Please contact any of the attorneys in our Dietary Supplements, Cosmetics and Functional Foods Group if you have any questions regarding this alert.

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FDA's NDI Guidance Will Impact About 90% of the Dietary Supplement Industry

On July 1, 2011, the U.S. Food and Drug Administration ("FDA") published its long-awaited Draft Guidance on New Dietary Ingredient ("NDI") notifications for dietary supplements ("Draft Guidance"). The Draft Guidance can be found on FDA's website by **clicking here**. The notice of availability of the Draft Guidance was published in the Federal Register on July 5, 2011. While comments on the guidance may be submitted to the agency at any time, to ensure consideration by the agency, comments should be submitted by October 3, 2011.

The positions articulated by FDA in the Draft Guidance can be expected to have a significant impact on all those who manufacture or distribute dietary supplement products. The Draft Guidance must be evaluated very carefully to determine the effects it may have on your company. Even those companies that previously submitted NDI notifications that were filed without comment should evaluate whether the use of the NDI is consistent with the four corners of the notification, including the dietary supplement formulation as stated in the original submission.

Note that the Draft Guidance is a fairly long document so we have put together a summary of the highlights, which you can read by **clicking here**. Please feel free to contact Todd Harrison, Claudia Lewis, or Michelle Jackson with any questions you might have or for assistance in filing comments with FDA, evaluating your current products, or preparing NDI notifications to be filed with FDA.
