

http://www.fda.gov/Drugs/InformationOnDrugs/ucm142454.htm

Go

OCT NOV

45 captures 8 Jun 09 - 10 Dec 12

2009

2010

U.S. Food and Drug Administration

Home > Drugs > Drug Approvals and Databases

Drugs

National Drug Code Directory Support Files

The Internet NDC Directory contains the following information, which is updated at least monthly:

Files can be imported into most databases using ASCII file import. The filenames below are not linked. All of the files are found within the zip compressed file, [ZIPTEXT.ZIP1]

National Drug Code Directory Support Files

Filename Description

tbldosag.txt The Directory contains 3 tables that list descriptors and codes describing

tblroute.txt the data. They are:

thlunit.txt Dosage Forms, Routes of administration, and Unit Codes.

National Drug Code Directory ASCII Data Files

The 11 data files contain the product and firm data. The files have one or both linking elements:

LISTING_SEQ_NO NOT NULL NUM(7)

FDA generated unique identification number for each product. Only used in information systems to link tables together; not used publicly.

LBLCODE NOT NULL NUM(7)

FDA generated identification number for each firm. Used as the first segment in the NDC and can be used to link tables together basec on Firm.

Filename Description

1. LISTINGS DATA [LISTINGS.TXT]

EACH PRODUCT HAS A UNIQUE LISTING SEQ NO; EACH FIRM SEQ NO CAN HAVE MULTIPLE LISTING SEQ NO'S. Each line in this file represents a product for an individual firm. The listing includes such information as the product's name, firm's seq number, dose form(s), and Rx/OTC.

LISTING_SEQ_NO NOT NULL NUM(7) COL: 1-7

FDA generated unique identification number for each product.

NOT NULL CHAR(6) COL: 9-14

Labeler code portion of NDC; assigned by FDA to firm. The labeler code is the first segment of the National Drug Code. While always displayed as 6 digits in this file; for labeler codes 2 through 9999, some systems display it as 4 digits; for labeler codes 10,000 through 99,999 it is 5 digits. Can be used to link to the FIRMS.TXT file to obtain firm name.

PRODCODE NOT NULL CHAR(4) COL: 16-19

Product code assigned by firm. The produce is the second segment of the National Drug Code. It may be a 3-digit or 4-digit code depending upon the NDC configuration selected by the firm.

STRENGTH NULL CHAR(10) COL: 21-30

For single entity products, this is the potency of the active ingredient. For combination products, it may be null or a number or combination of numbers, e.g., Inderide 40/25.

UNIT NULL CHAR(10) COL: 32-41

Unit of measure corresponding to strength. This non-mandatory field contains the unit code for a single entity product, e.g., MG, %VV.

RX OTC NOT NULL CHAR(1) COL: 43

Indicates whether product is labeled for Rx or OTC use (R/O).

TRADENAME NOT NULL CHAR(100) COL: 45-144 Product's name as it appears on the labeling.

2. PACKAGES DATA [PACKAGES.TXT]

MAY OCCUR MULTIPLE TIMES PER LISTING SEQ NO

Stores packages for an individual listing. The packages table includes all packages for a corresponding listing. The PKGCODE field contains the last one or two digit segment of the NDC.

LISTING SEO NO NOT NULL NUM(7) COL: 1-7

Linking field to LISTINGS.

PKGCODE NULL CHAR(2) COL: 9-10

The package code portion of NDC code. The package code is the last segment of the NDC.

PACKSIZE NOT NULL CHAR(25) COL: 12-36

The unit or number of units which make up a package.

PACKTYPE NOT NULL CHAR(25) COL: 38-62 Package type, i.e., box, bottle, vial, plastic, or glass.

[FORMULAT.TXT]

3. FORMULATIONS DATA MAY OCCUR MULTIPLE TIMES PER LISTING SEQ NO.

Lists active ingredients contained in product's formulation.

LISTING SEQ NO NOT NULL NUM(7) COL: 1-7

Linking field to LISTINGS.

STRENGTH NULL CHAR(10) COL: 9-18 This is the potency of the active ingredient.

UNIT NULL CHAR(5) COL: 20-24

Unit of measure corresponding to strength.

INGREDIENT NAME NOT NULL CHAR(100) COL: 26-125 Truncated preferred term for the active ingredient. MAY OCCUR MORE THAN ONCE PER LISTING SEQ NO.

4. NEW DRUG APPLICATION DATA [APPLICAT.TXT]

LISTING SEO NO NOT NULL NUM(7) COL:1-7 Linking field to LISTINGS.

APPL NO NULL CHAR(6) COL:9-14

Number of New Drug Application if applicable. If none has been provided by the firm then the value 'Other' i

used.

PROD NO NULL CHAR(3) COL:16-18

Number used to identify the products of a New Drug Application.

5. FIRM NAME DATA [FIRMS.TXT]

EACH FIRM HAS A UNIQUE FIRM SEQ NO WHICH CAN OCCUR MULTIPLE TIMES IN THE LISTINGS FILE.

Contains the firm's full name, and compliance address. The compliance address is the mailing address where

the FDA sends listing information to the firm.

LBLCODE NOT NULL NUM(6) COL:1-6

FDA generated identification number for each firm. The number is padded to the left with zeroes to fill out to

length 6.

FIRM NAME NOT NULL CHAR(65) COL:8-72

Firm name as reported by the firm.

ADDR HEADER NULL CHAR(40) COL:74-113 Address Heading as reported by the firm. STREET NULL CHAR(40) COL:115-154 Street Address as reported by firm.

PO_BOX NULL CHAR(9) COL:156-164 Post office box number as reported by firm. FOREIGN ADDR NULL CHAR(40) COL:166-205

Address information report by firm for foreign countries that does not fit the U.S. Postal service

configuration.

CITY NULL CHAR(30) COL:207-236 STATE NULL CHAR(2) COL:238-239 ZIP NULL CHAR(9) COL:241-249

USPS Zip code.

PROVINCE NULL CHAR(30) COL:251-280 Province of Foreign country if appropriate.

COUNTRY NAME NOT NULL CHAR(40) COL:282-321

6. ROUTE OF

LISTING SEQ NO NOT NULL NUM(7) COL:1-7

ADMINISTRATION DATA

Linking field to LISTINGS.

[ROUTES.TXT]

ROUTE_CODE NULL CHAR(3) COL:9-11

The code for the route of administration. File will allow all assigned values for this element.

ROUTE_NAME NULL CHAR(240) COL:13-252 The translation for the route of administration code. MAY OCCUR MULTIPLE TIMES PER LISTING SEO NO.

7. DOSAGE FORM [DOSEFORM.TXT]

LISTING SEQ NO NOT NULL NUM(7) COL:1-7

Linking field to LISTINGS.

DOSEFORM NULL CHAR(3) COL:9-11

The code for the route of administration. File will allow all assigned values for this element.

DOSAGE NAME NULL CHAR(240) COL:13-252 The translation for the route of administration code.

8. TBLDOSAG.TXT

THIS FILE CONTAINS A COMPLETE LIST OF THE DOSAGEFORM CODES USED IN THE DIRECTORY

DOSEFORM CHAR(3) COL:1-3 The code for the dosage form.

TRANSLATION CHAR(100) COL:5-104

The translation for the DOSAGE FORM code.

9. TBLROUTE.TXT

THIS FILE CONTAINS A COMPLETE LIST OF THE ROUTE CODES USED IN THE DIRECTORY

ROUTE CHAR(3) COL:1-3

The code for the ROUTE OF ADMINISTRATION.

TRANSLATION CHAR(100) COL:5-104 The translation for the ROUTE code.

10. TBLUNIT.txt

THIS FILE CONTAINS A COMPLETE LIST OF THE POTENCY UNIT ABBREVIATIONS USED IN THE DIRECTORY.

UNIT CHAR(15) COL:1-15

The potency unit abbreviations used in the directory.

TRANSLATION CHAR(100) COL:17-115
The translation for the UNIT abbreviations.

11. REG_SITES.txt

This file contains a list of all currently active and registered domestic manufacturing facilities. **UNLIKE THE FILES ABOVE, IT IS A TAB DELIMITED FILE, WITH THE FIRST LINE CONTAINING THE COLUMN HEADERS**. The data elements are:

FEI: FDA Establishment Identifier. The unique ID number for each site.

LAST_REG_YEAR: Last year the annual registration obligation was fulfilled. Some older, inactive sites may be an the list. The records need to be undeted by the firm and/or EDA

on the list. The records need to be updated by the firm and/or FDA.

NAME: Registered firm name STREET: street address CITY: name of city STATE: name of state

ISO_COUNTRY_CODE: identifies the country.

12. SCHEDULE.txt

This file identifies those listed products in the directory which have a DEA schedule designation.

LISTING_SEQ_NO NOT NULL NUM(7) COL:1-7 Linking field to LISTINGS.

SCHEDULE NOT NULL NUM(1) COL:9

13. ZIPPED NDC DIRECTORY DATA The 7 NDC text data files and 3 tables zipped into 1 file. (Approximately 68 Megabytes in self extracting file)

[ZIPTEXT.ZIP²] 4.2 MB

Links on this page:

- 1. /web/20101112214144/http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM070838.zip
- 2. /web/20101112214144/http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM070838.zip