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FDA Releases Final Guidance and Urges Companies to be 'Recall Ready'

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- As covered on this blog, on April 24, 2019 FDA announced a new, draft guidance on ways to help companies prepare to quickly and effectively remove from the market any violative food or other products subject to FDA's jurisdiction. The purpose of the guidance is to clarify FDA's recommendations for industry and FDA staff regarding timely initiation of voluntary recalls under 21 CFR part 7, subpart C – Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities.

- On March 4, 2022, FDA published notice that its Final Guidance is available on *Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C*. In addition to editorial changes made to improve clarity, changes from the draft to the final guidance include:

    - the addition of "correction" and "market withdrawal," with these terms' regulatory definitions, in the terminology section of the guidance;

    - the addition of language encouraging the use of electronic communications for conveying voluntary recall communications about FDA-regulated products; and

    - the deletion of section IV (''References'').

- FDA did not respond to a comment that suggested replacing the word "should" with "may" as a way to provide more flexibility in recommendations that "a firm should consider establishing metrics appropriate to its recall plan" and "should implement procedures to identify indicators that there may be a problem with a distributed product that suggests it is in violation of the FD&C Act and other laws administered by the FDA."

- Finalizing this guidance on initiating voluntary recalls is FDA's latest action to improve the speed at which violative products are removed from the market. We have blogged on FDA's earlier issuance of guidance on public availability of lists of retail consignees to effectuate certain human and animal food recalls; mandatory recalls for human and animal foods; and public warnings and notifications for all FDA-regulated products, which reiterates a policy to rapidly post new recalls to the FDA's weekly Enforcement Reports, a public listing of all recalls monitored by the FDA.

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