Texas
Enforcement Priorities for Sterile Compounding Pharmacies

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Executive Director/Secretary

FDA's Federal-State Meeting to Discuss Pharmacy Compounding

March 21, 2014

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2013 Texas Legislative Session

- The Texas Pharmacy Act was amended to specify that:
  - New sterile compounding pharmacies may not open until inspected;
  - Out-of-state sterile compounding must reimburse TSBP or our agent for an inspection;

2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended to specify that:
  - Existing sterile compounding pharmacies may not renew their registration unless they have:
    - been inspected as specified by the Board in rule; and
    - reimbursed the Board for all expenses incurred by the Board in inspecting the pharmacy, if the pharmacy is located in another state.

2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended to specify that:
  - A pharmacy that compounds a sterile product must notify the Board:
    - Immediately of any adverse effects reported to the pharmacy or known by the pharmacy to be potentially attributable to a sterile product compounded by the pharmacy; and
    - Not later than 24-hours after the pharmacy issues a recall for a sterile product compounded by the pharmacy.

2013 Texas Legislative Session (cont.)

- TSBP was given additional appropriations to:
  - Hire 7 additional personnel directly related to the inspection of sterile product pharmacies; and
  - Additional funding to test sterile products and/or the environment in sterile compounding pharmacies.

Job #1

- After NECC.
  - Identity of pharmacies that compound sterile products.
  - Revises licensing system to specifically identify those pharmacies that compound sterile products.
  - Conduct priority inspections of known sterile compounding pharmacies.
- After additional funding received in 2013.
  - Additional training of current inspectors; and
  - Hiring and training of new inspectors.

Priorities for Enforcement

- Inspections of Pharmacies that:
  - Compound High Risk Products.
  - Have had previous “poor” history with TSBP.
  - All sterile compounding pharmacies.

Experiences

- As a result of recent inspections, 2-pharmacies were ordered to ceased compounding of High-Risk Products.
- Tools Available to TSBP “shut down” compounding operations:
  - Issuance of a “Warning Notice” with immediate due-date.
  - Summary Suspension of a license.

Testing of Compounded Products

SUMMARY OF COMPOUNDED SAMPLE TESTING PROGRAM FY 2009 – FY 2013						
	FY2009	FY2010	FY2011	FY2012	FY2013	5-Yr. Avg.
Total # Samples Tested	46	86	37	28	58	51
# Non-Sterile Samples Tested	35	58	27	20	9	29.8
# Potency Failures	6	13	4	2	1	5.2
# Sterile Samples Tested	11	28	10	8	49	21.2
# Potency Failures	1	8	4	1	2	3.2
# Sterility Failures	0	0	0	1**	0	<1
# Fungal Failures*	N/A	N/A	N/A	N/A	0	0
# Endotoxin Failures	0	0	0	0	0	0

*Fungal Testing began in FY2013 **Nasal product

Thank You!