naturopathic medicine at Bastyr University in Seattle, Washington. He earned his Bachelor's degree in Philosophy and German at the State University of New York at Albany and the Julius Maximilians Universität, in Würzburg, Germany. He completed all medical school prerequisites at the State University of New York at Cortland. Dr. Endres has

been the Co-Chair and a member of numerous expert panels assembled for the evaluation of self-affirmation of GRAS determinations.

Dr. Endres is noted for his work in the field of cancer research conducted at Bastyr University Research Institute as well as the Fred Hutchinson Cancer Research Center both located in Seattle, Washington. A particular area of interest is in complex extracts of various plant parts and how they affect human breast cancer cell lines that are estrogen receptor positive compared with estrogen receptor negative cell lines.

In addition, he has extensively studied the anti-proliferative effects of *Curcuma longa* (Turmeric) and Capsicum species extracts on numerous colon cancer cell lines as well as complex garlic extracts on breast cancer cell lines.

He is the recipient of research grants, which gave him the opportunity to conduct research in the United Kingdom, and to collaborate with investigators at such institutions as Westminister University, Middlesex University, and Oxford Natural Products (London). Dr. Endres has presented research at various venues including American Medical Association (AMA) sponsored conferences, where in 2001 he received an Award of Excellence in Research. In 2002 he was an invited presenter at the International Scientific Conference on Complementary, Alternative and Integrative Medicine Research that was held in Boston by Harvard Medical School.

In addition to being a licensed primary care physician in Seattle, he owned and operated Vail Valley Naturopathic Sports Medicine, LLC in both Vail, Colorado.

Dr. Endres held a position as a teaching assistant in laboratory chemistry, and a research assistant in natural products research, with a focus on production, purification, and analytical chemistry of whole plant extracts, at the Research Institute of Bastyr University, which is considered the world's leading fully accredited four-year post-graduate University of naturopathic medicine.