Coalition Survey Results

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Coalition Survey

- Number of respondents = 31
- Number of NDAs = 2
- Number of ANDAs = 28
- Number of facilities = ?
What types of applications have you filed with the FDA for a PET drug? (Select all that apply)  **Total response = 31**

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>6.5%</td>
<td>2</td>
</tr>
<tr>
<td>ANDA</td>
<td>90.3%</td>
<td>28</td>
</tr>
<tr>
<td>None</td>
<td>3.2%</td>
<td>1</td>
</tr>
<tr>
<td>IND/Other text responses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IND (8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eIND (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RDRC (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DMF (2)</td>
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<td></td>
</tr>
</tbody>
</table>

**Total response = 31**
If you have filed an NDA, for which PET drug(s)?

Respondents 31: 1 answered/30 skipped question
If you have filed an NDA for a PET drug, what is the approval status?

Respondents 31: 3 answered/28 skipped question
<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>[F-18]FDG</td>
<td>92.6%</td>
<td>25</td>
</tr>
<tr>
<td>Sodium [F-18]Fluoride</td>
<td>66.7%</td>
<td>18</td>
</tr>
<tr>
<td>[N-13]Ammonia</td>
<td>59.3%</td>
<td>16</td>
</tr>
<tr>
<td>Other (List here):</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

Total Respondents 31: 27 answered/4 skipped question
If you have filed an ANDA for a PET drug, what is the approval status?

Total respondents 31: 27 answered/4 skipped question
Have you received written or oral communication from the FDA regarding the review of your application?

- Yes
- No
Please indicate which review(s) have been started/completed for your application:

Total response 31: 29 answered/2 skipped question
Comments Related to Review of PET Drug Applications

1. Lack of Experience by the Review Staff (15 comments)
   a) Lack of experience on part of FDA review staff
   b) Encourage FDA to use Coalition for expertise for their reviewers
   c) Difference in CDER and OGD

2. Testing for Aluminum (6 comments)
   a) Why is Al analysis requested?

3. Supporting Documentation for Equipment and Supplies (6 comments)
   a) Suggest how to inform the FDA on type of information applicants typically have
   b) Suggest how applicant can deal with vendors to solve problems

4. Changes to RLD (3 comments)

5. USP vs. non-USP (3 comments)
   a) Product not USP
   b) Monographs for approved drugs will not be removed from USP

6. Facilities e.g. specific air classification for cyclotron and “Hot Chem” rooms (2 comments)

7. Environmental Monitoring (1 comment)
Since Filing your application(s), how many times have you been inspected by the FDA?

Total response 31: 31 answered question
For each inspection, how many FDA Form 483 observations did you receive?

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>1 - 2</th>
<th>3 - 4</th>
<th>More than 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Inspection</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Second Inspection</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Third Inspection</td>
<td>0</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>

If you have had more than three inspections, what is the total number of 483 observations you have received (optional)?

<table>
<thead>
<tr>
<th></th>
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<th>3 - 4</th>
<th>More than 4</th>
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<tbody>
<tr>
<td></td>
<td>0</td>
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</table>

Total Respondents 3: Answered question 18/Skipped question 13
Do you feel that you need additional support or education on the review process or inspections?

Total Respondents 31
Comments Related to FDA Inspections

1. No issues (3 comments)
2. Lack of Experience by the Inspectors (8 comments)
   a) Untrained inspectors or trained in Part 211
   b) Visual inspection
3. Inconsistent Inspections (5 comments)
   a) Inconsistent criteria
   b) No respect for inspectee’s time
4. Lack of Experience of PET Drug Producer (2 comments)
5. Aseptic Technique & Microbiology (10 comments)
   a) Speciation on media tubes
   b) Excess EM requirements
   c) Aseptic processed in hot cell
6. Ratchet Effect (12 comments)
   a) 211 instead of 212
   b) Videographic smoke studies
7. Electronic Filing (3 comments)
   a) Expensive XML software/eCTD format or expensive to outsource
8. Miscellaneous (8 comments)
   a) Osmolality