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Tuesday, April 2, 2019

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Webinar- FDA's Produce Safety Rules in 2019: What can we expect?

Review of rules under the Food Safety Modernization Act

DESCRIPTION:
In this timely webinar, we will review FDA's Produce Safety Rule – a program under the Food Safety Modernization Act (FSMA). The Produce Safety Rule seeks to control food safety risk from certain fruits and vegetables grown for human consumption. FDA promulgated the final rules in 2016 with staggered compliance dates, based on the covered farms' revenue. Some of the compliance dates have already passed; however, FDA stated that it would begin enforcing the requirements starting early 2019.

When FDA's enforcement begins, there will certainly be confusion, as is always the case with the implementation of any new regulatory programs. Here, we will summarize what we already know by briefly reviewing the Produce Safety Rule's requirements and the Rule's interaction with the Foreign Supplier Verification Program. We will address the likely enforcement approach that FDA will take with the Produce Safety Rule, and how each affected party should be prepared for the Rule's implementation.

INSTRUCTORS:
Cori Annapolen Goldberg
Partner, Reed Smith LLP

Cori Goldberg is a partner in Reed Smith LLP's Life Sciences Health Industry Group. She focuses her practice on FDA regulatory and compliance issues for the food, drug, and medical device industries; government and internal investigations; and white collar criminal defense. Cori has regulatory, investigational, and transactional expertise. Cori advises her food law clients on FDA and USDA issues, including labeling analysis, FSMA implementation, importation issues, food safety, and corporate compliance concerns. She assists clients during FDA inspections, in responding to FDA 483s and agency enforcement actions, and with recalls and market withdrawals of products. Her practice includes the provision of regulatory assistance during corporate transactions involving food companies. She also represents large corporations in investigations by the US Department of Justice, the US Food and Drug Administration, and other federal and state agencies. Cori has been honored as a Rising Star in Food and Drugs by NY Metro Super Lawyers and as a Rising Star by the Healthcare Businesswomen's Association. Cori serves on the Committee on Food Law of the Food, Drug, and Cosmetic Law Section of the NY State Bar Association.

Sung W. Park
Attorney, Reed Smith LLP

Sung is an associate in the Life Sciences Health Industry Group in the Washington D.C. office. His practice focuses on providing regulatory counsel to companies developing, distributing, and marketing FDA-regulated products, and responding to regulatory and administrative enforcement actions by federal and state agencies such as FDA, USDA, and state Attorneys General offices.

Sung has counseled companies on designing regulatory routes for food and drug products, reviewing product labels and promotional materials, and worked with FDA district offices and headquarters to minimize any potential regulatory risk and to ensure that the companies' supply chain is not disrupted. As a bilingual attorney who has worked with many international companies, Sung understands the concerns that international manufacturers and distributors have when attempting to market their product in the United States.