COVINGTON

FDA Seeks Public Input on how to Rollback/Streamline Regulations

September 8, 2017

Food and Beverage

As part of the Trump Administration's move towards regulatory efficiency, FDA announced yesterday and published today in the Federal Register, the opportunity for public input on the Administration's comprehensive review of its regulations.

FDA will be accepting comments until Thursday, December 7, 2017.

In line with the Administration's promise to alleviate unnecessary regulatory burdens,[1] Anna Abram, FDA's Deputy Commissioner for Policy, Planning, Legislation and Analysis, explains that FDA is "taking a closer look to see if we need to revise, update, and in some cases eliminate existing regulations." FDA is seeking input on "how current regulations could be reshaped to achieve our public health objectives through more efficient approaches." Ms. Abram's states that all FDA's regulatory reform efforts will be science-based: "Science will remain FDA's North Star when it comes to our role in devising regulatory policy."

Over the past year, food and beverage companies have been grappling with FSMA implementation and FDA's revised requirements for Nutrition Facts labels and serving sizes, and companies continue to encounter challenges with other recent as well as long-standing FDA regulations. FDA's request for input provides companies the opportunity to give FDA real on-the-ground insights and suggestions regarding how to streamline regulatory requirements to make them more efficient and practical while still achieving FDA's rigorous public health goals. FDA is asking for specific feedback on regulations and has requested stakeholders to consider several questions, including:

- Is the regulation still current, or is it outdated or unnecessary in some way?
- Is this regulation duplicative of requirements in other FDA regulations or other Federal Agency regulations?
- Have regulated entities had difficulties complying with the regulation?
- Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third party organizations?
- Do the entities covered by these standards or guidance take steps to meet the standards and to document that they meet the standards?

[1] See our previous alerts on the Trump Administration's regulatory rollback Executive Orders (cited as drivers for the rollback in the Unified Agenda) here and here.

- Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g., reporting, recordkeeping, or labeling requirements?
- Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection?
- What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?

FDA requests that comments include supporting technical, scientific, economic, or other data. Finally, FDA has requested that comments be submitted in a specific table format shown in the Federal Register.

Covington's Food and Beverage attorneys, in conjunction with its Public Policy and Government Affairs experts, are deeply engaged in tracking and providing strategic advice on federal administrative and legislative activities. We work with clients on all regulatory and litigation activities impacting foods, beverages, and dietary supplements. We have extensive expertise drafting and submitting comments to FDA on behalf of individual companies and trade associations. We will continue to track and provide updates on FDA's and the Trump Administration's regulatory reform efforts.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food and Beverage practice or members of the Public Policy and Government Affairs group:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Gary Heimberg	+1 202 662 5009	gheimberg@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com
Gabe Neville	+1 202 662 5445	gneville@cov.com