October 1, 2009

PDA Metro Meeting

“The State of the Pharmaceutical Industry”

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Compliance Officer
New Jersey District
TOPICS

- New Consent Decrees
- Warning Letters
- Seizures
- Criminal Actions
- FDA-483 Trends
- Misc.
Globalization
Increase in imported products
Opened foreign Offices
Dedicated Foreign Inspection cadre
Hired new investigators
Risk based approach
<table>
<thead>
<tr>
<th>Category</th>
<th>FY'08</th>
<th>FY'07</th>
<th>FY'07</th>
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<tbody>
<tr>
<td> </td>
<td>FDA</td>
<td>NWJ</td>
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<tr>
<td>WL</td>
<td>445</td>
<td>7</td>
<td>471</td>
</tr>
<tr>
<td>Seizures</td>
<td>8</td>
<td>0</td>
<td>6</td>
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<tr>
<td>Injunctions</td>
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<td>12</td>
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<tr>
<td># EI (Dom)</td>
<td>15245</td>
<td></td>
<td>15581</td>
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<tr>
<td>(For)</td>
<td>947</td>
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Seizures
Fiscals Years 1993 – 2008
<table>
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<tr>
<td>2008</td>
<td>445</td>
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<tr>
<td>2007</td>
<td>471</td>
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<tr>
<td>2006</td>
<td>538</td>
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<tr>
<td>2005</td>
<td>535</td>
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<tr>
<td>2004</td>
<td>725</td>
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<tr>
<td>2000</td>
<td>1154</td>
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CDER WARNING LETTERS

The bar chart shows the number of warning letters over the years from 1999 to 2007. The highest number of warning letters was in 1999, with a significant drop in subsequent years.
<table>
<thead>
<tr>
<th></th>
<th>FY-04</th>
<th>FY-05</th>
<th>FY-06</th>
<th>FY-07</th>
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<tr>
<td><strong>Drug</strong></td>
<td>9</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>1</td>
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<tr>
<td><strong>Total</strong></td>
<td>9</td>
<td>15</td>
<td>17</td>
<td>18</td>
<td>8</td>
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</table>
TOP GMP CITES
for
FY ‘08
FDA-483 (Drugs)

#1) 211.22
#2) 211.100(b)
#3) 211.110(a)
#4) 211.160(b)
#5) 211.100(a)
Examples of recent FDA-483 Observations

The aseptic filling of drug products on the _____filling line at the speed of______has not been validated.

Your firm does not conduct adequate monitoring of bioburden after hold times of intermediates or pooled buffers during purification.

Your firm failed to maintain computerized systems in a validated state.
RESPONSE TO FDA-483

- Executive summary including time frames for corrective actions.
- Original FDA-483 comment with your response and attachments.
- List of corrections already made by date.
- Sent within 30 day’s to the NWJ-DO Director of Compliance.
- If not thorough then:
  - Example, “Your follow up to these documented deviations did not include training of operators or those supervising formulation operations.”
WARNING LETTER’S (WHAT TRIGGERS THEM)

- Re-occurring violations, significant violations that show adulteration or misbranding.
- No response to FDA-483 or response was not adequate (packages are reviewed by CDER/CVM, which will include any response from firm).
CONCLUSION

- BE READY FOR INSPECTION (PLAN)
- DAILY WRAP UP/DISCUSSION
- FINAL DISCUSSION
- HANDLING OF FDA 483
- PREPARING A RESPONSE
CONTACT

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