

Case Studies

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September 28, 2023

Learning Objectives

- Identify the most common listing deficiency issue
- Recognize various types of strength errors
- Examine consequences resulting from strength errors

Case Study #1 – Strength Error

- Antiseptic – Chlorhexidine 4%

INGREDIENT DETAILS

Denominator Strength: *	<input type="text" value="1"/>	Unit of Measure: *	<input type="text" value="mL"/>
Type: *	<input type="text" value="Active Ingredient, Moiety is Basis of Strength"/>		
Ingredient UNII - Name: *	<input type="text" value="(5908ZUF22Y) CHLORHEXIDINE ACETATE"/>		
Strength: *	<input type="text" value="4"/>	Unit Of Measure: *	<input type="text" value="mg"/>

Case Study #1 – Calculation Error

- Chlorhexidine 4%
 - $4\% = 4\text{g} / 100\text{mL}$
 - $4000\text{mg} / 100\text{mL} \rightarrow 40\text{mg} / 1\text{mL}$
- As entered in CDER Direct
 - $4\text{mg} / 1\text{mL} = 0.4\%$
- Consequence
 - Listed strength is 10 times less than actual amount

Case Study #2 – Strength Error



- Anti-perspirant – Aluminum Chlorohydrate 10%

INGREDIENT DETAILS

Denominator Strength: *	<input type="text" value="100"/>	Unit of Measure: *	<input type="text" value="mL"/>
Type: *	<input type="text" value="Active Ingredient, Ingredient is Basis of Strength"/>		
Ingredient UNII - Name: *	<input type="text" value="(HPN8MZW13M) ALUMINUM CHLOROHYDRATE"/>		
Strength: *	<input type="text" value="10"/>	Unit Of Measure: *	<input type="text" value="mg"/>

Case Study #2 – Unit of Measure Error

- 10% = 10g/100mL
- As entered in CDER Direct
 - Aluminum Chlorohydrate 10mg/100mL
 - Strength = 0.01%
- Consequence
 - Listed strength is 1000 times less than actual amount

Case Study #3 – Strength Error

- Wart Remover – Salicylic Acid 40%

Drug Facts	
Active Ingredient	Purpose
Salicylic Acid 40%.....	Callus removal

4 MEDICATED PATCHES

INGREDIENT DETAILS	
Denominator Strength: *	<input type="text" value="4"/>
Type: *	<input type="text" value="Active Ingredient, Ingredient is Basis of Strength"/>
Ingredient UNII - Name: *	<input type="text" value="(O41PZ4LPZ) SALICYLIC ACID"/>
Strength: *	<input type="text" value="40"/>
Unit of Measure: *	<input type="text" value="1"/>
Unit Of Measure: *	<input type="text" value="mg"/>

Case Study #3 – Invalid Strength



- As entered in CDER Direct
 - Salicylic Acid 40mg in 4
- What is the strength?
 - 40mg in 4 patches
 - 10mg in each patch

Case Study #3 – Invalid Strength



- Salicylic Acid 40%
- Strength 40% = 40g/100g or 0.4g in 1 g
- How many grams in each patch?
 - 1g in 1 patch
 - 4 patches in 1 box
- Consequence
 - Listed strength does not report actual amount in patches

Case # 3 – Corrected Strength and Packaging



INGREDIENT DETAILS

Denominator Strength: *

1

Unit of Measure: *

g

Type: *

Active Ingredient, Moiety is Basis of Strength

Ingredient UNII - Name: *

(O414PZ4LPZ) SALICYLIC ACID

Strength: *

0.4

Unit Of Measure: *

g

PACKAGING

INNERMOST LEVEL

Check for Deletion ⓘ

☐

Package NDC:

55555-5555-1

Package Type: *

PATCH

Quantity: *

1

Unit of Measure: *

g

Combination Product Type:

Type 0: Not a Combination Product

Marketing Status:

active

Marketing Start Date:

09-28-2023

Marketing End Date:

OUTERMOST LEVEL

Check for Deletion ⓘ

☐

Is this a sample package ?

☐

Package NDC:

55555-5555-4

Package Type: *

BOX

Quantity: *

4

Unit of Measure: *

1

Combination Product Type:

Type 0: Not a Combination Product

Marketing Status:

active

Marketing Start Date:

09-28-2017

Marketing End Date:

Case Study #4 – Strength Error

- Dextromethorphan 15mg per teaspoon
- Content of labeling
- Box Image

Drug Facts

Active ingredients

Dextromethorphan HBr, USP 10 mg

Drug Facts

Active ingredient (in each 5 mL, 1 teaspoon)	Purpose
Dextromethorphan HBr, USP 15 mg.....	Cough suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

Case Study #4 – Mismatched Strength



- Content of labeling has a strength different from the image of the representative label
- Consequence
 - Potential 1/3 mis-dosing
 - Confusion for patients and health care providers

Case #5 – Strength Error

- Laxative – Glycerin 2g Suppositories

This label contains important information. Do not discard.	
Drug Facts	
Active ingredient (in each suppository)	Purpose
Glycerin, USP 2 grams	Laxative
Uses ♦ relieves occasional constipation (irregularity) ♦ generally produces bowel movement in ¼ to 1 hour	

Case Study #5 – Strength Error

- Glycerin 2g Suppositories

This label contains important information. Do not discard.

Drug Facts	
Active ingredient (in each suppository)	Purpose
Glycerin, USP 2 grams	Laxative
Uses ♦ relieves occasional constipation (irregularity) ♦ generally produces bowel movement in ¼ to 1 hour	

INGREDIENT DETAILS

Denominator Strength: *	<input type="text" value="100"/>	Unit of Measure: *	<input type="text" value="g"/>
Type: *	<input type="text" value="Active Ingredient, Moiety is Basis of Strength"/>		
Ingredient UNII - Name: *	<input type="text" value="(PDC6A3C0OX) GLYCERIN"/>		
Strength: *	<input type="text" value="83"/>	Unit Of Measure: *	<input type="text" value="g"/>

Case Study #5 – Sloppy Errors

- As entered in CDER Direct: 83g in 100g
- No rhyme or reason in mistake
- Consequence
 - Completely wrong strength
 - Manual override will be required to fix any initial strength error

Summary

- Strength errors are the most common listing deficiencies
- Errors can be due mistakes in calculation, unit of measure, entry (invalid strengths), mismatches, and/or carelessness
- Strength errors can have real world impacts

Questions?

Compliance questions: edrls@fda.hhs.gov

Technical questions: cderndirect@fda.hhs.gov

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