

FDA Inspections and Enforcement Update: Changes in FDA Inspectional Procedures

**Inter-governmental Working Meeting
on Drug Compounding
September 20, 2016**

**Kathy Anderson
Office of Unapproved New Drugs and Labeling Compliance
CDER, Office of Compliance**

Overview

- Updated inspection process for pharmacies - earlier assessment of compliance with section 503A
- Forward-looking goals:
 - Better prioritize oversight of non-outsourcing facility compounders, to focus on compounders distributing drug products interstate that have the potential to adversely affect large numbers of patients.
 - Increase frequency of outsourcing facility inspections.

Note: we will talk more about FDA enforcement actions during today's final session on FDA-state collaboration

Updated inspection process for pharmacies - earlier assessment of compliance with 503A

- FDA announced that effective August 1, 2016, its investigators will not include observations that represent deviations solely from current good manufacturing practice (CGMP) requirements in any issued Form FDA 483 if it appears, based on a preliminary assessment, that the firm compounds drug products in compliance with certain conditions of section 503A.

Updated inspection process for pharmacies - earlier assessment of compliance with 503A

- After the inspection, FDA will conduct a thorough review of the evidence to evaluate whether the firm compounds all of its drugs in accordance with certain conditions of section 503A and other applicable provisions of Federal law.
- If FDA's more thorough post-inspection review reveals that a facility fails to produce drugs in accordance with the conditions of section 503A, FDA intends to consider citing observations that represent deviations solely related to CGMP requirements in any regulatory action it decides to pursue.

Updated inspection process for pharmacies – earlier assessment of compliance with 503A

Why did we do this?

- In response to concerns raised by states and other stakeholders that FDA was including observations that represent deviations solely related to CGMP requirements in Forms FDA 483 without consideration as to whether the pharmacy may be exempt from the CGMP requirements under section 503A.

Updated inspection process for pharmacies - earlier assessment of compliance with 503A

Remember that:

- Section 503A exemptions, including the exemption from CGMP requirements, are only applicable when an entity is in compliance with section 503A.
- Regardless, other statutory provisions, such as the prohibition on insanitary conditions, always apply. FDA will continue to include observations related to those statutory provisions where observed.

Forward-looking Goal:

Better prioritize oversight of non-outsourcing facility compounders, to focus on compounders distributing drug products interstate that have the potential to adversely affect large numbers of patients.

- In the short-term, FDA intends to prioritize oversight of compounders with multiple out-of-state licenses that have been subject to prior disciplinary action.
- In the long-term, to assess patient exposure, we would like to use information about the **volume** of drug products compounders ship **interstate**.
 - Do NABP or any states already collect this information.? If not, are NABP and the states willing to collect this information? And share it with FDA?

Forward-looking Goal:

Increase frequency of outsourcing facility inspections

- FDA recognizes that it bears primary responsibility for timely oversight of outsourcing facilities.
- FDA recognizes that states may require more frequent inspections to support state licensure than FDA currently conducts, and desire that FDA take action more quickly following inspections.
- It is our goal to increase the frequency of outsourcing facility inspections over time, as well as decrease the time between inspections and subsequent FDA actions.
- It continues to be our goal to inspect outsourcing facilities two months post registration, but may encounter delays if a registered firm is not yet operational.

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**U.S. Food and Drug Administration
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