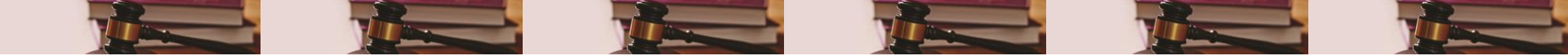

FDA Inspection Developments and Reform – What Lies Ahead for Medical Products

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New Inspection Protocol Project

- Referenced in announcement by then-Commissioner Gottlieb in 2018
  - First phase included development of protocol for aseptic processing surveillance and PAIs
  - Pilot included 10 surveillance inspections and 10 PAIs since launch in 2014
  - Protocol went through revisions and incorporated input from many stakeholders at FDA, including CDER and ORA
- Purposes include focusing “on measuring and describing the state of quality” at sites, identifying “excellence in manufacturing”, and informing CDER decision-making
- “The new inspection protocol aims to enhance consistent and comprehensive coverage of critical areas, including targeting the highest risk products and processes”

New Inspection Protocol Project

- FDA has not released the protocols that have been finalized to date, although there have been statements disclosing certain points about the protocols
  - Ex. Inspectors using pre-loaded tablets
  - Ex. Six “performance levels” [3 levels of failure, 1 acceptable, and 2 exceeding compliance]
- However, FDA has not released the final protocol(s)
  - Possibly subject to release under FOIA; FDA does not believe this to be the case
  - Benefits to both FDA and industry from transparency

FDA Drug Shortages Report – Rating System Proposal

- Report proposed creation of a rating system to rate "quality management maturity" of sites
  - Goal to incentivize drug manufacturers to invest in achieving Quality Management System maturity
  - Based on "specific objective indicators"
  - Companies could then disclose ratings on a voluntary basis to public or purchasers
  - Theory is that system would give competitive advantage to manufacturers with mature systems

Site Engagement Program

- Voluntary program, offering enhanced interaction between sites & FDA to prevent/mitigate shortages
- Gives sites opportunities to “gain clarification on FDA’s expectations for pharmaceutical quality”
- FDA believes sites may benefit from “[o]pen and comprehensive dialogue” that could “reduce the frequency and/or duration of an on-site surveillance inspection”
- What will FDA make public regarding the results of this program?
  - Agency has stated it will not make information public during current introductory stage
  - Information transparency would be helpful – summary of advice offered would benefit industry and further program goals

Nonbinding Feedback Following FDA Inspections of Device Sites

- Guidance published in February pursuant to 704(h)(2)
  - Offers sites nonbinding feedback from FDA following issuance of a 483
  - Goal to help device firms determine if proposed actions to address inspectional observations are adequate
  - Must be submitted to FDA within 15 business days of issuance of 483 (timeframe identical to response to 483)
  - Must meet certain statutory criteria

Impact of EO on Improved Agency Guidance

- President Trump signed EO on “Promoting the Rule of Law Through Improved Agency Guidance Documents” on Oct. 9
- States that agencies should “treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract”
- Also sets forth additional requirements
- EO impact on FDA inspections
  - FDA inspectors often rely upon guidance during inspections
  - Potential for more notice-and-comment rulemaking

Thank you!