U.S. FOOD & DRUG ADMINISTRATION

Case Studies

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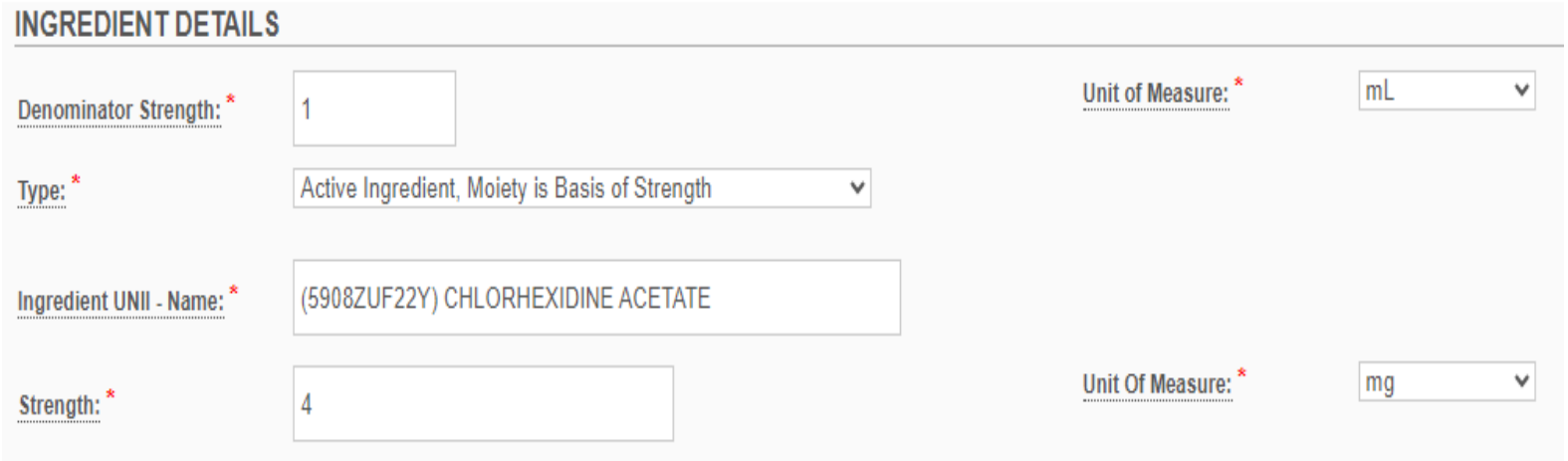
September 28, 2023

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%

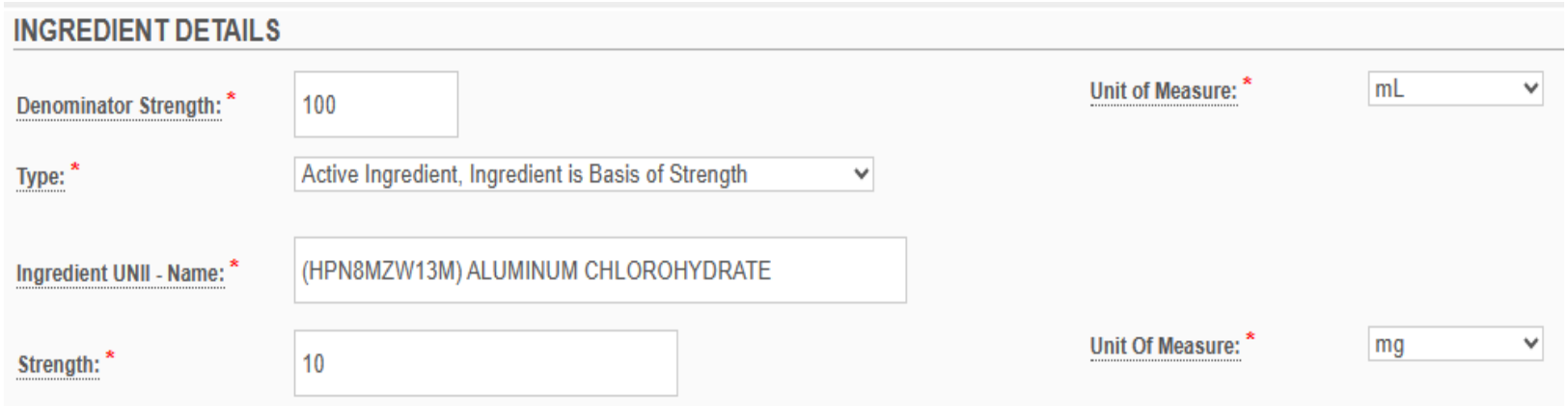


Case Study #1 – Calculation Error

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

Case Study #2 – Strength Error

- Anti-perspirant – Aluminum Chlorohydrate 10%



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%

INGREDIENT DETAILS

Denominator Strength: *	4	Unit of Measure: *	1
Type: *	Active Ingredient, Ingredient is Basis of Strength		
Ingredient UNII - Name: *	(O414PZ4LPZ) SALICYLIC ACID		
Strength: *	40	Unit Of Measure: *	mg

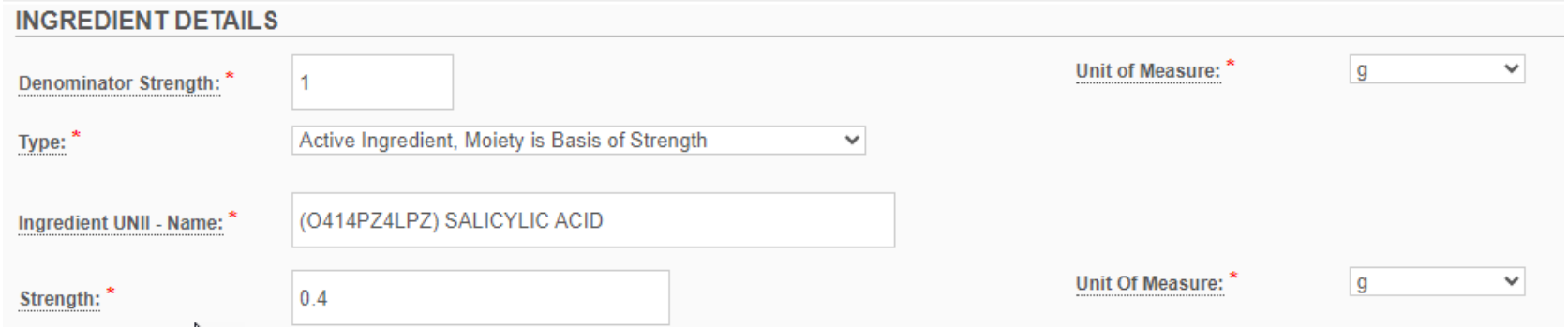
Case Study #3 – Invalid Strength

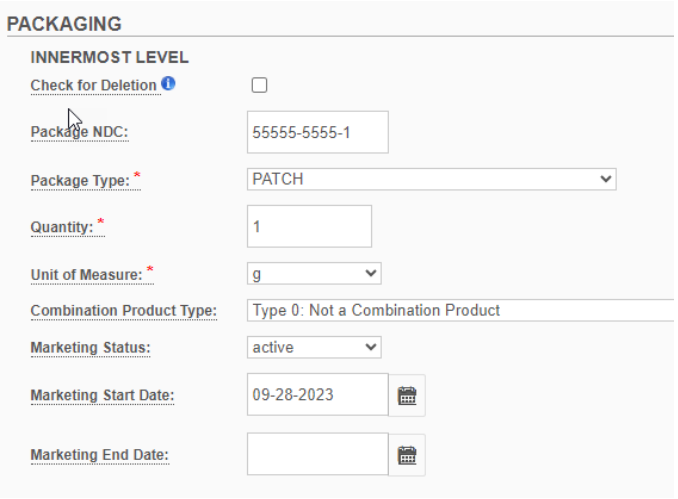
- As entered in CDER Direct
  - Salicylic Acid 40mg in 4
- What is the strength?
  - 40mg in 4 patches
  - 10mg in each patch

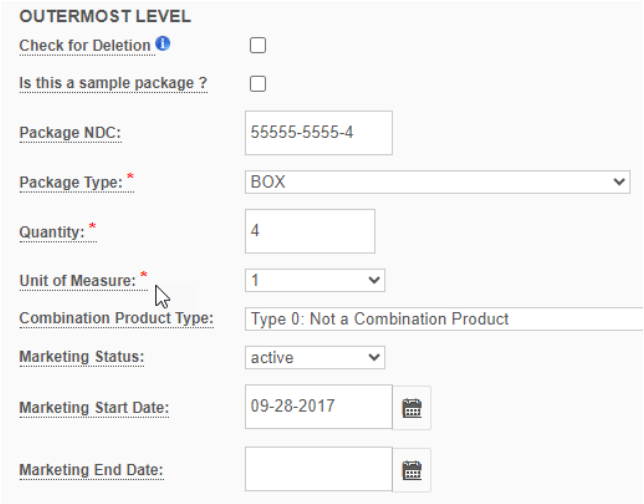
Case Study #3 – Invalid Strength

- 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







Case Study #4 – Strength Error

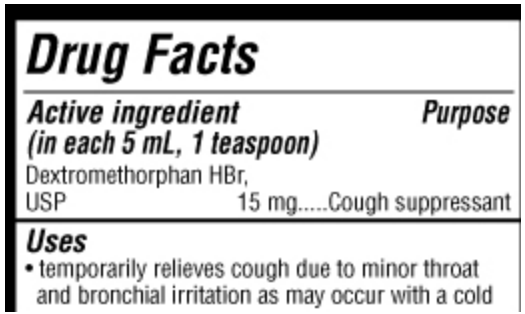
- Dextromethorphan 15mg per teaspoon
- Content of labeling

Drug Facts

Active ingredients

Dextromethorphan HBr, USP 10 mg

- Box Image

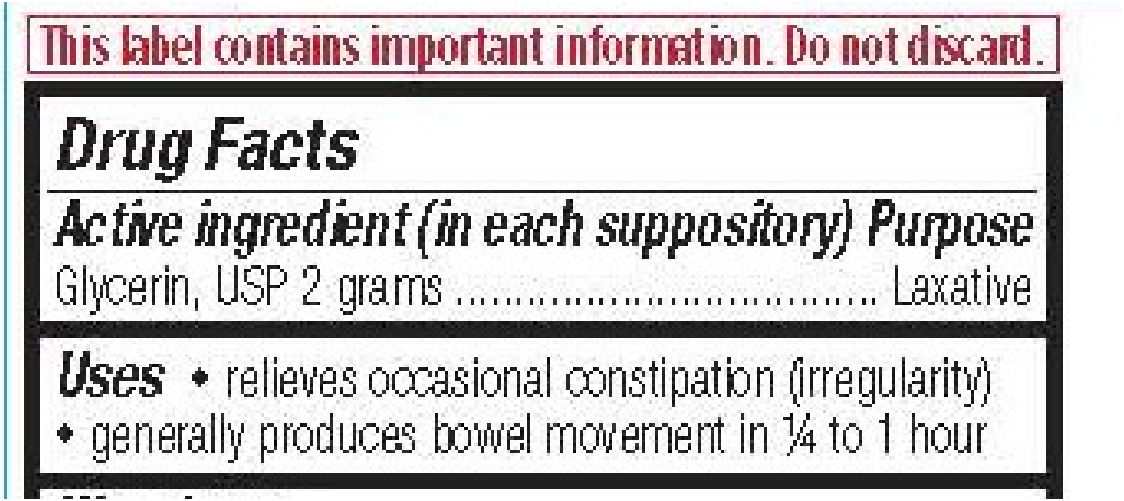


Case Study #4 – Mismatched Strength

- 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

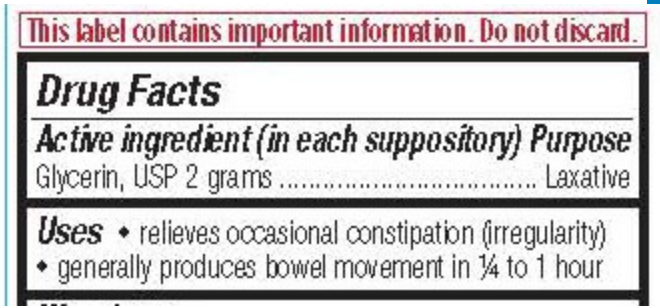
Active ingredient (in each suppository) Purpose

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: *	100	Unit of Measure: *	g
Type: *	Active Ingredient, Moiety is Basis of Strength		
Ingredient UNII - Name: *	(PDC6A3C0OX) GLYCERIN		
Strength: *	83	Unit Of Measure: *	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: cderdirect@fda.hhs.gov

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