

FDA CLARIFIES REGULATION OF COMPANY WEBSITES

The Food and Drug Administration (FDA), in response to a citizen petition filed by the Washington Legal Foundation (WLF), has clarified its position with respect to regulating the content of company websites as "labeling" under the Federal Food, Drug, and Cosmetic Act (FDCA).

Earlier this year, WLF had filed a citizen petition requesting that the FDA not regard information on company websites as labeling. WLF's filing was prompted by an alarming FDA Warning Letter sent to Ocean Spray Cranberries, Inc. of Massachusetts on January 19, 2001, the last day of the Clinton Administration. The FDA claimed that Ocean Spray's cranberry and grapefruit juices were "misbranded" and subject to seizure simply because of certain health claims and other information that appeared on the company's website. WLF was particularly concerned about the commercial free speech implications of regulating the content of websites.

In its recent response, the FDA agreed with WLF that "Internet information, particularly those websites that provide truthful and non-misleading information about FDA-regulated products, can serve a valuable and useful function." The FDA declined, however, to issue a regulation or guidance on the subject, but indicated that it would proceed in this area on a case-by-case basis. In doing so, however, the FDA gave some indication on how it may exercise its discretion in this area.

For example, the FDA suggested that if a company promotes and sells its product over the Internet, information provided on the Internet about the product could be considered "labeling," and thus, be subject to the FDA's labeling requirements. At the other end of the spectrum, the FDA suggested that Internet information that is similar in nature to print and other electronic advertising would be viewed as advertising, not labeling. The FDA also indicated that it is willing to work with companies on a case-by-case basis about posting information on their websites or linking to information on third-party websites.

* * *

For further information, contact Paul D. Kamenar, WLF's Senior Executive Counsel, at 202-588-0302.

