Top 5 Most Common Errors Across All Drug Listings

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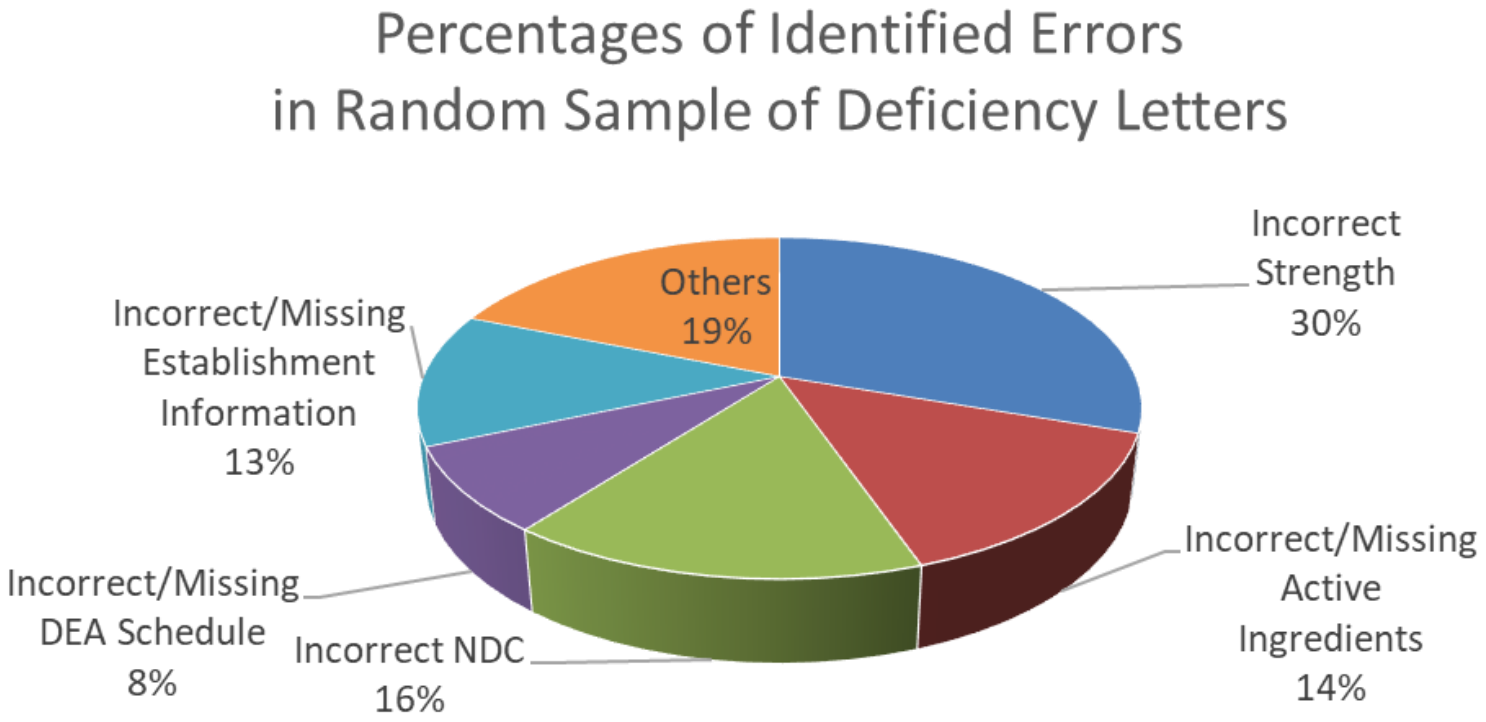
What are the Most Common Errors?

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



Source: eDRLS

Incorrect Strength - example

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

as directed by a dentist or physician.
- Children 2 to 6 years:
  - To minimize swallowing, use only a pea-sized amount.
  - Supervise children's brushing and rinsing until good habits are established.
- Children under 2 years of age: Consult a dentist or physician.

Inactive Ingredients

Glycerin, Water, Hydrated Silica, Sorbitol, Xylitol, Cocamidopropyl Betaine, Flavor, Xanthan Gum, Stevia Rebaudiana Leaf/Stem Extract, Cellulose Gum, Sodium Cocoyl Glutamate, Menthol, Squalane.

Questions or Comments

You may report an adverse reaction to: HEY HUMANS
c/o Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.

DIST. BY MAESA LLC, NEW YORK, NY 10281.

Drug Facts

Active Ingredients	Purpose
Sodium Fluoride 0.25% (0.15% w/v fluoride ion)	Anticavity

Uses
- Helps protect against cavities.

Warnings
- **Keep out of reach of children under 6 years of age.**
- If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Adults and children 2 years and older:
  - Brush teeth thoroughly, preferably after each meal or at least twice a day, or

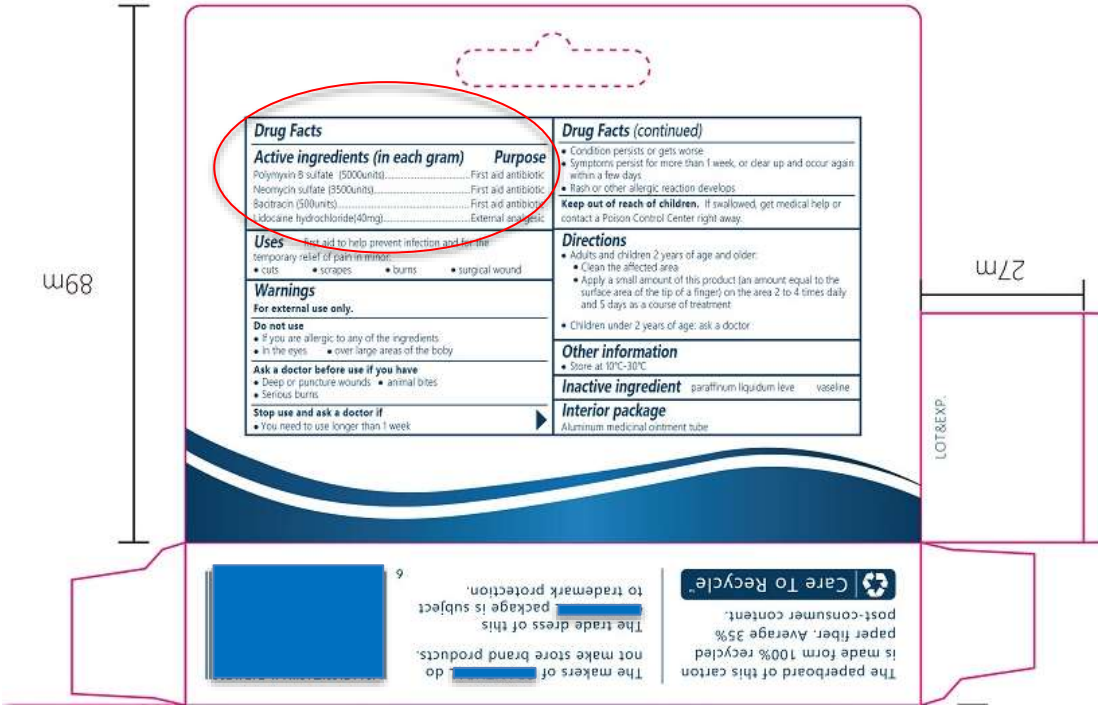
…but the drug listing data shows:

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 g in 96 g

Missing/Incorrect Active Ingredient - example

A first aid ointment's label displays:

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



…but the drug listing data shows:

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3500 [USP'U] in 1 g
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g

Incorrect NDC - example

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

…but the drug listing data shows:

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	xxxxx-912-10	100 in 1 CANISTER	03/30/2020	
1		245 mL in 1 PACKAGE; =		
2	xxxxx-912-20	200 in 1 CANISTER	03/30/2020	
2		490 mL in 1 PACKAGE; =		
3	xxxxx-912-07	70 in 1 PACKAGE	03/30/2020	

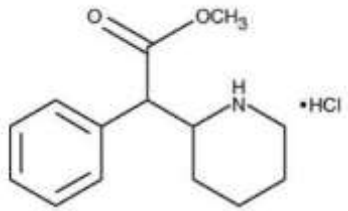
- *Incorrect NDCs may be caused by:*
  - *Contract Manufacturer displaying client's NDC on label (remember to remove before submitting)*
  - *Incorrect Configuration (5-4-1 vs 5-3-2)*
  - *Product or package code mismatch*
  - *Incorrect assignment of product or package NDC, e.g., a package code for 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…

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

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. …



…but the drug listing data shows:

Product Information			
Product Type		**Item Code (Source)**	0115-1736
Route of Administration	ORAL	**DEA Schedule**	

Want to know more about DEA Schedule?
Drug Scheduling (dea.gov) ***https://www.dea.gov/drug-information/drug-scheduling***

Missing/Incorrect Establishments

…but the drug listing data shows:

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
			API MANUFACTURE()

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)*

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