

Information Sharing and Technical Assistance

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Working With the States

- Notification of Compounding Inspections
- Joint Inspections
- State Provided Information
- FDA-State Information Sharing

Notification of Compounding Inspections

- OPQO Division II Geographical Areas
 - Former Districts: DAL, NOL, ATL, FLA, SJN
 - TX, OK, AR, LA, AL, TN, MS, GA, NC, SC, FL, PR
- Notifications/Invitations to Boards of Pharmacy (BoP) & State Health Departments

Joint Inspections

- 503A and 503B Compounding Pharmacies
- Inspections and Assistance
- State Enforcement Actions
- Sharing Information

State Provided Information

- BoP Inspections
- Complaints
- Other Information
- Resulting in FDA Assignment Inspections

State Provided Information

- Example of FDA Inspection:
 - 503A Compounding Pharmacy in LA, 2017
 - BoP contacted FDA with their inspectional findings and planned enforcement action
 - FDA inspection found significant insanitary conditions
 - An enforcement decision is in progress

State Provided Information

- Example of FDA Inspection:
 - 503A Compounding Pharmacy in FL, 2017
 - DOH contacted FDA with their inspectional findings
 - FDA inspection found significant insanitary conditions
 - At close of inspection, pharmacy agreed to voluntarily stop production of sterile products
 - FDA Public Alert was issued
 - Pharmacy agreed to recall product
 - DOH issued Emergency Order to stop operation

State Provided Information

- Example of FDA Inspection:
 - 503A Compounding Pharmacy in FL, 2017
 - DOH contacted FDA with their inspectional findings
 - FDA inspection found insanitary conditions
 - An enforcement decision is in progress

State Provided Information

- Example of FDA Inspection:
 - 503A Compounding Pharmacy in FL, 2017
 - BoP contacted FDA with adverse reaction complaint and their previous inspectional findings
 - FDA inspection found significant insanitary conditions
 - An enforcement decision is in progress

State Provided Information

- Example of FDA Inspection:
 - 503A Compounding Pharmacy in FL, 2017
 - DOH contacted FDA with their inspectional findings
 - FDA has issued an inspection assignment



FDA-State Information Sharing

- Sharing of Information
- Commissioned or 20.88 Agreements
- Working Relationship With All States