

NUTRI NEWS



**Douglas
Laboratories®**
Raising the Standard for Nutrition and Wellness™

Recent health and nutrition information from Douglas Laboratories

Special Edition

RAISING THE STANDARD CONTINUING A TRADITION OF QUALITY

by Natalie Shamitko and Andrew Halpner, Ph.D.

NutriNews usually deals with a current topic of interest related to supplementation and disease; however, it is also important to periodically update issues related to quality and explore areas of interest within the supplement industry. Since there is often discussion about the quality of dietary supplements, this issue will serve as a continuation of our “Raising the Standard” issue from last year and update the quality measures that Douglas Laboratories has in place to ensure our ability to manufacture the highest quality product. We will highlight our recently acquired ISO 9001 certification and 17025 accreditation of our laboratories as well as discuss other developments in the dietary supplement industry.

With the popularity of dietary supplements at an all-time high, health professionals and their patients have a wide variety of product lines from which to choose. Even pharmaceutical companies are now offering multivitamins in the hope that consumers will make the connection between the perceived quality of their drugs and their recently offered vitamins. It can be a daunting task, but how does one sort through the fact that everyone claims to offer “quality” products? In fact, the term “quality” has been so overused that has lost much of its meaning. Quality cannot simply be defined by the raw materials used in a product, or by the amount of marketing surrounding a given product. Quality is truly a synergy between many factors, including the raw materials, the procedures and practices in place to assure that those materials move through the manufacturing process correctly, the testing of the product, and the experience of those implementing the procedures. The result is a finished product of a consistent quality, backed by all of the expertise and labor while adhering

to a specific set of standards. Even the best raw material, when handled improperly or analyzed incorrectly will not guarantee a quality finished product. How the raw materials are treated through the entire manufacturing process is a crucial factor when determining how the end result will turn out. Many companies have quality control procedures in place, but we would like to explain how we at Douglas deliver exceptional quality, starting from the raw materials that go into each product to the technical support we provide once we ship the product.

For 50 years, Douglas Laboratories has been committed to providing the most superior dietary supplements available. We are continuously “raising the standard,” and are dedicated to providing the most complete information and services to further the health and knowledge of each and every customer. Superior products begin with superior raw materials and every raw material that enters our building is inspected and quality control approved. All materials go through a rigorous inspection to ensure they meet predetermined standards that have been set for each raw material. As an added step, we

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also meet face to face with raw material manufacturers on an annual basis to ensure that we have a sound understanding of each material and can address any new advances that may have developed in the previous year. Unlike many other dietary supplement manufacturers, we have our own in-house microbiological laboratory that is partitioned off from the rest of our facility and operates using a separate air-flow system. Before ingredients can be used in any product, they are subjected to testing in our microbiology lab for contamination including yeast, mold, E. coli and other potential pathogenic organisms including staphylococcus, salmonella and pseudomonas to ensure that the materials meet or exceed the requirements of the United States Pharmacopoeia (USP). Only after quality control approval has been granted can the raw material be released for use in one of our products. The manufacturing process itself is performed under tight controls by a team of highly skilled, dedicated staff, who strictly adhere to written Standard Operating Procedures (SOPs) prepared in

accordance with Good Manufacturing Practices (GMPs), as listed under Nutritional Supplements in USP 25. All manufacturing takes place in temperature and humidity-controlled conditions, and is under constant supervision. To further ensure precision and accountability, we have recently added the ability to electronically follow the entire manufacturing process, from the receipt of the raw material to the finished product. This allows us to track the progress of a product at all points through the production process and allows the various departments that work on the product to better interact, ensuring a quality supplement.

In addition to microbiology, our facilities have both physical properties and chemical analysis laboratories that ensure raw materials and finished products meet specific standards of quality, purity and safety. The physical analysis laboratory tests the weight, thickness, hardness, disintegration and dissolution of finished products, making certain that capsules and tablets disintegrate and release their nutrients in a timely manner. Using highly sophisticated analytical instruments, including HPLC (High Performance Liquid Chromatography), ICP (Inductively Coupled Plasma, used for mineral analysis), and UV-VIS (Ultra Violet, Visible Light Spectrophotometer), the chemical analysis laboratories test for



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the measurement of various vitamins, minerals and herbals to ensure that our products meet our meticulous standards of quality, many of which exceed the limits defined in the USP. Analyses in our laboratories have been compared with independent lab reports on many occasions and have consistently been on target. In fact, many independent laboratories are often quite surprised and impressed when they learn the depth of our analysis capabilities and experience. To further enhance our analytical capabilities we have just upgraded our chemical analysis laboratory by purchasing a new and even more sensitive ICP instrument. This new acquisition will allow us to measure trace elements in the PPB (parts per billion) range, which is over 1000 times more sensitive for many elements than our current instrumentation. With this acquisition every major analytical instrument in our in-house laboratories will be less than two years old.

Completion of ISO 9001 Certification and ISO 17025 Accreditation

Douglas Laboratories is proud to announce that we have completed our in-house laboratory certification and accreditation program to meet both the ISO 9001 and ISO 17025 standards, ensuring that we are compliant with one of the highest and most recognized standards of quality in the world. To the best of our knowledge, we are the only company manufacturing dietary supplements for physicians to have its laboratories ISO 9001 certified and ISO 17025 accredited. While the term "ISO" may be familiar as displayed by various companies (including Federal Express, Boeing, and Proctor and Gamble to name a few), it is important to understand what this certification and accreditation truly represents. The International Organization for Standardization (ISO) is a worldwide federation of 111 national standards bodies who's primary objective is to promote the development of manufacturing, trade and communication among business organizations worldwide through the development of standards. The term "ISO 9001" refers to a detailed set of quality management standards that a company must adhere to in order to meet

the conditions of certification. The more rigorous ISO 17025 provides a third-party accreditation of our laboratories, which serves to demonstrate that our laboratory has the technical and managerial capabilities to perform specific tests and measurements using correct, validated procedures and equipment. This accreditation demonstrates a number of important factors including:

- Personnel are competent and have the applicable theoretical and practical backgrounds to properly perform their work
- Written procedures are used for the sampling, handling, transport, storage, and preparation of items to be tested
- When applicable, testing methods are those published as international or national standards
- Testing methodology is validated to confirm that it is appropriate for each particular test

The emphasis that ISO 17025 accreditation places on method validation is of particular interest. Anyone can develop a method by which they analyze one or more compounds, but it is the validation of the method and the adherence to a set of tightly controlled procedures that is the key to being assured of accuracy and reproducibility. Of course, even a validated method will give you poor results if the instruments being used are not properly calibrated. Consequently, strict maintenance and calibration schedules are in place for analytical instruments. We also have a dedicated Quality Control Manager to monitor and supervise the daily progress of our quality systems, as well as an experienced Ph.D. in pharmaceuticals who monitors and oversees the entire Quality Control department. Our staff of highly skilled Chemists, Microbiologists and other scientists have the combined experience and dedication to ensure that you receive the best possible product. Their hard work, knowledge and determination was invaluable to our successful ISO certification and accreditation. We are proud to offer yet another level of assurance that

our products and procedures are unsurpassed in the industry. Figure 1 shows our dedicated Quality Control team members.

Fish Oil Supplements

Fish oil supplements have been receiving a significant amount of attention lately for both their health benefits as well as claims regarding their purity and quality. Concerns have been raised that fish oils may be contaminated with heavy metals or other toxins. Fish oil used by Douglas Laboratories is taken from clean, unpolluted waters and prepared using a molecular distillation method that serves to eliminate heavy metals and other potential contamination. The fish used to create our fish oil products come mostly from the cold waters of the Atlantic and Pacific oceans. An additional complication that has recently entered the world of fish oil is use of the phrase “pharmaceutical grade fish oil.” This phrasing can be seen on some internet sites and is being used to describe a specific classification of fish oil that is somehow “better” than other forms. While the term sounds official, “pharmaceutical grade fish oil” does not exist. For something to be truly considered “pharmaceutical grade” it must have a classification and

appear in an official compendium, such as the USP. This would then define exactly what the substance is, what it should and should not contain, amount of active components, etc. No such compendial designation exists for fish oil. Don’t get caught in the trap of the term “pharmaceutical grade fish oil.” A quality fish oil product should be derived from fish taken from clean water, processed via a method using molecular distillation, and supply a significant amount of omega-3 fatty acids. Mercury, lead, arsenic, and cadmium should all be < 0.1 ppm. Figure 2 shows a recent independent analysis of our DEPA product. Note that heavy metals are all < 0.1 ppm.

Bovine Spongiform Encephalopathy (“Mad Cow Disease”)

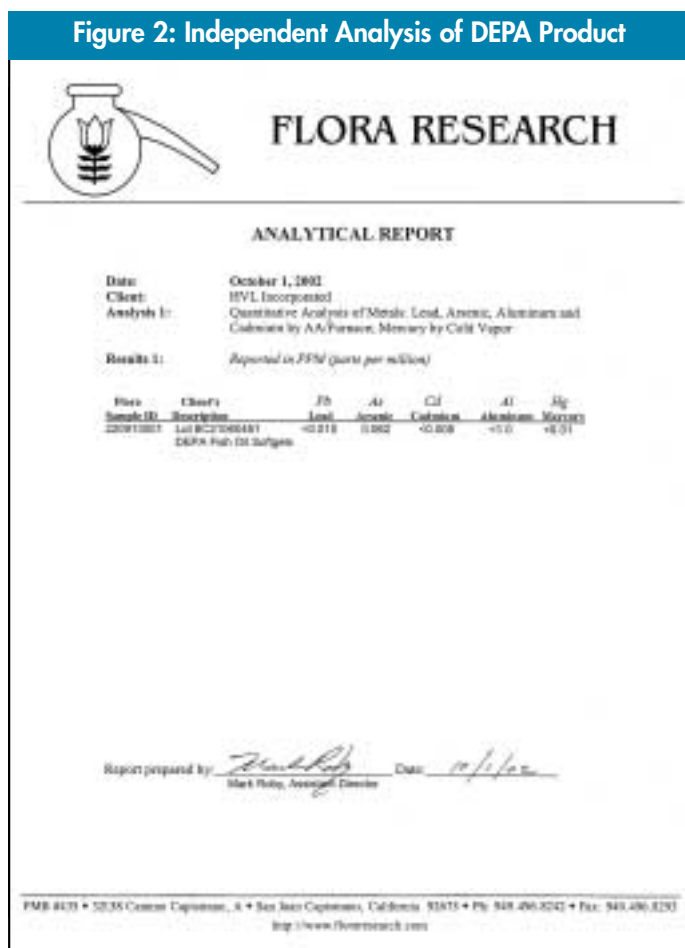
Mad Cow Disease is a term coined to describe a condition discovered in 1985 in cattle called Bovine Spongiform Encephalopathy, or BSE. In 1996 it was learned that BSE was transmissible to humans and was linked to a variation of a disease called Creutzfeldt-Jakob Disease, or variant CJD. Cattle in which BSE has been found has been limited to a number of countries including Great Britain and Europe.

As Douglas Laboratories does offer a number of items that are derived from bovine origin, we feel it is appropriate to



Figure 1: Members of our Quality Assurance and Laboratory Testing Team (from left to right): Angela Hughes – Technician II HPLC Lab, Melissa Gillott – Senior Microbiologist, George Porter III – Quality Control Manager, Justin Webb – Technician I ICP Lab. (Not pictured: Dr. Naeem Shaikh – Vice President, Research and Development)

Figure 2: Independent Analysis of DEPA Product



assure you of the quality and safety of the material used in our products. Bovine-derived materials are sourced exclusively from countries deemed by US regulatory authorities to be “BSE-free.” These countries include Argentina, Asia, Australia, Canada, New Zealand, and the United States. All bovine-derived products that we receive are imported according to USDA permits, which require documentation from governmental agencies detailing the health and absence of disease in the animals.

The Douglas Difference

Douglas Laboratories takes great pride in our uncompromising approach to providing you with products that meet the highest levels of quality. We constantly evaluate evolving technologies to incorporate into the development and manufacture of new and existing products. Douglas Laboratories’ unparalleled quality, manufacturing flexibility, decades of experience, breadth of product line and cutting edge technology are indeed raising the standard by which to measure dietary supplements within the industry.

Frequently Asked Questions

As part of our commitment to quality, we provide trained, dedicated staff members to answer any technical questions our customers may have. Available during regular business hours, our technical team goes to great lengths to provide accurate, reliable information on nearly 1000 products. Not surprisingly, there are some common questions that many of our customers have. The questions below are some of the most frequently asked. As always, our customers are always free to call us with any technical questions.

Alpha Lipoic Acid

Q: Where does our Alpha-lipoic acid come from and is it tested for epi-lipoic compounds?

A: Our material comes from Italy and it is tested for epi-lipoic compounds. Epi-lipoic compounds are considered to be contaminants of lipoic acid and should only be present in trace amounts.

DHEA and Pregnenolone

Q: Where is DHEA (or Pregnenolone) derived from?

A: DHEA and pregnenolone are indirectly derived from Wild Yam. Wild Yam does not contain DHEA or pregnenolone; instead, Wild Yam provides starting materials for the synthesis of DHEA and pregnenolone.

Excipients

Q: What are excipients? What excipients do we use in our products?

A: Excipients are ingredients used in products to allow them to be manufactured correctly. They are added to make powders flow smoothly, without causing the machines to become clogged with sticky or fluffy powder. They are also added to achieve uniform potency along with correct size and shape of tablets and capsules. The excipients used in our products include vegetable stearate, silica and cellulose. They are not derived from animal products or common allergen-causing products (yeast, wheat, corn etc.). Unfortunately, in the past some companies have stated that the use of certain excipients

can result in decreased bioavailability of compounds, as well as other health problems. There are no published data to support the contention that excipients, when used properly in dietary supplements, result in decreased absorption. These claims are not being made from a sound scientific standpoint.

Expiration Date

Q: *Can a person take our products past the expiration date?*

A: To ensure each customer receives fresh, highly potent product, we place a “best used by” date on each of our products. Since time and exposure to heat, light and air will cause supplements to lose their potency, we recommend that our customers do not use products past their labeled dates.

Glucosamine

Q: *Where is glucosamine derived from? Can diabetics take it?*

A: Glucosamine is derived from shellfish. While the molecular structure of glucosamine does contain a glucose molecule, it is chemically different and follows different metabolic pathways. While there is anecdotal evidence that taking glucosamine may cause a rise in blood sugar levels, there are also data from a large study published in *The Lancet* investigating the effectiveness of glucosamine for osteoarthritis that reported no changes in blood sugar. To date, there has not been a clinical trial specifically designed to investigate this question.

Gluten/Wheat/Soy/Corn/Dairy

Q: *Do any of our products contain any corn, wheat gluten, soy protein, yeast, milk/dairy sugar, salt, artificial colors, flavors or preservatives?*

A: Nearly all of our products do not contain these ingredients. However, a few products would contain them, such as whey protein isolate or soy isoflavone-containing products. However, our labels will reflect when these ingredients are absent from the product.

Likewise, our excipients also do not contain these types of ingredients.

Kava Kava

Q: *Why do you no longer offer Kava?*

A: Over the past year significant concern has been brought to the scientific community regarding the use of Kava in dietary supplements. While we believe Kava is safe and effective and has a safe history of use for hundreds of years, we have taken the conservative approach of discontinuing Kava until these unresolved questions can be definitively addressed.

The safety of kava use began to be questioned late in 2001. After receiving several reports of hepatotoxicity, several governments in Europe chose to restrict or ban the use of kava, for fear that it may be the cause of liver damage. However, several questions have been raised regarding the link between kava and liver damage, including whether pre-existing liver damage was present, as well as if kava was taken in combination with other drugs that may have increased the risks of hepatotoxicity. Additionally, the amount of kava taken and the procedures and materials used to standardize it to certain active compounds have been questioned. Traditionally, kava has been used in ceremonies for several hundred years in Polynesia, without reports of severe side effects. Kava has also been used in several controlled clinical studies with no reported hepatic side effects. Currently, kava is under review by independent committees to accurately determine its role in liver hepatotoxicity.

Melatonin

Q: *Where does melatonin come from?*

A: Our melatonin is synthetic (man made). It does not come from the brains of an animal.

MSM®

Q: What does MSM® stand for? Where does it come from?

A: MSM® stands for methylsulfonylmethane. It is derived from DMSO (dimethyl sulfoxide).

MSM® is a registered trademark of Cardinal Nutrition

Recent Events in the News

Journal of the American Medical Association (JAMA) publishes article that recommends supplementation with a multivitamin.

While it is probably safe to say that 100% of the readers of this publication understand the importance of supplementing the diet with additional nutrients in the form of a multivitamin, the traditional medical community has been very slow at realizing the need for and making the recommendation to take a multivitamin. It has generally been the position of the traditional medical community that supplemental vitamins are unnecessary and that we can obtain all the nutrients we need from a healthful diet. While we have never agreed with such a position, it has taken quite some time for others to begin to see the credence of our position. In the June 19, 2002 issue of JAMA, Drs. Fletcher and Fairfield make the case for multivitamin supplementation in the general public. These authors note that, "the high prevalence of suboptimal vitamin levels implies that the usual US diet provides an insufficient amount of these vitamins." This realization is a large departure from the "party line." The authors go as far as recommending, "...that all adults take one multivitamin daily. This practice is justified mainly by the known and suspected benefits of supplemental folate and vitamins B₁₂, B₆, and D in preventing cardiovascular disease, cancer, and osteoporosis and because multivitamins at that dose are safe and inexpensive." Unfortunately, these authors stop at recommending only one multivitamin a day and fall short of realizing the benefits of higher dose supplementation. Hopefully the traditional medical community will continue to recognize the benefits of nutrition beyond what can be obtained in a healthful diet.

Continuing Scientific Support for Antioxidants

Researcher reports link between plasma vitamin E concentration and carotid atherosclerosis

A study published in the September 2002 issue of the American Journal of Clinical Nutrition examined the link between carotid artery plaques and the intake and plasma concentrations of vitamin E in 310 women from Italy. Interestingly, the occurrence of carotid plaque as measured by ultrasound was inversely correlated with increasing intake of vitamin E. Even after vitamin E levels were adjusted for plasma cholesterol, a significant inverse association was found between higher intake of vitamin E from the diet and the percent of individuals with carotid plaque. The risk for carotid plaques in those with a diet low in vitamin E was particularly strong in postmenopausal women. This study is significant as it is the first study to measure both dietary intake of vitamin E as well as plasma levels and correlate those values with carotid plaques. We should remember that dietary vitamin E does not consist only of alpha-tocopherol, but also contains the other tocopherols including beta, delta, and gamma.

New Recommendations for Healthy Eating

The National Academy of Sciences' Institute of Medicine (IOM) has issued a report with new Dietary Reference Intakes (DRIs) for macronutrients. The full report, "Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Protein and Amino Acids (Macronutrients)," gives new recommendations for healthy eating. While everyone has different philosophies and practices regarding what they consider to be a healthful diet, it is interesting to keep up with what the Institute of Medicine is reporting.

Earlier guidelines recommended that adults get 50% or more total calories from carbohydrates, 30 percent or fewer total calories from fat and 10-35% from protein. The new guidelines now recommend 45-65% percent of total calories from carbohydrates, 20-35% of total calories from fat and the protein recommendation remains unchanged.

Figure 3: Old Recommendations vs. New Recommendations of Dietary Intakes

	Old Recommendations	New Recommendations
Carbohydrates	50% or more total calories	45-65% of total calories
Fat	30% or fewer total calories	20-35% of total calories
Protein	10-35% total calories	10-35% of total calories (unchanged)

Figure 3 compares the old recommendations with the new ones.

Ranges for protein, carbohydrates and fat were established to help people make healthier choices in diet and activity, since unbalanced diets (high-fat, high-carbohydrate, etc.) can cause serious health problems, including obesity, as well as an imbalance in the ratio of HDL (high density lipoprotein, "good" cholesterol) and LDL (low density lipoprotein, "bad" cholesterol).

Exercise plays a great role in healthy living as well. Previously, it was recommended that people get at least 30 minutes of moderate exercise (such as brisk walking, swimming, or cycling) every day. Currently, it is now recommended that adults get at least one hour of moderate exercise a day to maintain a healthy weight and proper cardiovascular fitness.

The report gave additional recommendations:

- Intake of carbohydrates equal to at least 130 g/day for adults and children. This recommendation is based on the minimum amount of carbohydrate needed to produce sufficient glucose for the brain to function properly. The report also recommends that added sugars (found in soft drinks, pastries, cookies, candy, and other foods) comprise no more than 25 percent of total calories.
- Consumption of as little saturated and *trans* fat as possible. Both saturated fatty acids and *trans* fatty acids

increase risk of heart disease by raising serum LDL-cholesterol levels. They are not essential and provide no known health benefit. Saturated fat can be found in whole milk, meat, butter and other products. Trans fat is found in margarine, cookies, crackers and fast food, and is listed on the label as partially hydrogenated oils.

- Both women and men should still have a protein intake of 0.8 g/kilogram body weight/day. For the first time, the report also makes recommendations for intake of all nine essential amino acids found in dietary protein.
- Fiber should be consumed every day. For adults under 50, males and females require 38 and 25 grams of total fiber, respectively. For adults over 50, males and females require 30 and 21 grams of total fiber, respectively. The report also provides a definition of fiber, noting the existing lack of a uniform definition of fiber for regulatory purposes. "Total fiber" is defined as the sum of "dietary fiber" and "functional fiber." "Dietary fiber" is the edible, non-digestible component of carbohydrates and lignin naturally found in plant foods. "Functional fiber" is fiber that has been shown to have similar health benefits to dietary fiber but which are isolated or extracted from natural sources or are synthetic (e.g., pectin extracted from citrus peel).

For additional information, The National Academies website is: www.nationalacademies.org.