Gay Dodson, R.Ph.
Executive Director/Secretary

Texas Enforcement Priorities for Sterile Compounding Pharmacies

FDA’s Federal-State Meeting to Discuss Pharmacy Compounding
March 21, 2014
Board of Pharmacy Members

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Phyllis A. Stine – Abilene

Joyce Tipton, R.Ph., MBA – Houston

Charles F. Wetherbee – Boerne
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;
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.
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

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Total # Samples Tested</td>
<td>46</td>
<td>86</td>
<td>37</td>
<td>28</td>
<td>58</td>
<td>51</td>
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<tr>
<td># Non-Sterile Samples Tested</td>
<td>35</td>
<td>58</td>
<td>27</td>
<td>20</td>
<td>9</td>
<td>29.8</td>
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<tr>
<td># Potency Failures</td>
<td>6</td>
<td>13</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>5.2</td>
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<tr>
<td># Sterile Samples Tested</td>
<td>11</td>
<td>28</td>
<td>10</td>
<td>8</td>
<td>49</td>
<td>21.2</td>
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<tr>
<td># Potency Failures</td>
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<td>8</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3.2</td>
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<td># Sterility Failures</td>
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<td>0</td>
<td>0</td>
<td>1**</td>
<td>0</td>
<td>&lt;1</td>
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<td>N/A</td>
<td>N/A</td>
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<tr>
<td># Endotoxin Failures</td>
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*Fungal Testing began in FY2013  **Nasal product  3/21/2014
Thank You!