

Common Errors with Repackaged or Relabeled Drug Listings

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Agenda

- Definitions
- Stats
- Regulations
- Common errors

Definitions: Repack & Repacker



- **Repack or repackage** 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 repacking or relabeling, with the exception of medical gases. Each such NDC must be associated with the corresponding NDC(s) for repacked 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

Marketing Information

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

Labeler

Establishment

Common Errors

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Do s a g e F o r m	Route	Strengt h
<u>DISCN</u>	<div data-bbox="562 740 813 907" data-label="Text"> <p>[REDACTED] M [REDACTED] HYDROCHLOR</p> </div>	[REDACTED]	<u>N012345</u>			

Common Errors

- 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



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

Common Errors

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

- 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

Mismatched package quantity between labeling and SPL

NDC



Meloxicam Tablets, USP

15 mg


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

500 TABLETS
Rx only

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]

2009/2015
Rev.: 04/17

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

Common Errors

- 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

- 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)

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Common Errors

- 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





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ADMINISTRATION

Questions?

Thank You

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