



# FDA and State BOP Inspections: How Are Inspections Impacting Patient Access?

PROTECT ★ PROMOTE ★ ADVANCE

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# Basic Strategies For Navigating FDA Inspections

**If you are a compliant 503A pharmacy, claim your exemption.**

– FDA may inspect:

- Building, equipment, materials, containers, labeling

– FDA may not inspect:

- Records, files, papers, processes, controls, financial data, pricing data, most sales data, most personnel data, most research data



# Basic Strategies For Navigating FDA Inspections

**First-hand experiences—**



# Latest Trends in Form 483 Reports

**Aseptic technique – observed during compounding processes**

**“Inadequate” documentation of equipment certifications**

**Media fill testing that does not simulate actual aseptic operations**

**Cross-contamination during non-sterile compounding**

**FDA returning to 2012-style inspections**



# DOJ's Enforcement of Guidance Documents

## **Attorney General Jeff Sessions (11/16/17)**

- Guidance documents are for information-only
- Statutes, regulations, and formal rules govern

## **Associate Attorney General Rachel Brand (01/25/18)**

- Noncompliance with a guidance document is not presumptive or conclusive evidence of a regulatory violation



# Joint Inspections – FDA and BOP

## **Increasing trend of FDA to “deputize” State Boards of Pharmacy**

- BOP inspectors attend inspections with FDA
- FDA pressures BOP to take its own enforcement action

## **Develop a good relationship with your BOP before the FDA inspection**

- Become involved with your local BOP
- Be responsive to BOP recommendations/enforcement actions
- Encourage the BOP to stand up to jurisdictional encroachments



# State Coalitions Are Needed

**Coordinate and empower State Boards of Pharmacy**

**Identify and respond consistently to trends in FDA inspection practices**

**Coordinate best practices among pharmacies**