Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA inputs the full NDC number and the information submitted as part of the listing process into a database known as the Drug Registration and Listing System (DRLS).

Several times a year, FDA extracts some of the information from the DRLS data base (currently, properly listed marketed prescription drug products and insulin) and publishes that information in the NDC Directory. The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution.

The current edition of the NDC Directory is limited to prescription drugs and insulin products that have been manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution. The products have been listed in accordance with the Drug Listing Act and regulatory provisions concerning the submission of drug product information to FDA.

There are a number of reasons why a drug product may not appear in the NDC Directory, such as:

- the product may not be a prescription drug or an insulin product
- the firm has notified the FDA that the product is no longer being marketed;
- the firm has not complied fully with its listing obligations and therefore its product is not included until complete information is provided.

How is the NDC Directory Organized?

1. Product Trade Name or Catalog Name

The product names used in the NDC Directory are generally supplied by the manufacturer (also called “labelers” or “firms” for purposes of listing) as required under the Act. All product names appearing in the NDC Directory are limited to a maximum of 100 characters. Minor editorial changes were made in some cases when information normally included with the name appears elsewhere in the product description. For example, where strength is ordinarily listed as a component of the product name, but also appears in other data fields, the strength may

have been removed from the product name. The designations, "United States Pharmacopeia" (USP) or "National Formulary" (NF) may also have been deleted from product names. But the terms "not NF" and "not USP" may have been left as part of the name. Symbols indicating trademarked or registered products also are omitted because of computer input capabilities. But these deletions are not intended to contradict patent, trademark, registration, or copyright laws or regulations.

2. NDC Number

Each listed drug product listed is assigned a unique 10-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes and types. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

An asterisk may appear in either a product code or a package code. It simply acts as a place holder and indicates the configuration of the NDC. Since the NDC is limited to 10 digits, a firm with a 5 digit labeler code must choose between a 3 digit product code and 2 digit package code, or a 4 digit product code and 1 digit package code.

Thus, you have either a 5-4-1 or a 5-3-2 configuration for the three segments of the NDC. Because of a conflict with the HIPAA standard of an 11 digit NDC, many programs will pad the product code or package code segments of the NDC with a leading zero instead of the asterisk.

Since a zero can be a valid digit in the NDC, this can lead to confusion when trying to reconstitute the NDC back to its FDA standard. Example: 12345-0678-09 (11 digits) could be 12345-678-09 or 12345-0678-9 depending on the firm's configuration. By storing the segments as character data and using the * as place holders we eliminate the confusion. In the example, FDA stores the segments as 12345-*678-09 for a 5-3-2 configuration or 12345-0678-*9 for a 5-4-1 configuration.

3. Dosage Form

The complete list of dosage form codes are listed in a downloadable file.

4. Routes of Administration
The complete list of codes for routes of administration are listed below in the downloadable file TBLROUTE.TXT.

5. Active Ingredient(s)
The active ingredients are listed in a separate file FORMULAT.TXT which is linked to LISTINGS.TXT via the LISTINGS_SEQ_NO field in each file.

6. Strength
The drug strength is indicated after the active ingredient. For those products with equivalent ingredients, the strength expressed is that of the equivalent. For some combination products, the strength is that which is commonly recognized for that formulation. The product itself also has a strength/unit. For products with a single active ingredient, the indicated strength is the strength of that active ingredient. For multiple active ingredient products, the strength is either "COMBO" or a concatenation of the multiple strengths.

7. Unit
The complete list of abbreviations for units and their definitions are in TBLUNIT.TXT.

8. Package Size and Type
The package size and types appear in the NDC Directory as reported by the firm.

9. Major Drug Class
The Major and Minor Drug Class codes are no longer available at this site. FDA plans to review the use of the AMA DRUG Evaluation Subscription classification scheme. This review is necessary because this classification scheme has not been updated since 1976 and therefore many new molecular entities are not included.

10. FDA approved application number
A number in this field is the NDA/ANDA number, which signifies that this product has been approved by FDA for marketing based upon a review of the safety and effectiveness of the drug, including review of 1) whether adequate and well-controlled investigations show that this drug is safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling; 2) the methods used in, and the facilities and controls used for, the

manufacture, processing, and packing of this drug and whether they adequately preserve the drug's identity, strength, quality, and purity; and 3) the drug's proposed labeling. For additional information regarding NDA and ANDA approval, see section 505 of the Act, 21 U.S.C. § 355. The FDA Orange Book (http://www.fda.gov/cder/orange) has additional information on drug products and application holders, which can be accessed using the NDA/ANDA number.

'OTHER' in this field signifies that this product may not be approved for both safety and efficacy under an NDA or ANDA, may be subject to the Drug Efficacy Study Implementation (DESI), and/or may be one for which FDA currently lacks sufficient data to provide information. DESI is a retrospective evaluation of the efficacy of drugs that had been approved on safety grounds alone between 1938 and 1962, and drugs identical, related, or similar to those drugs. This evaluation was necessitated by the 1962 amendments to the FD&C Act, which added the requirement that a drug be evaluated for efficacy, not only for safety, for FDA approval.

For further information about **NDC**, please visit their website .