Working with the FDA and FDA's data

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Change in Office Perspective

We have changed from having licensing, inspection and enforcement working separately. Each sees aspects of a business' background, policies, disciplines, drugs, customers/patients, inspections.

We attempt to integrate findings and do our research early in the process.

It is easier to share information now, than to monitor and discipline the facility later. We spend an average of 1 to 2 days on each new compounding application.

Where do we spend that time?

- Find **true** owners and officers: we estimate about 40 to 50% of owner or officer or PIC information is wrong or incomplete.

- We also estimate that for about 20 to 25% of applications we find owner or officer evidence of court findings of fraud.

- Search for unapproved products such as HCG, copies of products on the market, drugs which have never been through the FDA process, unsafe usages or dosages, etc.

Reviewing Applications, cont.

Review state inspections, VPPs, 483s, recalls and warnings.

For 483s, apply USP 797 relevant data to 503A's
Do not use subjective observations such as 'head inside hood.'
Use facility data such as test results, logs, policies, training records, environmental monitoring, distribution patterns.

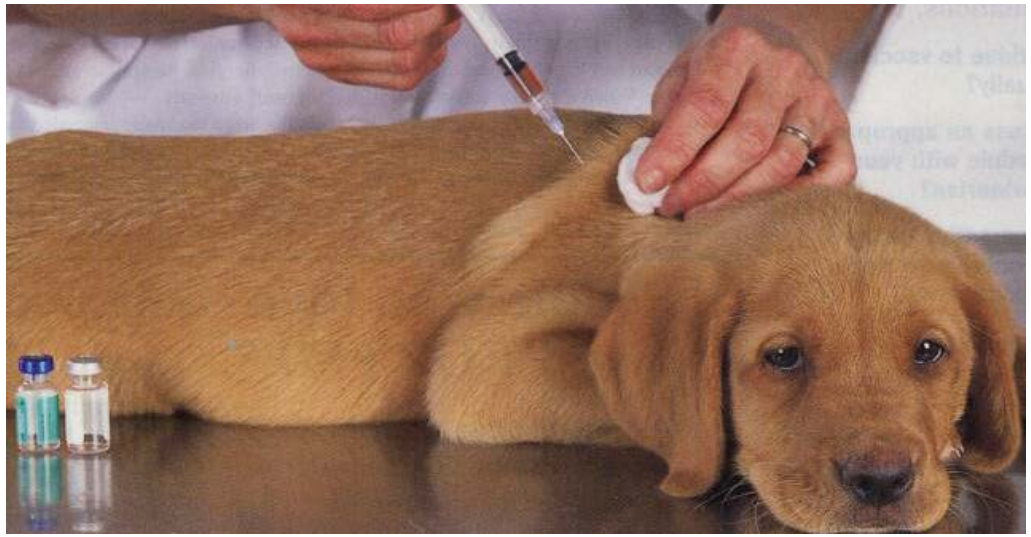
Any compounding methods or procedures, environmental monitoring and BUD policies.

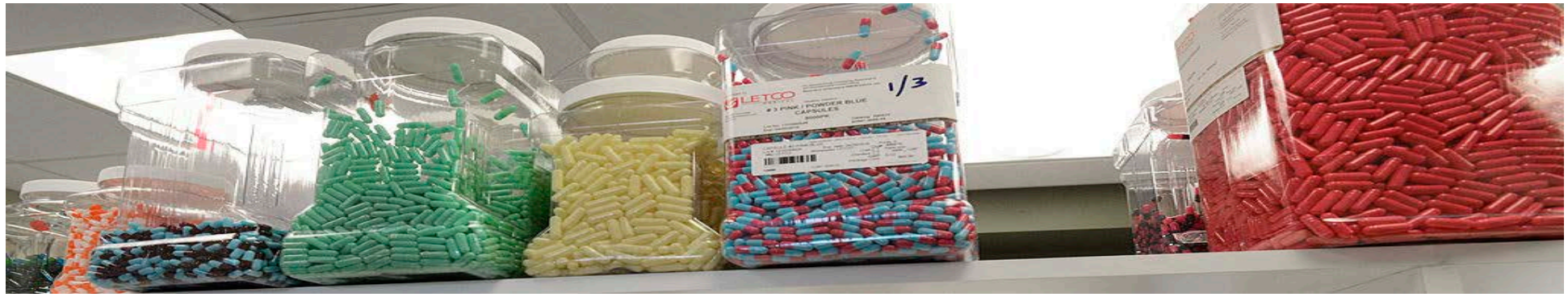


Inspecting together with FDA

We usually receive adequate notice from FDA if they are planning to inspect a facility in our state.

We attempt to always accompany the FDA during an inspection and we conduct our own inspection during the same time period.





- We do discuss information and are present for the exit interview. However, we do not copy each other's findings.

- If the state finds cause to issue an emergency suspension, we will do so. As example, we were both present during an inspection of a facility which had tested positive for mold over a three month period but continued to compound. The state made it's own decision to suspend operations, but included the FDA in the conversation.

Most recent cooperative inspection.

- Inspected a facility for which the Alabama Board had previously withdrawn sterile compounding license.
- After meetings, retraining, use of a consultant, the Alabama Board re-issued a license.
- When we returned for re-inspection, in conjunction with the FDA, the facility was worse than previously. We issued an emergency closing.
- The hearing covered 8 days, 3 opposing lawyers and multiple expert witnesses.
- We asked the FDA to allow their investigator to testify.

FDA support …

- The FDA investigator was available for two and a-half days during the hearing.
- She testified to the FDA findings, which mirrored the state findings. There were some findings which the FDA had documented, but the state had not. These were very helpful in making our case.
- The result was that the attorneys for the pharmacy offered a concession. They surrendered their Alabama license for 2 years and agreed to a $240,000 fine.
- Today, the pharmacy states that it is unable to continue financially, based on USP 795 compounding only.

Overall …..

We have had a helpful and cooperative relationship with the FDA for the past 4 years. We can call to discuss questions or concerns. They contact us at times to discuss our law or rulings. The investigators and directors with whom we work have been friendly and collaborative, and I feel we all benefit from it.