

The logo features a stylized blue icon on the left, composed of overlapping shapes that resemble a map of North America or a similar geographical outline. To the right of the icon, the word "PERRIGO" is written in a bold, blue, italicized sans-serif font. The entire logo has a slight drop shadow effect.

**PERRIGO**

## Experience with NDC Numbers

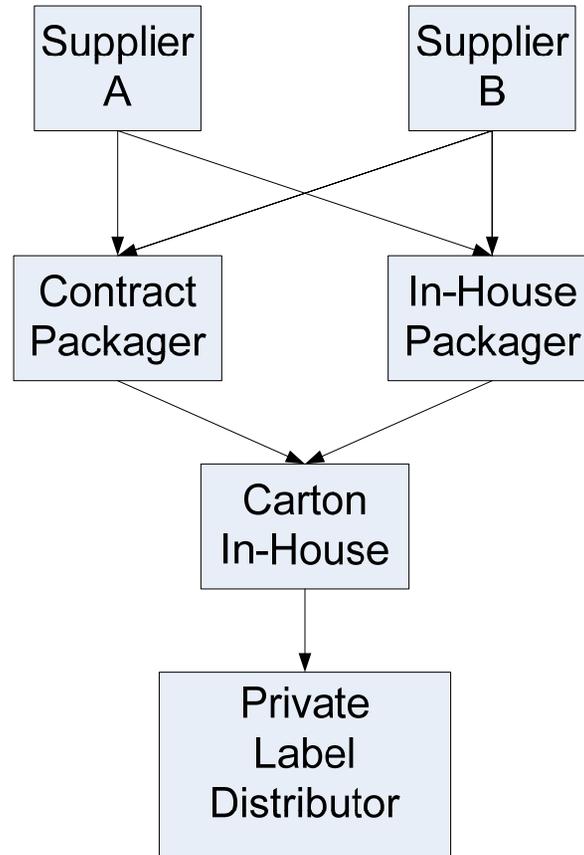
- Manufacturer
- Packager/ Repackager
- Labeler/ Relabeler
- Distributor
- Private Label Distributors
- Trained by the FDA
- Participated in e-drug listing pilot program
- List with FDA on a quarterly basis
- ~ 7000 active NDC numbers

## Complexity

### Factors that Change NDC Numbers Today

- Acquisitions
- Changes in signature lines
- Product reformulations that involve active ingredient changes
- Private Label Distributor changes vendor

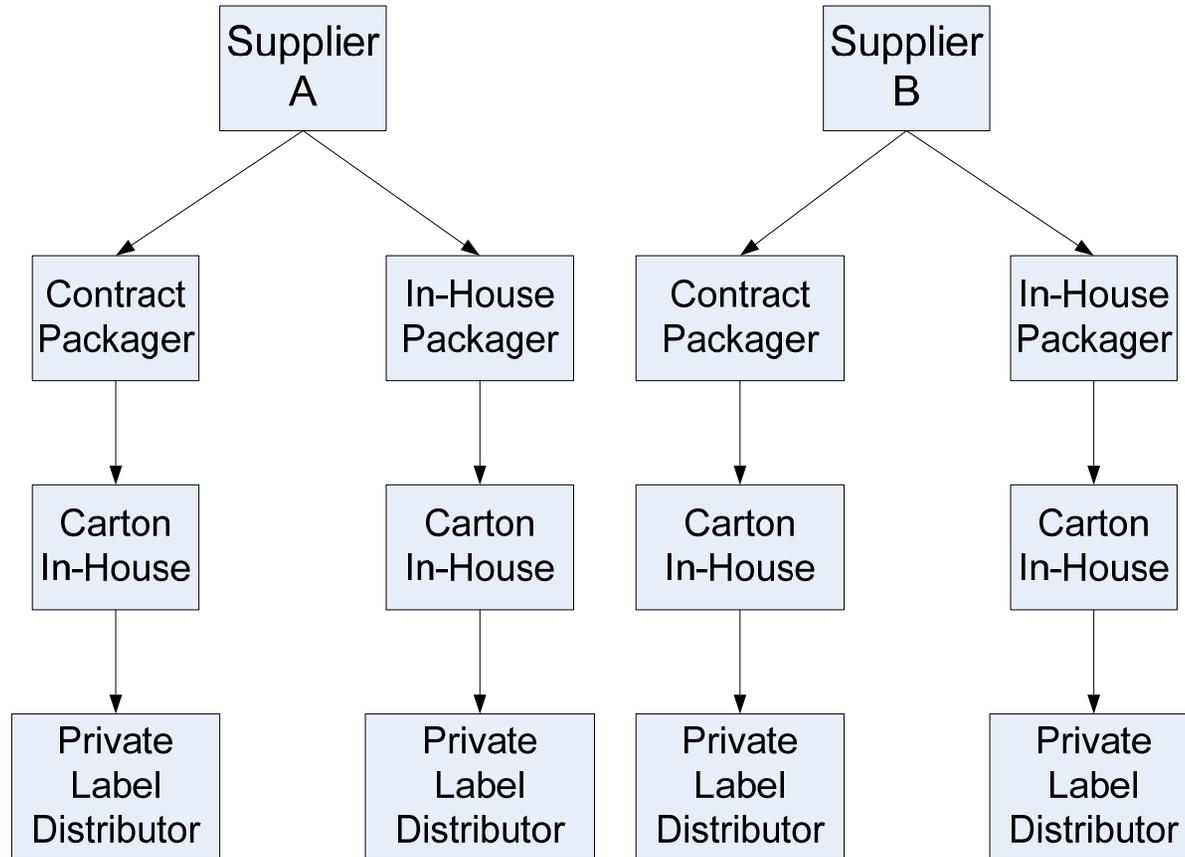
# Supply Chain Scenario Present Day Example



## **Added Complexities of the Proposed Rule Additional Factors That Will Change NDC Numbers**

- Change in inactive ingredients
- Change in manufacturers
- Change in contract packagers

# Supply Chain Scenario Proposed Rule Example



## Impact of Added Complexity

### An Average Product: 30 Customers, 3 Size Codes/Customer

#### Current Process:

- 90 NDC numbers to manage
- Infrequent NDC changes
- One label/size/PLD
- Able to react to product supply needs to prevent retail shortages
- \$90K/ label conversion

#### Proposed Process:

- 360 NDC numbers to manage
- Increase in frequency of changing NDC numbers
- Multiple labels/size/PLD
- Unable to react to product supply needs resulting in retail shortages
- \$360K/label conversion

# RESULT

Volume + Complexity =  
Increase in Possibility of Errors

# Recommendations

- Maintain the current rules for assigning NDC numbers
- Remove the ability for Private Label Distributors to assign NDC numbers and drug list
- Implement the electronic drug listing
- Invest in education regarding current requirements
  - Offer FDA led classes
  - Guidance documents