Published on *The National Law Review* https://natlawreview.com

FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities

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- On May 6, 2025, the U.S. Food and Drug Administration (FDA) announced its intend to expand the use of unannounced inspections at foreign manufacturing facilities that produce food, as well as essential medicines and other medical products intended for American consumers. This builds upon FDA's Office of Inspection and Investigations Foreign Unannounced Inspection Pilot program in India and China and aims to ensure that foreign companies will receive the same level of regulatory oversight and scrutiny as domestic companies.
- FDA stated that it will also evaluate the agency's policies and practices for improvements to the foreign inspection program, which will include clarifying policies for FDA investigators to refuse travel accommodations from regulated industry, including lodging and transportation arrangements.
- FDA conducts approximately 12,000 domestic inspections and 3,000 foreign inspections each year in more than 90 countries, according to the FDA press release. While US manufacturers undergo frequent, unannounced inspections, foreign firms have often had weeks to prepare, though FDA supposedly found deficiencies more than twice as often than during domestic inspections.
- Despite this announcement, anonymous FDA officials noted that the recent staffing cuts in FDA have made it harder for the inspections teams to keep up with demands.
- FDA Assistant Commissioner for Inspections and Investigations Michael Rogers stated that, "FDA's rigorous, science-based global inspections of manufacturing facilities ensure that the food and drug products that enter the US marketplace, and the homes of American consumers, are safe, trusted, and accessible. These inspections provide real-time evidence and insights that are essential for making fact-based regulatory decisions to protect public health." Michael Rogers will be retiring from FDA on May 14, 2025.

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National Law Review, Volume XV, Number 135

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