

FDA Notice Clarifies Past Federal Preemption Policy Statements

October 7, 2011

The Food and Drug Administration (“FDA”) recently completed an evaluation of the legal basis for federal preemption policy statements the agency has issued under the Federal Food, Drug & Cosmetic Act (“FDCA”) during the past 10 years. FDA initiated the review in response to a memorandum issued by President Obama in May 2009 which directed federal agencies to undertake a review of their policy statements concerning federal preemption to ensure that such statements have “[a sufficient legal basis.](#)”

In follow-up to the agency’s review, on September 28, 2011, FDA issued a [notice](#) that is intended to clarify past FDA federal preemption policy statements. Such statements characterize the scope of implied and express federal preemption that applies to FDA regulations implementing particular FDCA provisions that concern prescription drug and biological product labeling, nonprescription drug products, food standards of identity, and food and dietary supplement product labeling. For [more information](#) on the specific policy statements affected by the FDA notice, read the Kelley Drye client advisory.