# Case Studies

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# Learning Objectives

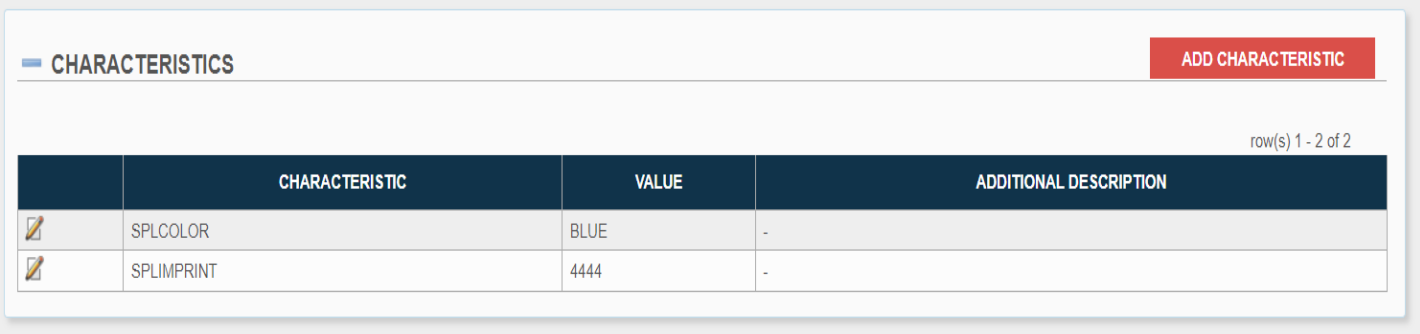
- Examine different cases to identify common listing errors
- Explain when a repackaged drug's NDC must change

# Case Study #1

- Wonder Pharma is repackaging ibuprofen 800 mg tablet, NDC 55555-001-01 into 10 count blister packs
- Wonder Pharma has been sourcing ibuprofen from Amazing Pharma (Source NDC 0012-4444)
- Wonder Pharma switches supplier to Fabulous Pharma (Source NDC 0014-6666)
- How should Wonder Pharma update its listing?

# Case Study #1

- Under § 207.35(b)(6)
  - The proposed new NDC must include a new product code when there is a change to any of the following information
    - The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any)



# Case Study #1

- If the new contract manufacturer's ibuprofen differs in any of the above characteristics
  - Wonder Pharma must 'COMPLETE' the marketing status of their current listing
  - Enter a 'MARKETING END DATE' corresponding to the expiration date of the last lot repackaged from the previous source drug
  - Wonder must create a new listing and assign a new NDC

# Case Study #1

- If the new contract manufacturer will make the ibuprofen to match the characteristics of the old source drug
  - Wonder Pharma must remove the establishment manufacturing the previous source drug
  - Add the new establishment manufacturing the new source drug
  - Wonder Pharma may retain the same NDC, however we strongly recommend assigning a new NDC to maintain accurate and up-to-date listing data

# Case Study #2

**HOW SUPPLIED**

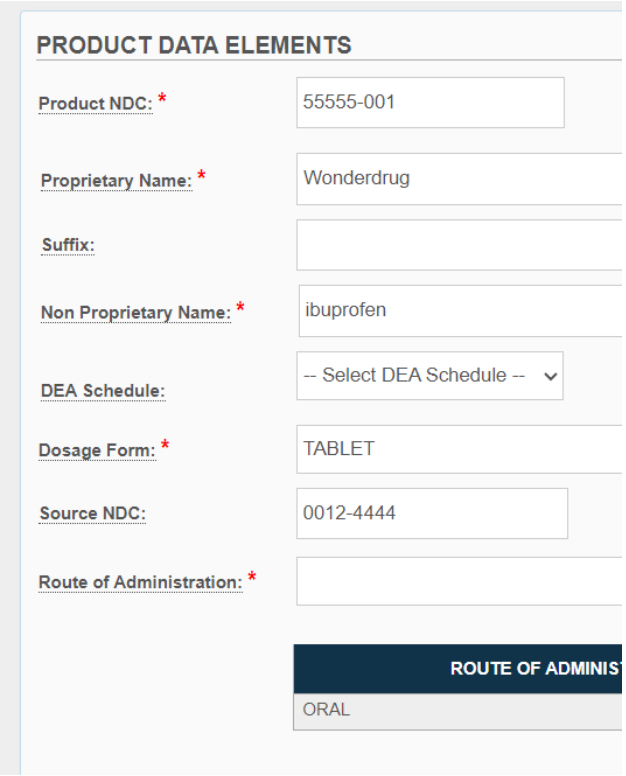
Ibuprofen 800 mg (blue, capsule shaped, film-coated tablets engraved 4444 on one side)

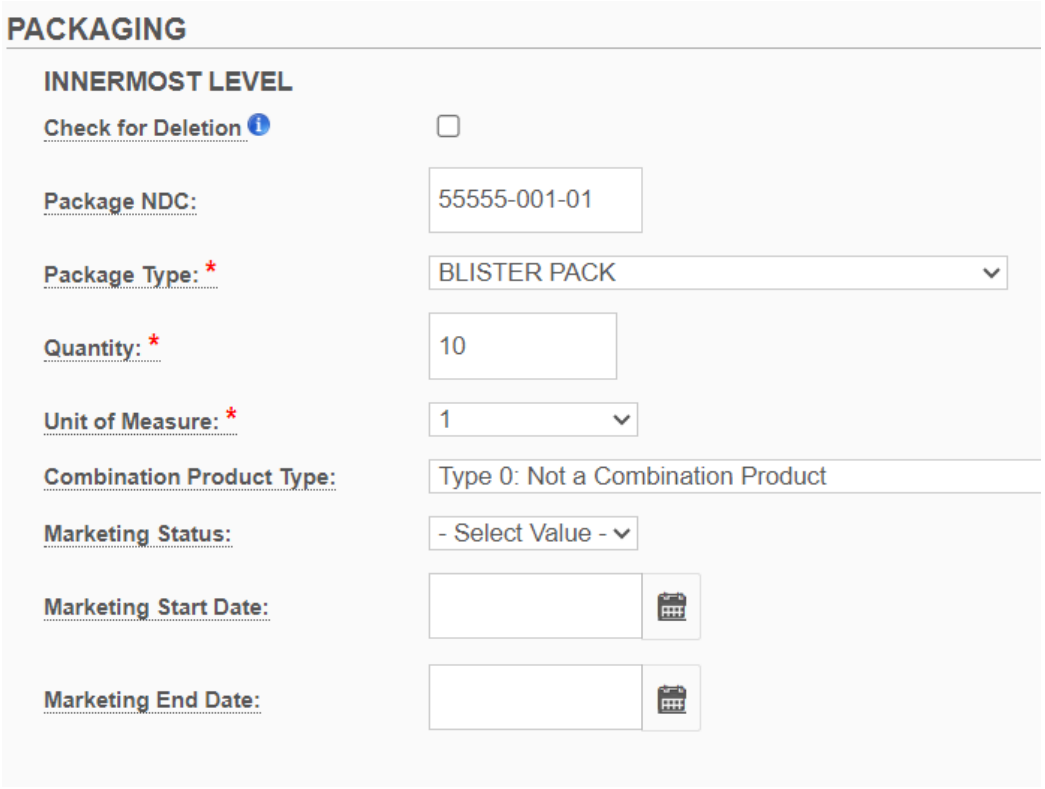
NDC 0012-4444-01 BOTTLES OF 1000

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

Rx only

# Case Study #2


PRODUCT DATA ELEMENTS
Product NDC: *
55555-001
Proprietary Name: *
Wonderdrug
Suffix:
Non Proprietary Name: *
ibuprofen
DEA Schedule:
-- Select DEA Schedule --
Dosage Form: *
TABLET
Source NDC:
0012-4444
Route of Administration: *
ROUTE OF ADMINIS
ORAL


PACKAGING
INNERMOST LEVEL
Check for Deletion
Package NDC:
55555-001-01
Package Type: *
BLISTER PACK
Quantity: *
10
Unit of Measure: *
1
Combination Product Type:
Type 0: Not a Combination Product
Marketing Status:
- Select Value -
Marketing Start Date:
Marketing End Date:

# Case Study #2

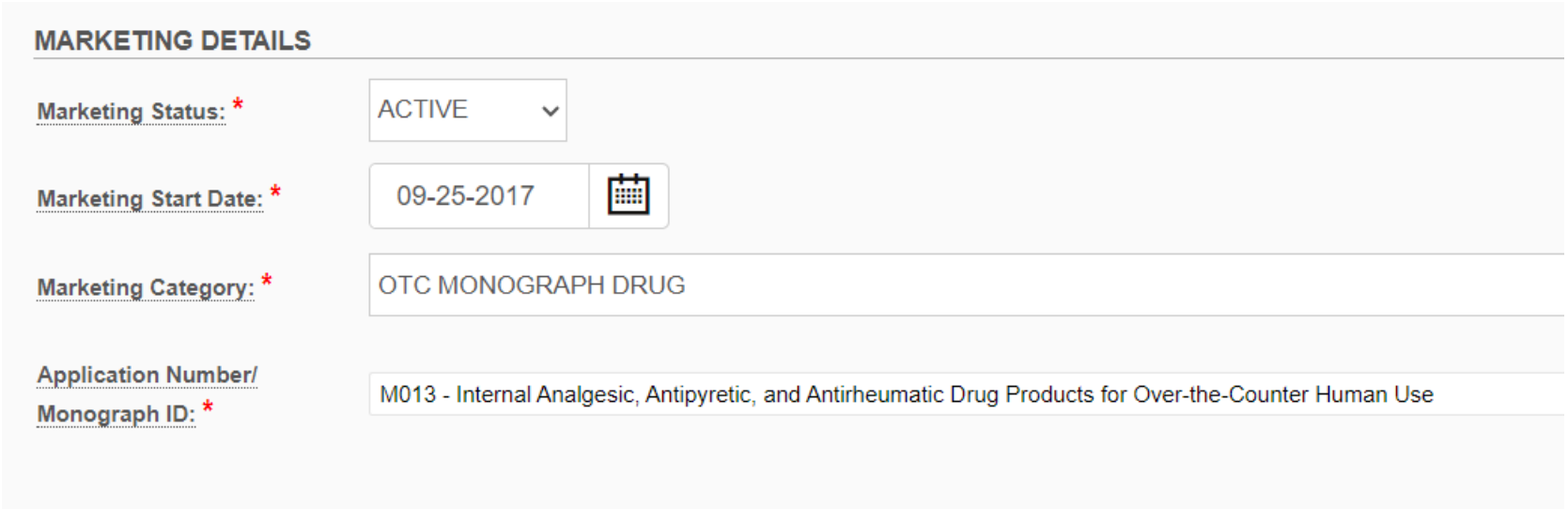
- How Supplied section cites the NDC and bottle size of the source drug (0012-4444-01, bottles of 1000)
  - Repackaged drug is 10 count blister pack
  - Most likely the entire content of labeling was copy and pasted from source drug
- NDC mismatch and package error exist in How Supplied section vs. SPL
- Repackager's NDC must be reflected in SPL, entire content of labeling including how supplied section and principal display panel

# Case Study #3

- Marketing category must reflect authority to market drug product in the U.S.
  - Application (NDA/ANDA/BLA)
  - OTC Monograph/Administrative Order
  - Unapproved
    - Homeopathic, etc.

# Case Study #3

## Ibuprofen 800 mg

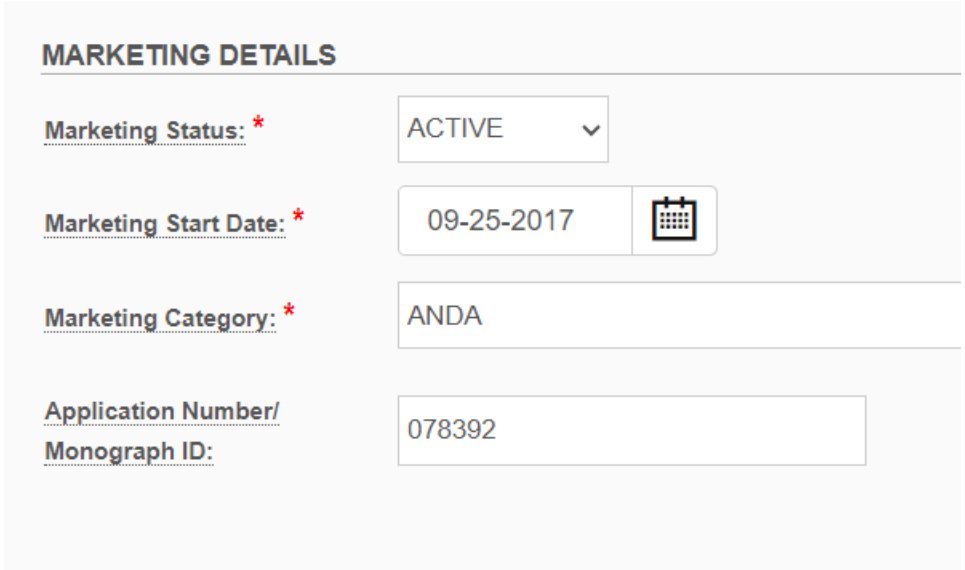


# Case Study #3

- OTC Monograph M013
  - Ibuprofen 800 mg is not cited in OTC Monograph
  - 800 mg is not OTC Monograph and ANDA must be cited

# Case Study #3

- ANDA 078392 - Is there an error?



# Case Study #3

- ANDA 078392 is for granisetron
- ANDA 078329 is correct ANDA for ibuprofen 800 mg
  - Transcription error (as above)
  - Random application numbers
  - Application number cited where firm does not have the right of reference

# Case Study #3

- Common marketing errors
  - Incorrect application number
  - Unauthorized use of application number
  - Incorrect OTC monograph
  - OTC monograph citation not updated
- All the above errors misbrands the drug product and subjects the listing for further compliance action

# Summary

- Changes in the source drug require drug listing updates and may require a new NDC
- Repackaged drug listing must reflect repackager's NDC, package size, and description, not just in the SPL, but also the entire content of labeling
- Marketing category must be an accurate reflection of a drug's authority to market drug products in the U.S.

# Questions?

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