Tony Subketkaew, Joanna Pearce Author Article in Regulatory Focus: ‘Supply Chain Disruptions: FDA Guidance and Temporary Policies’

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Tony Subketkaew and Joanna Pearce, associates in Haynes Boone's FDA Regulatory and Compliance Practice Group, authored an article in *Regulatory Focus* on FDA recommendations on supply chain disruptions. Read an excerpt below:

The complexity of modern supply chains is never more evident than when disruptions demonstrate in real time how many interdependent processes and entities have to come together to deliver a finished product to the end consumer. Today's consumers enjoy access to products made with components that can originate from multiple countries. A cheese pizza can be made with tomatoes grown in China, cheese from Italy, spices from India, and flour made from wheat grown and processed in the United States. This gives consumers access to a quality product comprised of the best, most cost-effective, globally sourced ingredients.

However, this supply chain complexity has drawbacks, which have been amplified and highly evident during the pandemic. Due to the perishable nature of most foods, manufacturers keep limited inventory on-hand, often receiving ingredients just before combining them with others and processing them into finished foods. Complex supply chains that source ingredients globally are particularly vulnerable to the risks associated with "just-in-time" sourcing. One crucial missing ingredient can prevent a manufacturer from meeting its supply commitments, especially if an acceptable alternative ingredient is not available domestically or a substitution is cost prohibitive. On the supplier side, limited inventory may force suppliers to make difficult decisions, such as choosing which customers will have their orders filled or whether to reduce supply across the board to all customers.

On top of these business considerations, there are also regulatory considerations. The FDA regulates a massive portion of the US economy, with FDA-regulated products accounting for about 20 cents of every dollar spent by US consumers and 15% of US imports and exports. The agency’s policies during the pandemic addressed the confluence of regulatory and business considerations to mitigate problems caused by supply chain issues. This article will highlight some of the specific steps taken by the FDA to provide flexibility in the form of guidance to affected regulated entities.

Excerpted from *Regulatory Focus*. To read the full article, click here.