

NDC Assignment to Drugs

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Learning Objectives



- Explain assignment of NDCs to drugs
- Describe the history of the NDC
- Describe NDC change requirements and restrictions



What is NDC?



- NDC is a 10-digit identifier for drugs in the U.S.
- Consists of three segments
- Separated by hyphens
- Three Segments of the NDC
 - Labeler Code
 - Product Code
 - Package Code



How are NDCs assigned?



- Registrant proposes an NDC for a drug at the time of drug listing submission to FDA
- FDA assigns the proposed NDC
- NDCs are assigned to drugs only
 - No dietary supplement
 - No medical food
 - No medical device

History of NDC



- 1969- NDC voluntary reporting
- 1972- Drug Listing Act
- 1996- HIPPA Implementation
- 2016- New registration and listing rule went into effect

NDC Change Requirements



- Product code:
 - A change in drug's established name or proprietary name, if any
 - A change in active ingredient or strength
 - A change in dosage form
 - A change in drug status
 - A change in drug's intended use
 - Any changes to the drug's distinguishing characteristics
- Package code:
 - A change to a package size or type

NDC Restrictions



- NDC cannot be reused for a different drug, even after a product is disconnected
- Using NDC may cause the product to be misbranded
 - If used to represent a different drug
 - If used for non-drugs such as medical devices
- If a previously discontinued drug resumes marketing, the same NDC should be assigned

Legal Conformance



- Assignment of an NDC does not denote approval of the drug, nor does it mean that the drug may be legally marketed
- Any representation that creates the impression that a drug is approved or is legally marketable (21 CFR 207.77(a)(b))

NDC and Drug Labeling



- Printing NDC in a human readable format on drug container label is not required but strongly encouraged
 - Human prescription drugs
 - How Supplied/Storage and Handling section of the PI
 - NDCs for the units/package sizes
 - Human OTC drugs
 - Appropriate NDC on the container label and carton labeling

NDC and Drug Approval Process



- NDC is not part of labeling approval during drug approval process
- To remediate any issue:
 - Applicants can reserve an NDC
 - Direct any NDC questions to eDRLS@fda.hhs.gov

Co-Packaged Products



- When at least one drug is co-packaged with other drugs or non-drug articles
- NDC assignment:
 - NDC proposed to the co-packaged product should be different than NDC proposed for each drug part
 - Non-drug parts should not include an NDC

Multi-Level Packaged Drugs



- Multilevel package includes different levels of packaging for one drug
 - Carton containing a blister pack or multiple vials
 - Assign a different package code to each level of packaging
 - Packaging levels of a drug should be provided in drug listing SPL

Challenge Question # 1

Which of the following can be assigned an NDC?

- A. OTC drug
- B. Medical device
- C. Human prescription drug
- D. Dietary supplement
- E. A & C

Challenge Question # 2

NDC proposed to the co-packaged product should be different than NDC proposed for each drug part

- A. True
- B. False

Summary



- NDC assignment is a separate process from the drug approval process
- Registrant proposes an NDC for a drug at the time of drug listing submission and FDA assigns the proposed NDC
- Printing NDC in a human readable format on drug container label is strongly encouraged
- Regardless of an NDC inclusion on a drug label or not, all drugs that must be listed with FDA, must be assigned an NDC

Questions



