

# **DSHEA – From Safe Harbor to Sinking Harbor: Is There a Way to Bypass the FDA's Regulatory Roadblocks?**

**by Conrad LeBeau**

On October 25, 1994, President William Jefferson Clinton signed the Dietary Supplement Health and Education Act (Public Law 103-417), also known as DSHEA.<sup>1</sup> This act was designed to protect the availability of nutritional, herbal, and dietary supplements for the American people, and to prevent the FDA from arbitrarily removing certain herbs and supplements from the market as “drugs” because of their health benefits in building health and preventing disease. The FDA retained the right to remove products that were unsafe but had the obligation of proving they were unsafe. Within DSHEA, Section 9, the FDA was allowed, although not required, to promulgate good manufacturing practices (GMPs) as regulations for dietary supplements modeled on those used for food. Under Sec. 8 of DSHEA, the supplement industry was required to notify the FDA of a “New Dietary Ingredient” that was not used in the food supply before Oct 15, 1994, or an ingredient in the food supply that was chemically altered after this date. In *Pearson v. Shalala*, the court stated: “Although there is apparently some definitional overlap between drugs and dietary supplements under the statute, it (DSHEA) creates a safe harbor from

designation as a ‘drug’ for certain dietary supplements whose labels or labeling, advertise a beneficial relationship to a disease or health-related condition.”<sup>3</sup>

However, with the FDA implementing GMPs for dietary supplements in 2007, and the Guidance Document on New Dietary Ingredients (NDI) notification requirements published in the Federal Register in July 2011, DSHEA as a “safe harbor” has become a “sinking harbor.” The FDA continues to totally censor published scientific research that certain foods and dietary supplements can prevent disease by tagging them with two labels – “drug” and “new drug.” In its role as government minders, the FDA practices “regulatory McCarthyism.”

It took the FDA 13 years from 1994 to 2007 to publish its proposed GMPs for dietary supplements in the Federal Register. The FDA's authority to write these regulations is based on the Administrative Procedures Act (APA) of 1946 that allows certain regulatory agencies of the federal government to write regulations to carry out the intent of Congress in implementing the law.<sup>2</sup> This is known as the Code of Federal Regulations (CFR). The APA vastly expanded the regulatory and paternalistic powers of the federal

government. These final regulations have the force of law by default, unless Congress votes them down within 60 days after the finalized regulations are published in the Federal Register. As Congress is usually distracted by multiple issues at any given time, or on recess, or campaigning for reelection, this rarely happens. Thus, federal employees who are neither elected nor accountable to the public write regulations that have the force of law. This legislation by default is not authorized in Article 1, Section 8, of the US Constitution. The proper and constitutional way that it should have been done was for Congress, not the regulatory agency, to hold public hearing and for Congress to have a final public vote of record to amend, scrap, approve, or disapprove the proposed regulations.

In his book *The Rise of Tyranny*, constitutional attorney Jonathan Emord reports that 180 regulatory agencies, including the FDA, have been given the authority to write regulations that have the force of law under the APA. Although regulations written under the APA can be challenged in the courts on the basis that they violate the intent of Congress or the US Constitution, this takes time, lots of money, and legal skill.



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A challenge to the constitutionality of the APA and its unauthorized delegation of power is long overdue.

### The Heavy Hand of the FDA's GMPs for Dietary Supplements (DS-GMPs)

Today, the natural food industry is burdened with overreaching and heavy-handed regulations brought on by the FDA. Under DSHEA, it was allowed to write GMPs for dietary supplements based on the existing GMPs used for food, but the agency did not follow the legal requirements in DSHEA. The FDA implemented GMPs for dietary supplements on September 24, 2007, that imposed an extremely wide range of unnecessary and expensive testing and record-keeping requirements.<sup>4</sup> The testing and record-keeping requirements were not based on existing GMPs for food as required in DSHEA, but instead created a new standard above and beyond that required for the manufacturing of pharmaceutical drugs.<sup>5,6</sup> These new GMP standards did not make dietary supplements safer, they simply made them much

more expensive. They added up-front costs of about \$100,000 in testing and recording-keeping expenses in the first year of implementation alone. Without improving safety one iota, they drove up the cost of manufacturing dietary supplements. DS-GMPs were implemented over a 3-year period beginning in June 2008. The first phase covered manufacturers with 500 or more employees. In June 2009, dietary supplements manufacturers with 20 to 500 employees were mandated to follow DS-GMPs. In June 2010, mom-and-pop businesses with fewer than 20 employees were required to follow DS-GMPs. Many of them, not having the financial resources to do so, have since closed their doors. Some have moved their manufacturing operations outside of the US. An estimated 300 small manufacturers of nutritional supplements are now being forced out of business by a mountain of red tape from the FDA's DS-GMPs.

### How the FDA Entrapped the Dietary Supplement Industry

Around 2007, FDA attorneys in Rockville, MD, began instructing FDA inspectors in the field to tell manufacturers of nutritional

supplements that they must add the words *dietary supplement* to their product labels. Ordinarily, FDA field inspectors won't give you legal advice on labeling on any topic, but especially for health claims. They say they are just gathering information. The advice to add the words *dietary supplement* to the label of thousands of health products was literally a legal trap that FDA lawyers set for the natural food industry. FDA attorneys took advantage of the public's ignorance of what the law says and how it is interpreted and applied. Those two words *dietary supplement* gave the FDA extraordinary power to impose new legal requirements and expenses on the industry. The supplement industry did not know that the GMPs that the FDA was about to spring on it would add hundreds of millions of costs to the largest of the supplement providers while driving hundreds of small nutritional and supplement manufacturers out of business.

One lesson that has been learned the hard way is never to support any "health freedom" legislation that empowers the FDA to write rules under the APA to regulate private business. Legislation that allows the FDA to grant permission to state a health product's intended uses are not needed, as the right of free speech already exists under the Constitution. The right of manufacturers of nutritional and herbal supplements to choose the words that determine the intended uses of their health products exists under the First Amendment; to wit: "Congress shall make no law... abridging the freedom of speech, or of the press..."

The repeal of laws and regulations that are unconstitutional is the only legislation which the supplement industry should support. DSHEA, for example, is fraught with restrictions (Sec. 5 and Sec 6) on the First Amendment by setting all kinds of unconstitutional limitations for using health claims. The only compelling state interest in labeling of nonpatented health product is to

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prohibit untruthful and fraudulent health claims. Today, health foods and supplements are the only consumer products whose intended use must be preapproved by the federal government. No constitutional authority exists for the federal government to act as “minders” at the FDA and censor truthful scientific and expert opinion.

### **Relabeling Dietary Supplements As ‘Food’ Is One Way Out of the FDA’s DS-GMPs as Well as the New NDI Notification Requirements**

One fact not widely known in the dietary supplement community is that for the manufacturer of a nutritional supplement to be legally obligated to follow the FDA’s GMPs for dietary supplements, the product must be labeled as a “dietary supplement.” The words *dietary supplement* must be printed on the product label; otherwise, the product is considered a “food.” Section 3 of DSHEA (Public Law 103-417) and codified under 21 USC Sec 321 requires that for a health product to be a “dietary supplement” it must contain a dietary ingredient such as a vitamin, mineral, herb, botanical, amino acid, or other dietary substance, and it must be “labeled” as a “dietary supplement.”

### **Labeling Choices: What Options Does a Manufacturer Have?**

Today, there are thousands of food products that contain added vitamins, minerals, and even herbs, and they are not labeled or sold as “dietary supplements.” Examples from your local grocery store are “Vitamin Water,” colas, and other beverages with added vitamin C; breakfast cereals such as Total with added B vitamins; orange juice with added calcium; soda with herbal extracts; and bread made with enriched flour containing iron and B vitamins.

There are also thousands of health products called “dietary supplements” that are not legally required to be labeled as “dietary supplements.” Wisconsin US Senator Ron Johnson recently pointed this out to me in his

letter of Jan. 2, 2012, when he stated: “Under current law, manufacturers decide whether a product is classified as a food or as a dietary supplement.” However, many manufacturers of nutritional supplements, who are not versed in the finer points of the law, do not realize that they have this choice. It would be to their economic advantage to remove the words *dietary supplement* from the labels of their health products. By default, the supplements would then fall under the GMPs for foods, not dietary supplements. This alone can save a supplement manufacturer hundreds of thousands of dollars each year by eliminating the needless and repetitive testing and record-keeping requirements that the FDA imposes on manufacturers of dietary supplements. Whether a health product is sold as a beverage, tea, powdered drink, or tablet or capsule, because it is ingestible, it is legally classified as a food unless it is labeled as a “dietary supplement.” However, if it is intended to treat a disease, the FDA will classify it as a “drug” whether or not it is labeled as a food or as a dietary supplement.

At the same time, the manufacturer can also eliminate the following words from the product label: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” However, if you are making a claim of a disease linked to the deficiency of a nutrient in the product, you are required under the Nutrition, Labeling and Education Act of 1990 (NLEA) to add that statement to the label. Today, many dietary supplements contain this FDA disqualifying statement and are not required to do so because the labeling of the product contains no information linking a nutrient deficiency to a disease.

The GMPs for foods are relatively simple to understand and implement. The GMPs for manufacturing drugs are more detailed but not excessive. For dietary supplements, some of

the safest products on the planet, the GMPs promulgated by the FDA are extremely costly, redundant, and time consuming. Of the three basic GMPs, the ones for food are the simplest to comply with and the least costly. FDA requirements for DS GMPs are that every ingredient be tested before the product is made and the final product is tested again. Every test has to be initialed and signed and the manufacturer of dietary supplements must hire one person to manage quality control who will spend more time keeping records than manufacturing the product. Small businesses are closing their doors, unable to financially implement the FDA’s DS-GMPs. One answer, for the immediate future, is to manufacture and market dietary supplements as “foods.” This removes FDA jurisdiction over the dietary supplements in two areas – the GMPs and the NDI notification requirements for “new” ingredients in dietary supplements.

### **Modifying Labels: If Not *Dietary Supplement*, What Do You Call It?**

The expression “As a dietary supplement ...” precedes instructions on thousands of nutritional products. The answer to legally bypass the FDA’s draconian GMPs and NDI requirements is to delete the words *dietary supplement* from the product label and to substitute the name of the product or its key ingredients and to call it what it is. Examples: vitamin C: “As a source of vitamin C, take one or more daily”; multivitamin tablet: “as a source of multiple vitamins, minerals and trace minerals, take ...” herbal products: “as a source of echinacea, take ...” for kelp tablets: “as a source of natural iodine, take (number) of kelp tablets daily”; minerals: “as a source of calcium, take ...” for fiber products: “as a source of fiber, use ...” Repeat the same label patterns for all products so they are now all



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➤ “food” products. Other examples, “As a source of aged garlic, use ...”; “As a source of bee pollen or royal jelly, probiotics, take ...” You can also eliminate the phrase “As a source of” and just state “Suggested uses:”

In other words, eliminate the words *dietary* and *supplement* from your product label whether used together or separately. Although you can, you don’t need to label your food products “food product.”

### What Do You Tell FDA Inspectors on Their Next Visit to Your Business?

Be prepared. Go to [fda.gov](http://fda.gov) website and download the CGMP Guidance Document for Foods.<sup>5</sup> It may also help to post a sign in your establishment that says: “This establishment has discontinued the manufacture of dietary supplements. We now manufacture food products and strictly follow the cGMPs for foods under 21 CFR 110.” FDA inspectors may try strong-arm tactics by telling you that you must add back the words *dietary supplement* to your product label. You reply should simply be: “Show me the law in black and white that requires me to label

my products as dietary supplements.”

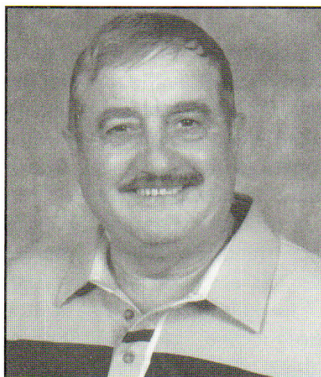
If you are shy about confronting an FDA inspector in this manner, then start a food division in your company and gradually introduce nutrients into your food products while slowly phasing out the dietary supplements that are giving you the biggest regulatory headaches. Remember that just because a nutrient is provided in a capsule or tablet form, it does not mean that you are required to call or label it a “dietary supplement.”

### The US Constitution and the Tenth Amendment

The framers of the US Constitution in 1792 established a government of limited powers with the balance of powers reserved to the states under the Tenth Amendment. While there is a multitude of case law supporting the endless expansion of federal powers, there is hope of positive change in the future. One reason is presidential candidates who want a smaller federal government and the restoration of the Tenth Amendment to its original meaning. The Tenth Amendment reserves to the states all powers not specifically named and delegated to Congress under Article 1, Section 8 of the US Constitution.<sup>8</sup> As for health claims, the FDA lost in the case of *Pearson v. Shalala* in 2001, in

which the Appellate Court ruled that total suppression of health claims for dietary supplements is not allowed under the First Amendment.<sup>3</sup>

This author, Conrad LeBeau, was in the health supplement business from 1988 through July 2010 and is uniquely qualified to write this article as a result of his legal research as a defendant from FDA allegations in a federal case involving health claims for nutritional supplements.<sup>7</sup> The present case resulted from sharing health information with his customers. The scientific information that he used was derived from the US National Library of Medicine. The FDA tags health products as “drugs” when information is provided on how they prevent or mitigate disease. After a year of legal arguments in federal court, the local US attorney in Milwaukee agreed to settle the case on a “conditional plea” for \$500 that also allows the defendant to take his legal arguments to the US Court of Appeals, and US Supreme Court, if needed. The case is now on appeal. LeBeau is seeking to have the Appellate Court narrow the definition of what a “drug” is to its original meaning (patented drugs and nostrums) and eliminate foods from the definition. This is one of a dozen legal issues being raised. More information about can be found at [keephopealive.org](http://keephopealive.org). Contact info: [conradlebeau@gmail.com](mailto:conradlebeau@gmail.com) or 414-231-9817



Conrad LeBeau is a self-educated investigative writer. In 1994, he founded Keep Hope Alive as a nonprofit educational organization. LeBeau has done thousands of online searches at the US National Library of Medicine since 1994 and has shared this information in numerous articles that he published in the *Journal of Immunity* at Keep Hope Alive for the past 17 years. Today the journal is published quarterly both in print and online at [keephopealive.org](http://keephopealive.org). LeBeau has also contributed to the publications *Progressive Health News*, and *Positive Health News*.

He has distributed copies of the *Journal of*

*Immunity* on the subject of the adverse health effects of cell phone towers to every member of Congress. LeBeau’s current books in print include the *Immune Restoration Handbook* and *Natural Remedies for Intestinal Health, Insomnia, Fatigue and Cell Phone Towers*, and *Hydrogen Peroxide, Aloe Vera Plus Other Home Remedies*. All of his books are available at [amazon.com](http://amazon.com).

### Notes

1. DSHEA – 21 USC 321 (Public Law 103-417) 21 USC 321 et seq.
2. Administrative Procedures Act – Public Law 79-404, 60 Stat 237, 5 U.S.C. 500 et seq.
3. *Pearson v. Shalala* 14 F. Supp.2d (D.D.C. 1998); *Pearson II* 130 F Supp. 2nd 105 (D.D.C. 2001), *Pearson III* 141 F Supp. 2nd 105.
4. Dietary supplement current good manufacturing practices (CGMPs) and interim final rule (IFR) facts [online document]. [www.fda.gov/.../DietarySupplements/GuidanceComplianceRegulatoryInformation/RegulationsLaws/ucm110858.htm](http://www.fda.gov/.../DietarySupplements/GuidanceComplianceRegulatoryInformation/RegulationsLaws/ucm110858.htm). March 16, 2009.
5. Food CGMP modernization – a focus on food safety [online document]. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/ucm207458.htm>.
6. Drug applications and current good manufacturing practice (CGMP) regulations [online document]. [www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm) - 11k - 2009-02-18.
7. *US vs. Vital Health et al.* 10-CR-253.
8. 10th Amendment, US Constitution; to wit: “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

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