Top 5 Most Common Errors Across All Drug Listings

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What are the Most Common Errors?

FDA has a robust set of automated validations to prevent errors from being submitted, but errors still get through

Percentages of Identified Errors in Random Sample of Deficiency Letters

- Incorrect/Strength: 30%
- Incorrect/Missing Active Ingredients: 14%
- Incorrect NDC: 16%
- Incorrect/Missing DEA Schedule: 8%
- Incorrect/Missing Establishment Information: 13%
- Others: 19%

Source: eDRLS
### Incorrect Strength - example

A toothpaste’s label displays Sodium Fluoride at .25%...

...but the drug listing data shows:

<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)</td>
<td>FLUORIDE ION</td>
<td>0.25 g in 96 g</td>
<td></td>
</tr>
</tbody>
</table>
Missing/Incorrect Active Ingredient - example

A first aid ointment’s label displays:

Polymyxin B sulfate 5000 units
Neomycin sulfate 3500 units
Bacitracin 500 units
Lidocaine hydrochloride 40 mg

…but the drug listing data shows:

<table>
<thead>
<tr>
<th>Active Ingredient/Active Moiety</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)</td>
<td>POLYMYXIN B</td>
<td>5000 [USP'U] in 1 g</td>
</tr>
<tr>
<td>NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)</td>
<td>NEOMYCIN SULFATE</td>
<td>3500 [USP'U] in 1 g</td>
</tr>
<tr>
<td>BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)</td>
<td>BACITRACIN</td>
<td>500 [USP'U] in 1 g</td>
</tr>
</tbody>
</table>
Incorrect NDC - example

Hand Sanitizer wipes show an NDC product code of -911-

...but the drug listing data shows:

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>xxxxx-912-10</td>
<td>100 in 1 CANISTER</td>
<td>03/30/2020</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>245 mL in 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PACKAGE; =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>xxxxx-912-20</td>
<td>200 in 1 CANISTER</td>
<td>03/30/2020</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>490 mL in 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PACKAGE; =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>xxxxx-912-07</td>
<td>70 in 1 PACKAGE</td>
<td>03/30/2020</td>
<td></td>
</tr>
</tbody>
</table>

- Incorrect NDCs may be caused by:
  - Contract Manufacturer displaying client’s NDC on label (remember to remove before submitting)
  - Incorrect Configuration (5-4-1 vs 5-3-2)
  - Product or package code mismatch
  - Incorrect assignment of product or package NDC, e.g., a package code for a carton of vials is printed on the individual vial
Incorrect DEA Schedule - example

Labeling for a Methylphenidate product states Schedule CII in both the insert and on the carton labeling...

...but the drug listing data shows:

<table>
<thead>
<tr>
<th>Product Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type: ORAL</td>
</tr>
<tr>
<td>Item Code (Source): DEA Schedule</td>
</tr>
<tr>
<td>DEA Schedule</td>
</tr>
</tbody>
</table>

METHYLPHENIDATE HYDROCHLORIDE- methylphenidate hydrochloride capsule, extended release [company name redacted]

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Methylphenidate Hydrochloride Extended-release Capsules, CII (10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg)
Rx only
Once Daily
DESCRIPTION
Methylphenidate hydrochloride extended-release capsules are a central nervous system (CNS) stimulant. …

Want to know more about DEA Schedule?
Drug Scheduling (dea.gov) [https://www.dea.gov/drug-information/drug-scheduling]
Common reasons for establishment data errors:

- **Registration of establishment has expired since it was first entered**
- **Change in manufacturer, or the addition of one**
- **Establishment is a distributor only (should not register nor be identified in listing as a manufacturer)**
- **Inspection reveals that other establishments in the supply chain are not included in the listing (API manufacturers, analytical labs, etc)**

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**Missing/Incorrect Establishments**

…but the drug listing data shows:

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>API MANUFACTURE()</td>
</tr>
</tbody>
</table>
Reminders
Before you click SUBMIT!!!

Does your strength match what’s on the label and carton?

Does your active ingredient list match what’s on the label?

Does your NDC number match what’s on the label?

Is your drug on the DEA Controlled Substances Act Schedule?
Check out www.dea.gov/drug-information/csa

When you review drug listing data, remember to update the establishment section!
Thank you for doing your part in preventing and eliminating errors