U.S. FOOD & DRUG ADMINISTRATION

Reviews of Outsourcing Facilities During COVID-19

Edisa L. Gozun, Pharm.D.
Acting Division Director

Pre-Operational Reviews

- Requests from outsourcing facilities and compounders considering registering as outsourcing facilities
  - Compliance with conditions of section 503B
  - Compliance with CGMP requirements
  - Expansion plans/proposed facility design

Pre-Operational On-Site Evaluations

- Prior to outsourcing facilities initiating drug production for distribution
- FDA will be on-site to assess
  - Facility design
  - Standard operating procedures
  - Other conditions that are critical to producing sterile drug products
- However, due to the pandemic, pre-operational on-site evaluations are currently on hold

How to Request Pre-Operational Reviews or On-site Evaluations

- Submit request to Compounding@fda.hhs.gov
- Additional information
  - Statement of purpose and objective for the meeting
  - List of individuals who will be attending the meeting
  - Proposed meeting duration and suggested dates/time
  - Proposed format of the meeting
  - Proposed agenda
  - List of specific questions

Remote Regulatory Assessments

- To work with outsourcing facilities to achieve control and compliance with applicable sections of FDCA during the COVID-19 pandemic
- Provide FDA with an understanding of firm's operational state

Remote Regulatory Assessments

- Outsourcing facilities requesting pre-operational site evaluations
- Newly registered outsourcing facilities
- Currently registered outsourcing facilities

Remote Regulatory Assessments

- Type of information for FDA review could include:
  - Facility design diagrams
  - Adverse event reports
  - Organizational chart
  - Product labels
  - Investigation reports

Questions?


FDA
U.S. FOOD & DRUG
ADMINISTRATION