



# Legal and Regulatory Status of Herbs and Phytomedicines in the U.S.

There appears to be considerable confusion about the regulation of herbs and other dietary supplements in the U.S. The herb and dietary supplement industries are characterized by a substantial level of laws, regulations, and proposed regulations on the federal level. Former FDA Commissioner Jane Henney, M.D. testifying before the House Committee on Government Reform (March 25, 1999) stated, "The FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the Food, Drug and Cosmetic (FD&C) Act, as amended by DSHEA."<sup>1</sup> As a result of DSHEA, dietary ingredients used in dietary supplements do not require pre-market documentation of safety for submission to the FDA unless they are *new dietary ingredients* (i.e., ingredients not sold before the passage of DSHEA in October 1994), subject to the notification requirement in Section 413(a)(2) of the FD&C Act. This has led critics of DSHEA to fear a potential "safety meltdown." Despite legitimate concerns about herb safety, the general lack of epidemiological evidence to the contrary suggests such a meltdown has not occurred since the passage of DSHEA, probably as a result of a combination of factors. These include the following considerations: (1) most dietary supplements have a very

long history of relatively safe use; (2) consumers usually use self-care products, such as dietary supplements, in a responsible manner; (3) most companies are meeting the legal requirements of DSHEA; and, importantly, (4) the FDA and the FTC have sufficient enforcement authority in this area and have engaged in the development of the new regulatory framework for dietary supplements.<sup>1</sup>

DSHEA places responsibility for ensuring herbal supplement safety on manufacturers, identifies how literature may be used in connection with sales, specifies types of statements of nutritional support that may be made on labels, specifies certain labeling requirements and provides for the establishment of regulations for GMPs. The FDA must model dietary supplement GMPs after food GMPs and may not impose standards for which there is no current and generally available analytical methodology. It is also important to point out that many dietary supplement companies have already been operating under GMPs that meet or exceed the proposed dietary supplement GMPs, particularly those companies who market their products outside of the U.S. or companies that also manufacture OTC drugs. Additionally, U.S. companies whose products are licensed as Traditional Herbal Medicines (THMs) in Canada or as Therapeutic

Goods in Australia must meet the GMP requirements of those countries, respectively. At press time (early 2003) the FDA had not yet published proposed rules for GMPs for dietary supplements, although such publication is considered imminent.

In passing DSHEA, Congress noted in the "findings" section of the Act that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." One of the purposes of passing DSHEA, therefore, was to provide consumer access to products and truthful information about those products, while maintaining authority for the FDA to take action against products that present safety problems or are improperly labeled.<sup>1</sup>

Under DSHEA, dietary supplements are typically classified as foods, and defined as any product intended for ingestion as a supplement to the diet; but are not intended to replace food in the diet. They are specifically exempted from the definition of drugs (i.e. intended to diagnose, cure, mitigate, treat, or prevent diseases) and thus are not subjected to the same rigorous testing and approval processes required by the FDA for drugs. Manufacturers must label dietary supplements as such. Effective



March 1999, supplement labels must carry a “Supplement Facts” panel, granting easier access to ingredients and suggested dosage.

One of the most misunderstood aspects of DSHEA is the issue of the FDA’s ability to protect the public from unsafe dietary supplements. Once a supplement is on the market, the FDA must prove that it is unsafe before imposing restrictions on its use. The “burden of proof” has now shifted from the manufacturer proving safety to the FDA proving that a substance poses an “imminent health hazard” once that determination has been made by the Secretary of Health and Human Services. The issue of regulation, herb safety, and the impact on the general public can often be mischaracterized and exaggerated in the media to the extent that even FDA officials have misstated the agency’s authority. According to Stephen H. McNamara, an attorney who specializes in food and drug law and formerly an attorney at the FDA, there are numerous provisions in the FDCA and DSHEA that give the FDA adequate authority to remove unsafe supplements from the market: “...it appears that the FDA has substantial and sufficient regulatory authority to protect the American public from any dangerous or otherwise unsafe herbs or other dietary supplement products despite statements

to the contrary from FDA officials.”<sup>2</sup>

DSHEA also required the establishment of an Office of Dietary Supplements (ODS) within the National Institutes of Health (NIH) and a Commission on Dietary Supplement Labels. The ODS is responsible for conducting and coordinating research relating to dietary supplements (including botanicals) and collecting and compiling a database of scientific research on botanicals.<sup>3</sup>

Consumer and professional confidence in herbal preparations and other dietary supplement products underwent a considerable degree of erosion during the late 1990s as various news organizations and independent groups reported that many of these products failed to meet a variety of labels claims related to content of certain ingredients, standardization markers, or other elements. While in some cases, these reports accurately reflected the wide variation in quality of herbal products, they sometimes were based upon improperly conducted analyses and/or inappropriate analytical methods.<sup>4,5</sup>

For an extensive account of the legal and regulatory history of herbs in the U.S., see Blumenthal and Israelsen.<sup>6</sup>

## References

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