

# Common Errors with Repackaged or Relabeled Drug Listings

Tasneem Hussain Pharm. D.  
FDA/OC/OU DLC/DRLB  
October 13, 2021



# Agenda

- Definitions
- Stats
- Regulations
- Common errors

# Definitions: Repack & Repacker

- **Repack or repack** means the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug
- **Repacker** means a person who owns or operates an establishment that repacks a drug or drug package. The term includes both domestic repackagers and foreign repackagers, unless otherwise specified
- 21 CFR 207.1



# Definitions: Relabel & Relabeler

- ***Relabel*** is defined as the act of changing the existing label or labels on a drug or drug package or changing or altering the existing labeling for a drug or drug package, without repacking the drug or drug package. The term does not include the addition or modification of information affixed solely for purposes of delivery to a customer, customer identification, and/or inventory management
- ***Relabeler means*** a person who owns or operates an establishment that relabels a drug
- See 21 CFR 207.1

# Definitions: Source Drug and NDC



- **Source NDC**- The NDC assigned to each drug received by the registrant for repackaging or relabeling, with the exception of medical gases. Each such NDC must be associated with the corresponding NDC(s) for repackaged or relabeled drugs... 21 CFR 207.53
- **Source Drug**- the original drug which is intended to be repackaged/repackaged or relabeled for commercial distribution.

# Stats

- We have ~ 1200 currently registered establishments with a business operation of repack and/or relabel
- We have ~ 63,600+ listing submissions by repackagers and/ or relabelers

# Regulations

- Section 510 of the Food, Drug, and Cosmetic Act -(FD&C) Act
- 21 CFR Part 207
- [eCFR :: 21 CFR Part 207 -- Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code](#)
- Registration requirements: 21 CFR 207.25 and 21 CFR 207.29
- Listing requirements: 21 CFR 207.53



# Common Errors

- Incorrect/ inappropriate use of application numbers
  - Kit is incorrectly assigned the same application # as the part of that kit
  - Discontinued application #s



# Common Errors I



**Marketing Information**



| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| NDA                | NDA012345                                |                      |                    |

**Labeler**

**Establishment**



# Common Errors II

| Mkt. Status  | Active Ingredient                                                                 | Proprietary Name                                                                  | Appl. No.      | Dose | Route | Strength |
|--------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------|------|-------|----------|
|              |                                                                                   |                                                                                   |                |      |       |          |
| <u>DISCN</u> |  |  | <u>N012345</u> |      |       |          |



# Common Errors III

- Incorrect usage of the source NDC
  - On the carton/ container label image or Principal Display Panel image (PDP)
    - Has the source NDC instead of the repackager's or relabeler's NDC
  - Under “How Supplied” section of the labeling
    - Has the source NDC instead of the repackager's or relabeler's NDC

# Common Errors IV

| Product Information     |             |                    |                        |
|-------------------------|-------------|--------------------|------------------------|
| Product Type            |             | Item Code (Source) | 11111-1111 (22222-222) |
| Route of Administration | INTRAVENOUS |                    |                        |

# Common Errors V

## HOW SUPPLIED

 (®  injection)

NDC 22222-222-02

carton containing 5 x 2 mL multiple-dose vials with 1% 20 mg/2 mL (10 mg/mL)

NDC 22222-223-02

carton containing 5 x 2 mL multiple-dose vials with 3% 60 mg/2 mL (30 mg/mL)

## STORAGE

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

# Common Errors VI

- Mismatched package quantity between the labeling and the listing SPL
  - Use of source drug's quantity in the labeling of the repackaged or relabeled drug
    - Label image has source drug's quantity
  - and SPL has repackager's or relabeler's quantity

# Common Errors VII

## Mismatched package quantity between labeling and SPL

NDC [REDACTED]

**Meloxicam  
Tablets, USP**

**15 mg**



Each tablet contains:  
Meloxicam, USP .....15 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature].

Keep in a dry place.

Dispense in a tight container.

**KEEP THIS AND ALL THE DRUGS  
OUT OF THE REACH OF CHILDREN.**

Code No.: HP/172/04

Manufactured by: [REDACTED]

Distributed by: [REDACTED]

2006285  
Rev.: 04/17

Attention Dispenser: Accompanying Medication Guide **MUST** be dispensed with this product

[REDACTED]

**500 TABLETS**  
Rx only

| Packaging    |                     |
|--------------|---------------------|
| #Item Code   | Package Description |
| 1 [REDACTED] | 60 in 1 BOTTLE; =   |

# Common Errors VIII

- Lack of updates after the source drug listing is updated
  - At a minimum twice yearly in June and December-same as all other registrants. See 21 CFR 207.57
  - “No Changes” certification SPL (Oct. 1 to Dec. 31)
- Some changes must be reflected immediately
  - Updated labeling: i.e., Black Box Warning







# Common Errors IX

- Updated SPL data elements: i.e., Marketing authorization
- Source drug discontinued
- Content of labeling section- Incomplete
  - Explained further under 21 CFR 207.1
  - Repackaged or relabeled prescription and OTC drugs' labeling must include the content of labeling -21 CFR 207.53(d)(1)(2)

# Common Errors X

**GABAPENTIN** gabapentin capsule

**HOW SUPPLIED**  
 300 mg Capsules (Yellow/Yellow colored, size "T" hard gelatin capsules with "104" printed on body of capsules containing white to off white granular powder Bottles of [redacted]  
 Bottles of [redacted]  
 Bottles of [redacted]  
 Bottles of [redacted]  
 Bottles of [redacted]  
 Bottles of [redacted]  
 Bottles of [redacted]

**300mg Gabapentin Capsule Package Label**

Take every 6 hours

Each capsule contains:  
 Gabapentin, USP 300mg

Oblong Yellow Capsule Printed:  
 "104" on the body

Product # [redacted]  
**Rx Only**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**WARNING: KEEP OUT OF REACH OF CHILDREN**

**STORE AT CONTROLLED TEMPERATURE 59-86°F.**

**GABAPENTIN**  
 gabapentin capsule

**Product Information**  
 Product Type: [redacted] NDC Code Source: [redacted]  
 Name of Administration: [redacted]

**Active Ingredient/Active Moiety:**

# Common Errors XI

- Inappropriate proprietary name usage for the repackaged or relabeled drug
  - Medication errors and safety concerns
- Mismatched information in carton or container labeling
  - Medication errors and safety concerns



# Useful Resources

- [Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry | FDA](#)
- [Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products; Draft Guidance for Industry | FDA](#)
- [Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors | FDA](#)
- [Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry | FDA](#)

# Summary

- Read and understand the regulations and requirements for repackagers and relabelers
- Train staff and maintain up-to-date internal SOPs
- Follow up with necessary updates
- Avoid FDA enforcement actions



# Closing Thought

Taking a little extra time, the first time,  
will save us all time.... later



# Questions?

Thank You

[edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

# Thank You!

