FDA Client Advisory

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It is No Joke: Two April Fool's Day Announcements Underscore Scrutiny of Dietary Supplements

EXECUTIVE SUMMARY

Dietary supplements are under increasing scrutiny from consumers, media, and regulators as more and more products flood the market. Two developments this week underscore this onslaught of attention.

FDA WARNS ONLINE MARKETERS OF WEIGHT LOSS DIETARY SUPPLEMENTS

On April 1, 2004, the Food and Drug Administration ("FDA") sent warning letters to 16 dietary supplement distributors, representing more than 25 different products that are promoted online. FDA is alleging that the distributors are making false and misleading claims about the efficacy of these products. For example, many claim to block fat absorption, carbohydrates, and starch, and allow consumers to lose weight without any changes in lifestyle. According to an FDA press release, the agency is concerned that these claims give consumers false hope and may result in significant health consequences for obese individuals who rely on these supplements as a sole means of weight loss. FDA has reviewed both the claims and the scientific evidence and concluded that the claims are not supported by reliable scientific evidence. The distributors must respond within 15 days of receipt of these warning letters with plans to correct these violations.

INSTITUTE OF MEDICINE PANEL RECOMMENDS INCREASED FDA OVERSIGHT OF DIETARY SUPPLEMENT MAKERS

Also on April 1, 2004, a panel of the Institute of Medicine, which is part of the National Academy of Sciences, issued a report on how to improve FDA's ability to assess the safety of ingredients in dietary supplements. The panel called for Congress to give FDA authority to require dietary supplement manufacturers to report to the FDA adverse effects linked to their products as well as positive and negative safety information from the manufacturers' own studies. In addition, the panel recommended that FDA be given additional funds from Congress to increase oversight of the dietary supplement industry, and to use information from animal studies to assess the safety of dietary supplements.

Critics of the current system say that the FDA's hands have been tied in responding to dietary supplement concerns in a timely manner. For example, according to critics, FDA did not act against popular dietary supplements such as ephedra and androstenedine ("andro") until years after serious health consequences related to their use were reported. The panel's recommendation parallels earlier recommendations of the American Herbal Products Association and Sen. Richard J. Durbin (D-Ill.), both of whom have called for adverse event reporting.

FOR MORE INFORMATION

Our team continues to monitor FDA and other organizations for additional developments important to our clients. For further information, please call (202) 342-8400 or email:

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