The Brand Memo and the FDA

- While guidance documents are not binding, FDA often relies on them when conducting inspections, the results of which can spawn a chain of enforcement-oriented events
- 483s are shared with state regulators which, especially in the pharmacy context, can create meaningful enforcement liability
- 483s form the basis for FDA's decision about the compliance status of an organization (now public)
- 483s can lead to Warning Letters, more frequent inspections, and more serious enforcement action (consent decrees, criminal enforcement)

FDA Guidance Documents – A Sampling

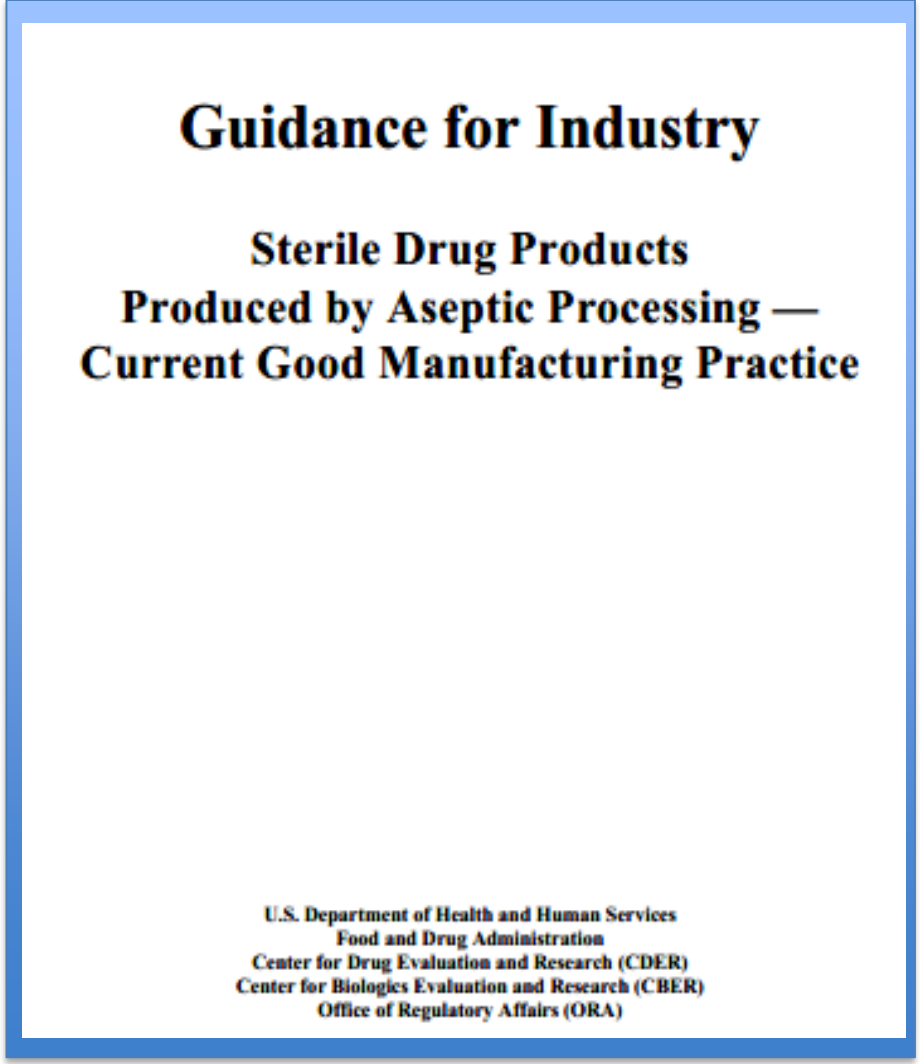
- Establishing Pre-Amendment Device Status
  - https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm
- Distinguishing Device Recalls from Device Enhancements Guidance
  - https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf
- When to file a 510(k) for a change to an existing device
  - https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf
- General versus specific intended use guidance
  - https://www.fda.gov/RegulatoryInformation/Guidances/ucm073944.htm
- Design Control Guidance for Medical Device Manufacturers
  - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070642.pdf

FDA Guidance Documents – A Sampling

- Data Integrity and Compliance with cGMP Guidance
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM495891.pdf
- Sterile Drug Products Produced by Aseptic Processing
  - https://www.fda.gov/downloads/Drugs/Guidances/ucm070342.pdf
- Insanitary Conditions at Compounding Pharmacies Guidance
  - https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm514666.pdf
- Compounding Copies of Commercially Available Drug Products Guidance
  - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf

FDA Guidance Documents – A Sampling

- Good Re-Print Practice Guidance
  - https://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm
- Responding to Unsolicited Requests For Off-Label Information Guidance
  - https://www.fda.gov/downloads/drugs/guidances/ucm285145.pdf
- Seafood HACCP and FSMA Guidance
  - https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569798.pdf
- Highly Concentrated Caffeine in Dietary Supplements Guidance
  - https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM604319.pdf



Access materials at fdli.org/annual2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	3/21-3/24/16 & 4/11/16
	FEI NUMBER [redacted]
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED [redacted]	
CITY, STATE AND ZIP CODE Lutz, FL 33549	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

February 15, 2017

Erica White, Executive Director
Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258

Dear Ms. White:

The purpose of this letter is to refer to the Florida State Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Florida BOP, [redacted]

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm failed to disinfectant equipment prior to introduction into the aseptic processing area. For example, the firm was observed introducing a pump into the ISO 5 hood without first disinfecting the pump and cord.

2. The firm failed to demonstrate through appropriate smoke studies that their ISO 5 buffer room is able to provide adequate protection to (b) (4) vials during the (b) (4) the ISO 5 hood (b) (4)

3. Personnel did not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during aseptic operations.