FDA SEEKS STAKEHOLDER INPUT ON REGULATORY REFORM EFFORTS

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Food, Drugs, Medical Devices and Cosmetics (FDA) Alert

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On September 8, 2017, the Food and Drug Administration ("FDA") became the latest in a line of federal departments and agencies to seek public input on approaches to modify regulations and reduce the burden on stakeholders. FDA released seven requests for information ("RFI") that spanned each of its industry-specific regulatory centers and included a broader request capturing all FDA regulatory and information collection requirements. [1] These RFIs provide an excellent opportunity for stakeholders, including health care institutions, drug and medical device manufacturers, and trade associations, to provide recommendations to FDA on enhancing regulatory efficiencies to further enable safe and effective innovation for patients. Comments are due to FDA by December 7, 2017.

FDA's announcement follows President Trump's January 30, 2017 and February 24, 2017 Executive Orders [2] directing federal departments and agencies to manage costs associated with complying with federal regulations and establish regulatory reform task forces to evaluate existing regulations and identify those that should be repealed, replaced, or modified.

To guide FDA's initial review of its regulations, the agency is encouraging stakeholders to consider the following factors when providing comments:

1. Is the regulation still current, or is it outdated or unnecessary in some way?
2. Have regulated entities faced difficulties in complying with the regulation?
3. Does the regulation impose requirements that are also addressed in voluntary or consensus standards or guidance by third party organizations?
4. Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records?
5. Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection?
6. What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

FDA has requested specific comments that include supporting data and suggestions on whether a particular regulation should be repealed, replaced or modified. Comments must be submitted using a specified format no later than December 7, 2017.

With the addition of Amanda Makki to our Public Policy and Law practice and Erica M. Jackson to our Health Care and FDA practice, K&L Gates is well positioned to facilitate stakeholder engagement with FDA and other policymakers in Washington, D.C. on this important effort. Our capabilities allow us to combine substantive experience in and knowledge of FDA-regulated industries with the policy and political insights of more than 50 bipartisan lawyers and government affairs professionals to develop comprehensive solutions for our clients.

Notes:
[1] The FDA centers included in the RFI are the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Center for Drug Evaluation and Research, the Center for Tobacco Products, and the Center for Food Safety and Applied Nutrition. See 82 Fed. Reg. 42,492 (Sept. 8, 2017).
[2] Exec. Order No. 13,771 (Jan. 30, 2017), *available at*: https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling; Exec. Order No. 13,777 (Feb. 24, 2017), *available at*: https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda.

