

December 11, 2006

# The Proposed Changes to NDC System

Legacy NDC Numbers and Compliance

Dr. Thomas F. Willer  
Director  
Global Regulatory Affairs



# The National Drug Code

- National Drug Code (NDC) numbers are one of the lynchpins of the healthcare system
- NDC numbers are used throughout the drug supply chain
- Users extend from pharmaceutical firms, distribution system, medical community, insurance industry, and government

# Current NDC Regulations

- 21 CFR § 207.35
  - New NDC numbers have three components:
    - Labeler Code: “...the manufacturer or distributor...”
    - Product Code: “...segment that identifies the drug formulation...”
    - Package Code: “...segment that identifies the trade package size and type...”
  - Labeler code is assigned by FDA, with
  - Product and Packaging codes assigned by manufacturer.

# Proposed NDC Rule

- Universal standard format
- Drug industry requests new NDC numbers
- FDA assigns new NDC numbers
- Current NDC numbers remain unchanged provided that those NDC numbers comply with the new rule when finalized
- Non-compliant NDC numbers will be reassigned by FDA

## Impact: Changing NDC Numbers

- The current NDC numbers identify products that are already in the drug chain
- Existing NDC numbers may have been in the system for decades and accepted by users

## Impact: Legacy NDC Numbers

Requiring revised NDC codes has significant issues:

- Industry or the FDA could potentially have to recode thousands of existing products
- Added characteristic to the Proposed NDC Rule:
  - New, additional, individual NDC codes for additional levels of packaging:
    - Unit (already exists)
    - Carton (proposed)
    - Corrugate / shipper (proposed)

## Impact of Any Significant Conversion from Existing NDC Numbers

- Potential interruption of drug supply
- Increased cost to healthcare consumers due to shifting of economic burden
- Industry-government-supply chain costs of maintaining two NDC number systems until “old” numbers pass drug expiration periods
- Impact on DEA products not addressed in Proposed Rule
- Increased operational costs due to NDC number reconciliation
- Millions of dollars in relabeling



# Proposed NDC Rule

- Clarifications needed:
  - What will be considered a “Compliant” NDC number?
  - How will the 3 year and 9 month implementation period be administered?
  - What is considered a unique package code?
  - Has FDA identified its resources to be able to manage a massive NDC number allocation system?

# Points for Consideration

- The desire for the government to change legacy NDC numbers is not obvious
- Legacy NDC numbers currently meet market and gov't. needs
- If change is desired, the implementation period should be extended from 3 to 5 years
- The FDA allocation of NDC numbers must be performed in an expeditious, and known, time period after a request is made
- There must be confidentiality of NDC requests prior to NDA or ANDA product approvals



# ISSUES: Companies, Consumers, Regulators

- New bar codes
- Bar code reader reprogramming
- Mergers and Acquisitions
- Timetable to Compliance
- New system learning curve
- Finite pool of NDC numbers
- Confidentiality
- Timeliness

Thank You

