

Sens. Hatch and Harkin Send Letter to FDA in Anticipation of NDI Guidance

June 22, 2011

Senators Hatch and Harkin, the principle architects of the Dietary Supplements Health and Education Act (DSHEA) (amending the Federal Food Drug and Cosmetic Act (FDCA)), submitted a [letter](#) yesterday to FDA Commissioner Margaret Hamburg "express[ing] their support for the upcoming new dietary ingredients (NDI) guidance." The Senators stated that the guidance should reflect the intent of DSHEA to "give FDA the tools necessary to help ensure the safety of dietary supplements and the accuracy of the limited claims allowed for them," and "minimize regulatory burdens that might inhibit consumer access to lawfully manufactured and labeled supplement products."

FDA plans to release the guidance on July 8, 2011, in accordance with the FDCA amendments made by section 113 of the Food Safety Modernization Act (FSMA). The FSMA amendments require the agency's guidance to clarify the circumstances under which a dietary supplement ingredient qualifies as a "new dietary ingredient" and companies are required to submit a new dietary ingredient notification to FDA which includes, "the evidence needed to document the safety of new dietary ingredients," and "appropriate methods for establishing the identity of a new dietary ingredient."