WHEAT vs. CHAFF

Sifting Through the Maze of Dietary Supplements

by Solomon Jones

HISTORY

After 15 years in the alternative health field I felt compelled to write this article on Dietary Supplements. The first venture into this area of knowledge first started with hydrogen peroxide and expanded into herbs and naturally derived compounds.

During this quest I discovered very high quality, beneficial products as well as many “snake oil” substances that were worthless and sometimes dangerous. In the process I developed a system for identifying the “wheat from the chaff,” *i.e. good supplements from worthless ones.* This paper is based on these findings.

DIETARY SUPPLEMENTS

First let’s look into the dietary supplement field;

- According to a survey conducted at Harvard, more then 4 in 10 Americans applied some type of alternative medical treatment in 1997. A survey of 1000 Americans show 9 out of 10 have used some form of Alternative Medicine, which represents a substantial increase of over 100 percent. *"It is the beginning of acceptance of some forms of 1998 alternative medicine into mainstream medicine in the US,"* said George Lundberg. *"Acceptance the good, old-fashioned way - by merit."* (Alternative medicine)
- They reported that visits to practitioners and alternative therapies, ranging from herbal medicines to energy healing, have increased 47% since 1990, propelled chiefly by middle age, health-conscious baby boomers. Half of people ages 35-49 reported using at least one of the surveyed treatments last year.
- Researchers found that Americans application of alternative therapies increased by 25 percent during a seven year period of the study (1990 to 1997) (Jack).
- Reuters reported that the popularity of alternative therapies among cancer patients alone reflects the continuing rise in the public acceptance of herbal medicines, acupuncture and other alternative treatments that have occurred over the past decade. According to those who conducted the *study "a majority (69%) of patients were introduced to alternative medicine by a friend or family member," i.e. 'word of mouth,'* and sixty million Americans went online in search of

health and medical information in 1998, this was reported in a poll by Louis Harris & Associates. Furthermore, over 90 percent who went online reported that they found the information they were looking for (Warrick, 1999).

- A study conducted by a chemical assay company found that over 80% of those polled would purchase dietary supplements over pharmaceuticals because of perceived adverse side effects.
- The United States was sixteen in 2003 compared to other nations in regard to the average life expectancy. By 2010 it was 36(Expectancy).
- WHO, The United Nations World Health Organization warns that diseases of the rich industrialized nations (cancer, heart attack, and other diseases in which diet and exercise play a part) are increasing as the customs of industrialized nations spread to other parts of the globe.
- Americans pay more for health care, over $850 billion in 1993, than citizens of any other country. In 2010 it is estimated that Americans pay over $2 trillion dollars for health care (Hennigan).
- In 100,000,000 Americans suffer from chronic illnesses, costing $425 billion a year in health care expenses.
- It is estimated that $234 billion is spent on indirect costs such as lost work days.
- Each year 2.4 Billion prescriptions are written in the United States.
- Over 770000 people are injured or die each year in hospitals from adverse drug events (ahrq). Up to 300,000 Americans are injured or killed each year from medical negligence involving mistreated disease, surgeries, drug reactions, and mis-prescribed drugs.
- 36% of hospital admissions are caused by side effects of other treatments and 53% of all surgeries are unnecessary (Health).
- In the year 1800, one in two hundred people developed cancer in their lifetime. By the year 1900, it had risen to one in thirty people developing cancer in their lifetime. By the year 2000, it had risen to one in three people developing cancer in their lifetime (D'Jang).

As you can see, more and more Americans are taking charge of their health.

HOW TO SEPARATE THE WHEAT FROM THE CHAFF

Imports:
Separating genuine, effective products from “snake-oil” is not as difficult as it may seem. Below are the steps many have developed over the years, that has help to identify truly effective, beneficial products.

Today’s Nutritional Supplements field is full of deceptive marketing practices. Companies engage in this type of practice to entice you into purchasing their products. This can lead to safety issues for you or family members.

If you are presently taking supplements, or are considering them, you owe it to yourself to set guidelines on how to best determine a high quality, safe and effective nutritional supplement.

Imported Dietary Supplements are increasing at an alarming rate. China's export market, one of the largest, has been one of the fastest growing markets in the world. From 1990-1996, the western pharmaceutical market grew almost 20% annually and has now expanded into a $14 billion market (Service).

Likewise, dietary supplements manufactured in China have taken off in the past several years. Experts estimate that the industry, currently worth $2.4-3.6 billion, will grow to $6.1 billion in 2000 and $12.1 billion in 2010. The industry promises to continue this trend as growing numbers of consumers seek products with curative, weight loss and other health enhancing effects unaware of the products origins (Missouri Arthritis Rehabilitation Research and Training Center).

There is one statement the rings loud and clear for imported dietary supplement products *“buyer beware.”* Rep. Dan Burton (R-Ind.) -- chairman of the Committee on Government Reform acknowledged that the booming interest in dietary supplements among Americans has fueled questions about whether consumers are at risk of using supplement products brought in from overseas.

“The origin of these products is not controlled,” says Dr. Domenic Sica, professor of medicine and pharmacology at the Medical College of Virginia in

Richmond, Virginia. *It's not safe just because a company says it's safe"* (Sica, 2003).

This does not necessarily include products who's raw material is purchased overseas and manufactured in the U.S. In these cases the U.S. manufacture can quality monitor the production process as well as the raw material.

Dr. Ronald M Lawrence, assistant clinical professor of the UCLA School of Medicine in Los Angeles, in an interview with Larry King on the American CNN TV Network warned about the impure grades of dietary supplements being imported from the Far East.

The Old "Bait and Switch."
A perfect example that companies use to deceive customers is the old "bait and switch" tactic. Many companies claim their products are backed by extensive research, however, in most cases this "extensive research" is nothing more then research conducted on the materials claimed to be "contained" within the product, not on the product or the actual material within the product. Are you confused yet? That's how the "bait and switch" tactic works.

In many cases when a company makes a claim about a material component contained within a product, this material component is produced at the clinics/research centers completing the testing, the component being tested is not taken from the product itself. The company is only using the materials name.

An example of this would be a brochure or ad claiming "250mg a day of material X reduces the chances of developing diabetes, our product contains 250mg of material X." Notice they are claiming that "material X" reduces the chance of developing diabetes, not the product itself. In most cases the material in the product may not have been tested.

The manufacture is relying upon previous data compiled somewhere else to make it appear that it was their product that was tested. See the "old bait and switch?"

STEP 1 – Identify the claims of the product

Identify the claims of the supplement. Even though you are not allowed to make health claims about a specific product, unless it has been proven/shown through medical studies and reviewed by the FDA to provide for said benefits, many a salesman, websites, etc…, will still claim certain benefits. Document all the legitimate benefits. Gather all the brochures and other information on the product that is available. Do not confuse customer testimonials with claim's, they are two different things altogether.

STEP 2 – Identify the ingredients/components of the product

Identify the components contained within the product and document them. If the products do not list all of the ingredients, or they are a "trade secret" this is a red flag and your best bet is to walk away.

STEP 3 – Research the ingredients/components

Go to PubMed, available from the National Library of Medicine. It is the largest medical archive in the world. It is available on the Internet. You can review the summary of studies for FREE. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi

PubMED is set up similar to Internet search engines. Simply type in the components (ingredient) name and click the "GO" button. Within a couple of seconds the results will appear.

Example 1:

For this example we will use the immunomodulator known as Beta glucan (Akramiene, 2007).The search on PubMED produced over 10000 results. To reduce and define the search parameters input the ingredient and the condition, example; beta glucan, cancer. The results of the combination will be closer to the first page and may well be on the first page, thereby reducing your search time.

Example 2:

The next example we will use Astaxanthin. It is a member of the carotenoid family, is an oxygenated pigment called a xanthophyll. It is a fat-soluble nutrient. Its unique molecular structure gives it superior antioxidant capacity (Wiki-Asaxanthin). The search on PubMED produced over 700 results.

It is here that you will discover if the claims of the components match the results of scientific/medical community. If you see matches then you move on to the quality review, if no matches occur, time to do a general search of the Internet and/or purchase at least 3 separate reference books on nutritional supplements.

- Research by books – here again, conduct your review as you would on PubMed.
- Review by Internet search engines – the Internet is notorious for providing unreliable, unsubstantiated information. To overcome this problem, investigate the individual who wrote it. The main identifying factor I use to determine a reliable source is the years of experience of the author in the field being studied. Next, the establishment credentials, *i.e. MD, PhD, etc…* although these credentials may not absolutely necessary.
- Try to locate at least three websites that contains the information you seek. Cross-reference the ingredients and the beneficial effects to see if they match.

Quality issues and background research on supplements.
Many scientific studies have been conducted on quality issues alone. One study, a summary of which is available on PubMed (PMID # 12050511) an investigation into the percentage of active Saw Palmetto versus what the label on the product was conducted. 6 different Saw Palmetto products were tested, 3 of them showed they had less then 20% of the active Saw Palmetto ingredient contained within them. So your chances are 50/50 if you just go out and purchase a Saw Palmetto product without first investigating the quality of said product. This was a study conducted a various manufactures of Saw Palmetto products.

Another independent study on Beta 1, 3-D Glucan produced similar results. Beta glucan as it is commonly referred to is unknown to a majority of the general public. Many health researchers considered it to be one of the most effective immune enhancing substances ever discovered. It is considered an external immunomodulator. External immunomodulators are compounds that have been shown to modify the immune systems response to a threat upon it. It is an all-natural, food source derived dietary supplement. It modulates and potentiates the macrophage (white blood cells), keeping them in a highly prepared state for any threat our immune system may encounter. With this balancing effect, all subsequent immune responses improve.

When your immune system is in this highly prepared state, the invading organisms do not have the time to build up force and strength before the immune system attacks, destroys and/or weakens the invader.

Beta glucan has over 1000+ general research papers ranging across 40 years. A majority of this health related research has been completed at some of the most prestigious institutions in the world, including Harvard Medical School, Tulane University, National Cancer Institute, Department of Defense and the Department of Agriculture, just to name a few.

These studies have been performed on literally every health condition/disease known to humanity, and time and time again it has proven itself to be second to none. It has also been shown to provide beneficial effects in the sports/athletic health fitness field.

Properly extracted, it has been shown to be completely safe and non-toxic. This substance is extracted from the cell walls of bakers yeast (Saccharomyces cerevisiae), a food source. Bakers yeast, and their extracts, have been given a GRAS rating. This is one of the highest, if not the highest safety rating a substance can achieve. The specifications for this rating can be found in 21CFR184.1983 -- Sec. 184.1983.

Much controversy surrounds Beta glucan products these days. This controversy centers around the quality issue(s) of purity level and molecule linkage. In order to be effective the material must contain the proper glucan purity level and 1,3-D/1,6 molecular linkage. The serious researcher will discover that many manufactures hide or do not apply these generally accepted standards to their manufacturing process. Further, proof of quality/content by independent verification is seldom made available to consumers or researchers, if available at all, except upon specific request or demand. Request of this nature have required, in some instances, court orders. This paper helps you determine what is a high quality product. Beta glucan was one of the more intense reviews. If you review the **quality manufacturing issues concerning Astaxanthin** you will discover what source is the best for producing a high quality product. In the case of Astaxanthin it is the algae Haematococcus Pluvialis (Naguib, 2001). Further, there are two types of Astaxanthin; natural and synthetic, and it is the one extracted from the natural source (Haematococcus Pluvialis) that has

shown beneficial results (Miyawaki, 2005). Also, you want to stay clear of the synthetic, which is used to color salmon grown on fish farms. This synthetic version of Astaxanthin uses petro-chemicals to create it. Another important procedure that you should look for is the use of super critical extraction to extract the Astaxanthin from the algae. Super critical extraction uses CO2 to which removes oxygen from the manufacturing environment to reduce and/or rancidity and contaminates.

When reviewing the ingredients of a product insure that the products label lists the active ingredients. For example;

STEP 4 – Review the finished quality requirements of the product.

Once you are satisfied with the ingredients in the product your next step is to verify the quality of the ingredients/product component.

At a minimum a reputable supplement manufacture will abide by the guidelines that are in effect for the food industry. These regulations are known as Current Good Manufacturing Practices (cGMP's). These regulations were established by the U.S. FDA.

These regulations outline the procedures on how to produce safe, high quality products.

cGMP Guidelines:

- Assure that personnel are properly trained, supervised and practice proper hygiene when on the job.
- Assure that every manufacturing facility operates under such requirements as good drainage, effective waste management, adequate space, lighting and ventilation, and appropriate pest control.
- Address everything from the maintenance of all equipment, utensil and work surfaces to the safe use and storage of cleaning agents and the use of plumbing
- Protect against the contamination of supplement ingredients during the manufacturing process
- Spell out the steps that govern the manufacture and testing of supplement products at every stage of production

- Cover the date of manufacture, equipment used, specific quantity and identity of ingredients, safety and quality control tests, and packaging records

This is the regulations that American supplement manufactures are required to adhere to. There are no “cGMP” requirements for a foreign manufacture. The FDA has no authority on manufactures in foreign nations and imports are not required to abide by these guidelines.

Presently there are four effective ID systems to follow for verification, any one may suffice or a combination thereof. They are;

ID SYSTEM ONE:

You can spend weeks or months discovering the textbook standards developed through reviewing peer review studies, many if which you can locate on PubMED, for example;

Example 1: Beta glucan does not have a certifying organization or usp standard (both are discussed later) to determine the quality of Beta Glucan products. Through the years of research a “textbook standard” has been developed to identify a high quality product. A summary of the “textbook standard” developed for Beta Glucan is as follows;

a. No one can debate that a Beta glucan derived from bakers yeast is safe, if, sufficient fats and proteins have been removed. In fact the FDA has issued a GRAS rating for baker's yeast and its extracts. This removal process must be done without disturbing the precise molecules that provides the cellular activity described in so many medical articles (You may have a key that starts your car, but if you bend or break it, it will not be able to start the car).
b. One company does not purify the baker's yeast they label as Beta glucan. Countless thousands have been duped over the "micro-sized" particle scam, on the pretense that the smaller they grind the particle size, the better it will pass through the system. Go to MEDLINE (PubMED), search the effective, human, oral dose. You will find that human studies show grams, not trace amounts used, to be effective.

c. Most products that claim to contain Beta-1, 3-D glucan(BG) have a purity level of only 2% to 7.5% of actual Beta glucan. Purity level is one of the most important aspects of highly effective Beta-1, 3-D glucan products. Effectiveness of Beta glucan products appear to greatly decrease if the purity level falls below 90%.
d. Is the Beta glucan material contained in the product been tested at least at one major university? Those tests should reflect the following:
    i. The carbohydrate (glucan is a polyglucose) content is a least 94%
    ii. The 1, 3 linkage portion of the glucan is at least 85%. (textbook perfect)
    iii. The 1, 6 linkage is within the textbook limits to confirm a proper molecule
    iv. The other glucan linkages are appropriate according to textbook limits
    v. There are no signs of excess mannose or glucose. (Spiking to create false data)
    vi. A combination of at least 2 independent labs to confirmed that the product has virtually non-detectable levels of fats (making the material indigestible as an immune modulator) and proteins (causing possible complications with persons with allergies).
    vii. Combinations of at least 2independent labs to confirmed that the average particulate size of the material is from 0-5 microns. (Czop's work at Harvard showed a 5 micron average) Of the material over 1 micron, the average size is from 3-5 microns. The sub-micron material shown by all labs is quite substantial (One lab indicates some 99%). The product sold by Sigma Chemical, similar in quality sells for over $200 per capsule. That product has only a 27% sub-micron population
    viii. Microphotography and expert analysis using standard scientific methods at a major university show that the Beta glucan products possess the same characteristics as those microphotographs published in respected peer-reviewed articles. Their data should also show that the material was is free from bacteria, coliforms, and other undesirable components.
    ix. Micro photography and expert analysis using standard scientific methods at a major university should show that the product material possess the same characteristics as those microphotographs published in respected peer-reviewed articles.

Example 2: Astaxanthin is another example of a product that specific guidelines can be developed for;

Natural versus Synthetic: Natural Astaxanthin produced from the algae Haematococcus Pluvialis has been shown to be a far more potent free radical scavenger and antioxidant then synthetic Astaxanthin. Further synthetic Astaxanthin is produced using petrochemicals. While they are essentially the same chemical formula, the molecular properties are different and it is this difference that provides for the natural Astaxanthin's safe and effective antioxidant properties. This difference is the fact that natural astaxanthin is paired with fatty acids, which are attached to the ends of the Astaxanthin molecule. This creates an esterified molecule.

Esters are more easily absorbed by the human body. Nearly all studies on astaxanthin that showed beneficial effects in humans were performed on the stereoisomer (isomeric molecules that have the same molecular formula) found in Haematococcus (Adilakshmi, 2006); (NCBI);(Naguib, 2001);(Miyawaki, 2005)

Natural astaxanthin is more stable than the microalgae because the extracted Astaxanthin complex is better protected within the oleoresin matrix than in the dry form of the microalgae meal (Oleoresin);(Capelli, 2006). The esterified form of Astaxanthin (as in the microalgae) additionally increases stability; an advantage over extracts of crustaceans, which are not as highly esterified. This in-turn leads to a more stable shelf-life (Mercke, 2003);(Clark, 35(7)).

Another important fact is when the microalgae Haematococcus Pluvialis is placed under stress to create its astaxanthin content, it also produces lutein, canthaxanthin and beta carotene in its own natural oil containing small amounts of omega 3 and 6 fatty acids, i.e. essential fatty acids [9]. This complex provides a more desirable group of carotenoids than a single dietary ingredient. These other carotenoids have also been shown to produce beneficial effects in studies.

Natural Sources: The source from which astaxanthin is extracted can play a critical role in a product remaining contaminate free. Shellfish, salmon and other organisms existing in the natural environment can introduce unwanted contaminants into the manufacturing process. A controlled environment greatly reduces and/or eliminates this issue. Insure that the astaxanthin product you are looking to purchase is derived from the best source. In this case numerous studies have shown that to be the Haematococcus Pluvialis algae and is growth in a controlled environment.

Supercritical extraction: One particular concern which continues to be a quality issue with astaxanthin, omega oils and any lipid based supplements is oxidation. Oxidation is actually what triggers the fishy flavor, rancid odor and a decrease in the nutritional value people find in these products. The double bonds of and lipid based product causes them to be considerably more vulnerable to oxidation and rancidity.Water

also plays a important role in oxidation, which is a main component in many manufacturing processes of these products. Water contains iron and copper, which they can be a catalyst in the oxidation process.

This innovative manufacturing procedure which requires the use of highly pressurized CO2 (carbon dioxide) significantly decreases the oxidation concern frequently observed in lipid based products. In this process CO2 is pressurized to a precise temperature and pressure. At this level it turns into a inert solvent which could draw out the active substances of different plant species without having the normal high temperatures or harsh chemicals solvents based in many other processes. Likewise oxygen, yet another primary catalyst in the oxidation process is not found in the supercritical extraction method. This drastically minimizes the oxidative process identified in the majority of lipid based products (Supercritical fluid extraction).The outcome of employing supercritical extraction is certainly much more concentrated and stable product. Supercritical CO 2 is biologically compatible, and has been given a generally regarded as safe (GRAS) designation by the FDA. The specifications for this rating can be found in 21CFR184.1983 -- Sec. 184.1983.

Supercritical extraction offers three principal benefits over traditional solvent extraction procedures;

- It produces exceptionally clean, completely solvent free extracts. It extracts far more of the plants functional elements
- It considerably lowers or removes the oxidation rate of the elements in contrast to conventional techniques
- It permits the production of extremely pure extracts with rigorous quality controls as well as optimum efficiencies and does not present any unwanted elements into the procedure such as chemical solvents and oxidation.

Analyzation: There are many companies that claim to produce high quality Astaxanthin products, however their methods of determining the concentration of astaxanthin is not standardized. The most technically sound and accurate method for determining the astaxanthin content of a product is by HPLC analysis. Determination of the astaxanthin content of Haematococcus algae by HPLC analysis has been accepted by the U.S.

Food and Drug Administration (21 CFR 73.185) and the Canadian Food Inspection Agency (Registration No. 990535); and it is used by Japan's official analysis agency, the Japan Food Research Laboratory (Cysewski, 2006).

This information took months to develop through independent research. You can this route; however there is less time consuming approaches;

ID SYSTEM TWO:

You can attempt to locate 3rd party independent studies conducted on a range of the same type of products. Some important points when taking this route;

a. What is the credibility of the labs doing the research? Are they university affiliated? Do they abide by government established guidelines? Does the manufacturer of the product make these results readily available?
b. How do these testing labs obtain the material being researched? Do they purchase themselves? This procedure greatly reduces the ability of a manufacture to play around with the product.
c. 3 or more different manufactures products are tested/compared against each other in the independent testing.

ID SYSTEM THREE:

Many very popular materials may have an organization(s) devoted to certifying quality of the material/components in products. For example aloe vera is a very popular product. An organization has been founded to define, identify and certify what makes a high quality Aloe Vera product.

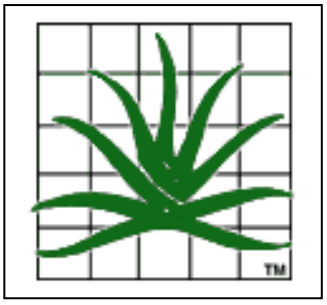
The International Aloe Science Council (IASC) is a non-profit trade organization for the Aloe Vera Industry world-wide. Its membership includes Aloe growers, processors, finished goods manufacturers, marketing companies, insurance companies, equipment suppliers, printers, sales organizations, physicians, scientists and researchers.

The guidelines established by the IASC to certify an acceptable Aloe product are;

a. Source of aloe raw materials must be certified by the IASC.Product Label and Company literature review must be completed.
b. Manufacturing records for the products to be certified will be reviewed by the inspector at time of visit.
c. Samples of the aloe raw material will be taken for analysis.

d. Production samples of the finished product will be taken for analysis.
e. Inspector will observe the manufacturing and filling of a standard size production run. The minimum batch size for certification is 55 gallons of product for liquids and 10 gallons for others. The certification program involves three separate areas:
    i. Complete review of labeling and literature used in reference to the aloe products. All labeling and literature must be submitted to the IASC office prior to the inspector visiting your production facility. This information will be reviewed for correctness as it applies to use of the IASC Seal of Certification. This review in no way implies acceptances by any state or federal governmental agencies. Artwork or labels must be submitted for certification purposes. The label itself is to be submitted as soon as it is available to speed up approval. This step assures the Council that what you commit to is what ends up in the final product. All literature, such as specification sheets and sales flyers should also be submitted for approval. Any changes to your label or literature is to be submitted and approved prior to being used. The IASC will accept artwork for labels or literature for approval. If we accept artwork, we will need the final label or literature sent to us within 60 days to assure that the final label or literature conforms to the approved artwork.
    ii. A physical review by the IASC Certification Inspector of: The formulation used in manufacturing of the product, the manufacturing procedures used to make the product, the packaging, warehousing, storage, and inventory records concerning the products to be certified. The inspector will conduct an on sight visual inspection of an actual production and filling operation used in reference to the aloe products. The inspector will collect samples of the aloe raw materials used to manufacture the product as well as finished filled product taken off of the filling line. The samples will be used to determine the analytical criteria.
    iii. Analytical analysis of the products to be certified: The products must meet all of the parameters for aloe content as defined by the IASC.

You may find these symbols on an aloe vera product that has been certified by the IASC.



If you rely solely on a certification agency for identifying a high quality product critical review of the agency itself is in order. This is required to insure it is not a “boiler room” operation. Some of the questions you should be asking are;

a) How long have they been established?
b) Are there professionals on staff?
c) Where are they located?
d) What are there certification procedures?

You may even wish to call the local Better Business Bureau

ID SYSTEM FOUR:

The USP standard. USP establishes state-of-the-art standards to ensure the quality of medicines for human and veterinary use. USP supplies standards for more then 3,800 medicines, dietary supplements and other health care products.

Today, the distinctive USP "Dietary Supplement Verified" mark may appear on several dietary supplements. The mark is intended to safeguard and inform the growing number of consumers who take dietary supplements. Below is a image of the mark;

The mark assures consumers that a supplement has passed five important quality tests under USP's Dietary Supplement Verification Program. They are;

a. Contains the ingredients listed on the label.
b. Has the declared amount and strength of ingredients.
c. Will break down easily in stomach fluids so the body can effectively absorb the nutrients in the supplement.

d. Has been screened for harmful contaminants such as heavy metals, microbes, and pesticides.
e. Has been manufactured in safe, sanitary, and controlled conditions.

In some cases manufacturers do not have the mark on their labels, instead claiming their product conforms or meets the USP standards. You will be able to locate this evidence upon the label itself.

Usually the wording “Conforms to USP <number> of weight” or “Meets USP <number> for disintegration” will be found on labels of manufactures who claim to conform and/or meet to the USP standard(s). However this does not necessarily mean the product has been certified by the USP organization. Only products that have been certified can carry the verification mark.

USP's dietary supplement monographs are published in the *USP-NF*, which the Dietary Supplement Health and Education Act, 1994 (DSHEA) recognizes as the official compendia for dietary supplement standards. According to the provisions of the DSHEA, a dietary supplement represented as conforming to USP standards will be deemed misbranded if it fails to do so.

A *USP-NF* monograph provides the tests, procedures, and acceptance criteria that help to assure product identity, strength, quality, and purity. The monographs are established by a process of public review and comment conducted through *Pharmacopeial Forum (PF)*.

USP evaluates dietary supplements submitted to the program based on:

a. Extensive laboratory testing.
b. Testing performed by scientific laboratories with demonstrated expertise in evaluating the complex composition of vitamin, mineral, and botanical compounds.
c. USP and USP-audited contract laboratories will perform testing to confirm manufacturer results.
d. Supplements tested against USP established standards for purity and ingredient content and performance characteristics (dissolution and disintegration).

Comprehensive review of quality control and manufacturing documentation.

a. Quality control documentation is reviewed to ensure compliance with acceptable specifications for dietary ingredients, excipients, packaging and labeling materials, and the finished product.
b. Testing method(s) and reference materials are reviewed for acceptability for use.
c. Stability data are reviewed to ensure that they support the marketed shelf life period in the commercial package at the storage conditions recommended on the product label.
d. Manufacturing documentation is reviewed to verify the acceptability of the master formula, the manufacturing process directions, packaging instructions, labeling for the product, and indication of quality assurance final release approval.
e. Evaluation of manufacturer compliance with USP and proposed FDA standards for GMP.GMP audits involve inspections of manufacturing facilities to assess compliance with USP and proposed FDA GMPs and existing comprehensive quality systems.
f. Mandatory criteria is stipulated for the organization and its personnel, document management, equipment and facilities, sample and components control, deviations, laboratory control, label control, shelf life evaluation, quality assurance review, process performance evaluation, and electronic records and computerized systems.
g. Audits are conducted by professionals specializing in the inspection of dietary supplement manufacturing operations.

Quality maintenance. Once a dietary supplement is granted the DSVP certification mark, USP will periodically conduct random off-the-shelf tests on verified products to ensure they continue to meet DSVP's strict standards. USP also will continue to conduct audits of manufacturer sites for GMP compliance on a three-year basis. During the intervening years, manufacturers will be required to conduct annual self-audits and report the results to USP for review.

There are two issues with the USP standard.

Issue one pertains to the fact **that not all dietary supplements components have had an established standard set yet.** This may be due in part by the

popularity of the product, or because the product/component is relatively new. As an example, Beta Glucan and Aloe Vera do not have an established standard, whereas Saw Palmetto does. To review all of the standards set for Dietary Supplement/components please visit; http://www.usp-dsvp.org/standards/monographs.html If a product/component does not have a USP standard researchers may rely on independent testing to identify a high quality product.

Issue two revolves around the fact that some manufactures do not entirely agree with the standards set by USP. They instead follow the USP manufacturing guidelines but develop their own standards that may actually exceed the USP standard.

As always consult a professional if have any concerns about any product you are taking, or wish to take.

(n.d.). Retrieved 2003, from Missouri Arthritis Rehabilitation Research and Training Center: www.muhealth.org/~arthritis/news/supplements.html
Adilakshmi, B. (2006). *Current Science* , June, Vol. 90, No 12, 25.
ahrq. (n.d.). *Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs*. Retrieved 4 20, 2011, from Agency for Healthcare Research and Quality: http://www.ahrq.gov/qual/aderia/aderia.htm
Akramiene, D. (2007). *Effects of beta-glucans on the immune system.* Retrieved 4 24, 2011, from PubMED.gov: http://www.ncbi.nlm.nih.gov/pubmed/17895634
Alternative medicine. (n.d.). Retrieved 4 22, 2011, from Wiki: http://en.wikipedia.org/wiki/Alternative_medicine
Capelli. (2006). *ASTAXANTHIN: Natural Astaxanthin, King of the Carotenoids.*
Clark. (35(7)). comparison of lycopene and astaxanthin absorption from corn oil and olive oil emulsions. *Lipids* , 803-6.
Cysewski. (2006, 4 4). *Analytical Methods for Measuring Astaxanthin*. Retrieved 4 2011, from Nutritional Outlook: http://www.nutritionaloutlook.com/article/analytical-methods-measuring-astaxanthin
D'Jang, A. H. (n.d.). *Frequently Asked Questions*. Retrieved 4 21, 2011, from Sante International: http://www.santelink.com/faq.html
Expectancy. (n.d.). *List of countries by life expectancy*. Retrieved 4 23, 2011, from Wiki: http://en.wikipedia.org/wiki/List_of_countries_by_life_expectancy
Health, R. (n.d.). *How Safe Is Conventional Medicine?* Retrieved 4 20, 2011, from Rebuild Health: http://rebuildhealth.com/hh/conventional.html
Hennigan, M. (n.d.). *Without reform, annual per employee health care costs for American companies will triple*. Retrieved 4 24, 2011, from Fin Facts: http://www.finfacts.ie/irishfinancenews/article_1019244.shtml
Jack, A. (n.d.). *Alternative Medicine Surges*. Retrieved 4 24, 2011, from Kushi Institute: http://www.kushiinstitute.org/html/articles.html
Mercke. (2003). Oral bioavailability of the antioxidant astaxanthin in humans is enhanced by incorporation of lipid based formulations. *Eur J Pharm Sci 19(4)* , 299-304.
Miyawaki. (2005). Effects of astaxanthin on human blood rheology. *J. Clin. Therap. Med.* , 21(4):421-429.
Miyawaki. (2005). Effects of astaxanthin on human blood rheology. *J. Clin. Therap. Med., 21(5):* , pp. 543-556.
Naguib, Y. (2001, 2). *Pioneering Astaxanthin.* Retrieved 4 18, 2011, from Chiropractic Resurce Information Website: http://www.chiro.org/nutrition/FULL/Pioneering_Astaxanthin.shtml
NCBI. (n.d.). Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/

Oleoresin. (n.d.). Retrieved 4 2011, from The Free Dictionary: http://www.thefreedictionary.com/oleoresin
Service, T. U. (n.d.). Retrieved 7 23, 2003, from www.export.gov/commercialservice/
Sica, D. D. (2003, 7 26). Supplement Dangers Risk that Some Dietary Supplements May be Contaminated. (A. News, Interviewer)
Supercritical fluid extraction. (n.d.). Retrieved 4 2011, from Wikipedia: http://en.wikipedia.org/wiki/Supercritical_fluid_extraction
Warrick, P. D. (1999). Use of Alternative Medicine Among Patients With Head and Neck Cancer. *ARCH OTOLARYNGOL HEAD NECK SURG/VOL 125* .
Wiki-Asaxanthin. (n.d.). *Astaxanthin.* Retrieved 4 19, 2011, from Wiki.com: http://en.wikipedia.org/wiki/Astaxanthin