SBA Office of Advocacy

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Advocacy Urges FDA to Consider the Effect on, and Analyze the Impacts of, its Guidance on Dietary Supplement Labeling on the Industry

- On February 28, 2008, the Office of Advocacy (Advocacy) filed a comment letter with the Food and Drug Administration (FDA), concerning a draft guidance document that will require, among other things, dietary supplement manufacturers to change the labeling of their products substantially to comply with the Dietary Supplement and Nonprescription Drug Consumer Protection Act. A complete copy of Advocacy's comment letter may be accessed at **http://www.sba.gov/advo/laws/comments**.

- On January 2, 2008, the FDA published a notice of the availability of a draft guidance in the *Federal Register* titled, **"**Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act" (73 Fed. Reg. 197, January 2, 2008).

- Representatives from small dietary supplement manufacturers approached Advocacy concerned that FDA's guidance would require labeling changes that exceeded the requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, and that the FDA's use of guidance would prevent the agency from analyzing how the requirements would economically impact their businesses. In its comment letter, Advocacy suggested that FDA take the industry's concerns into consideration and consider analyzing the economic impact of the guidance through notice and comment rulemaking.

For more information, visit Advocacy's web page at www.sba.gov/advo or contact Linwood Rayford at (202) 205-6533.