

FEDERAL HEALTH ARCHITECTURE PROGRAM



Federal Medication Terminologies (FMT) Enabling Health IT Interoperability



Topics

- Goal
- Background
- Components
- Accessibility
- Collaboration
- Summary

Goal

- *To make available comprehensive, freely and easily accessible standard medication terminologies to enable Health IT interoperability*
- *To facilitate federal interagency collaboration in order to provide:*
 - *Access to common language for communicating medication information*
 - *Processes for maintaining terminologies*
 - *Infrastructure for sharing that information*
 - *Identification of initial terminology components endorsed through Consolidated Health Informatics (CHI) and further development efforts to increase robustness of FMT*



U.S. Department of Health
and Human Services



U.S. Food and Drug Administration



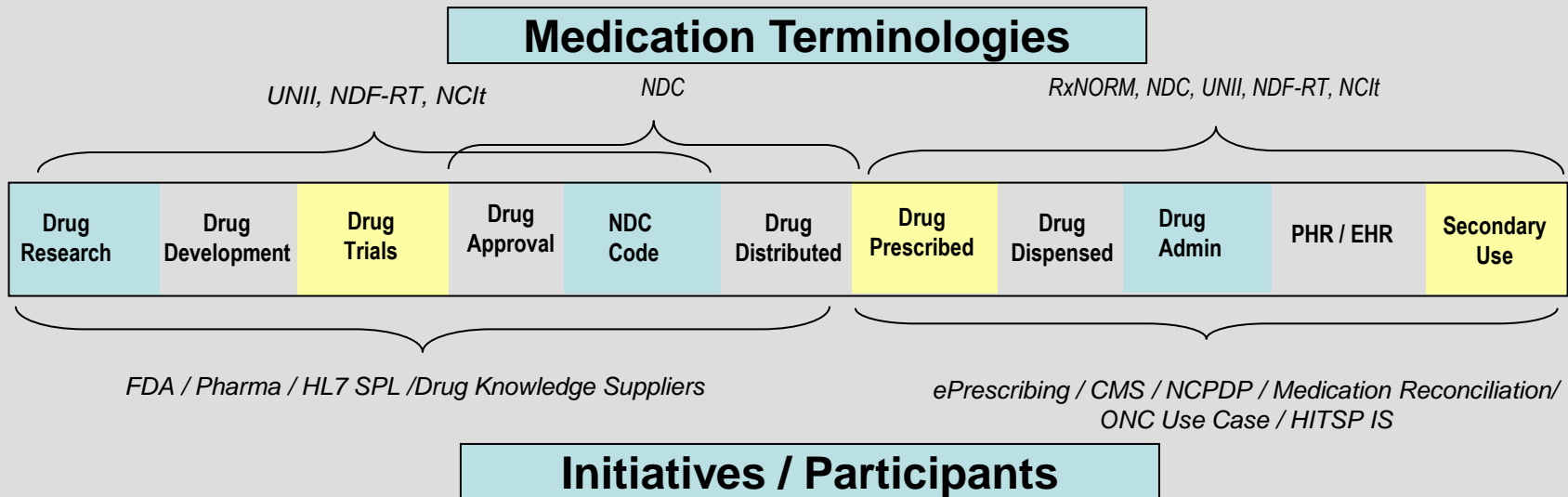


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Background

- Consolidated Health Informatics (CHI) 2003-2006
 - National Committee on Vital and Health Statistics (NCVHS) / CHI endorsed selection of medication standards <http://www.hhs.gov/healthit/chiinitiative.html>
 - Drug code, semantic clinical drug, classifications, ingredients, units
- Need for standardization of medication terminology





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Component Vocabulary Systems

- Food and Drug Administration



U.S. Food and Drug Administration



- Substance Registration System (SRS)
- Drug Registration and Listing (eLIST)

- National Library of Medicine



United States
National Library of Medicine
National Institutes of Health

- RxNorm

- Department of Veterans Affairs/
Veterans Health Administration



- National Drug File Reference Terminology (NDF-RT)

- National Cancer Institute



- NCI Thesaurus (NCIt)

- Agency for Healthcare Quality and Research



FMT Component Terminologies

- FDA SRS and eLIST
 - National Drug Code (NDC)
 - Unique Ingredient Identifier (UNII)
- NLM RxNorm
 - Semantic Clinical Drug (SCD)
 - Brand Name (BN)
- VA NDF-RT
 - Mechanism of action
 - Physiologic effect
 - Structural class
- NCI NCIt (SPL subset)
 - Pharmaceutical dose form
 - Route of administration
 - Unit of presentation
 - Package type



FMT Component Terminologies

- National Drug Code (NDC)
 - Maintained and distributed by FDA
(in conjunction with the manufacturers)
 - Tylox 100 capsules in a bottle - NDC - 0045-0526-60
 - Tylox 100 capsules in a blister pack - NDC - 0045-0526-79
- Unique Ingredient Identifier (UNII)
 - Maintained by FDA and EPA, distributed by FDA Substance Registration System (SRS)
 - Oxycodone hydrochloride UNII - C1ENJ2TE6C
 - Oxycodone - UNII - CD35PMG570
 - Acetaminophen - UNII - 362O9ITL9D
 - Peanut - UNII - QE1QX6B99R
 - Milk - UNII - 917J3173FT
 - Citronella oil - UNII - H711OZ709T
 - Tartrazine (FD&C Yellow #5) - UNII - I753WB2F1M



FMT Component Terminologies

- RxNorm
 - Maintained and distributed by NLM
 - Semantic Clinical Drug (SCD)
 - Diazepam 10 MG Oral Tablet – RxCUI 197590
 - Brand Name (BN)
 - Valium – RxCUI 202472



FMT Component Terminologies

- NDF-RT
 - Maintain by VA, distributed by NCI
 - Mechanism of Action
 - Adrenergic agonists – N000000012
 - Physiologic effect
 - Bronchodilation – N0000008321
 - Structural class
 - Alkaloids – 0000007503



FMT Component Terminologies

- NCI code sets
 - Maintained and distributed by NCI
 - NCI Pharmaceutical Dosage Form
 - Tablet, orally disintegrating – C42999
 - NCI Route of Administration
 - Oral – C38286
 - NCI Potency (Units of Presentation)
 - Spray - C48537
 - NCI Package type
 - Bottle – C43169



Federal Medication Terminologies (FMT) Components and Structured Product Labeling (SPL)

- SPL is an ANSI accredited HL7 standard for the exchange of product information
 - FDA uses SPL for exchanging information on approved prescription drug products
 - Future use for additional FDA regulated products (e.g., OTC, animal products)
- Federal Medication Terminologies Standards in SPL
 - FDA – NDC, Unique Ingredient Identifier (UNII)
 - VA NDF-RT- mechanism of action, physiologic effect and structural class
 - NCI - pharmaceutical dose form, route of administration, unit of presentation and package type
- Federal Medication Terminologies Standards supported by SPL
 - NLM – RxNorm SCD, RxNorm BN

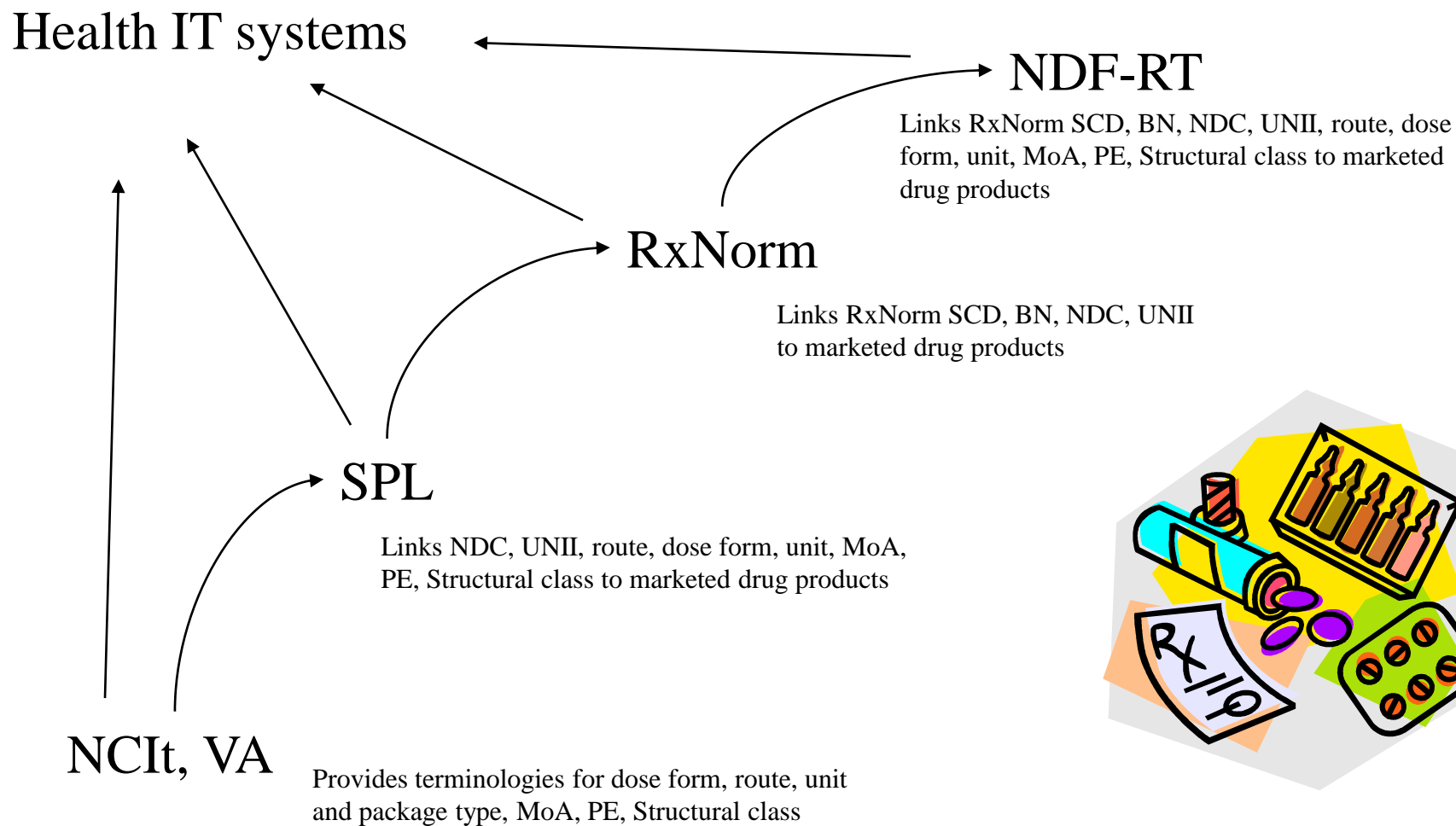


SPL and Other Federal Terminologies

- VA
 - VA/KP Problem List - MIGRAINE (disorder) (37796009)
- NCIt
 - For solid oral dosage form appearance
 - SPL Color - BLUE C48333
 - SPL Shape - ROUND C48348
 - For drug interactions
 - Contributing Factor -General - FOOD OR FOOD PRODUCT C1949
 - Type of Drug Interaction Consequence - PHARMACOKINETIC EFFECT C54386
 - Pharmacokinetic Effect Consequence - INCREASED DRUG LEVEL C54355
 - Limitation of Use - CONTRAINDICATION C50646
 - Sex - FEMALE C16576
 - Race - ASIAN C41259
 - Other
 - SPL DEA Schedule - CII C48675



FMT Support to Health IT Systems





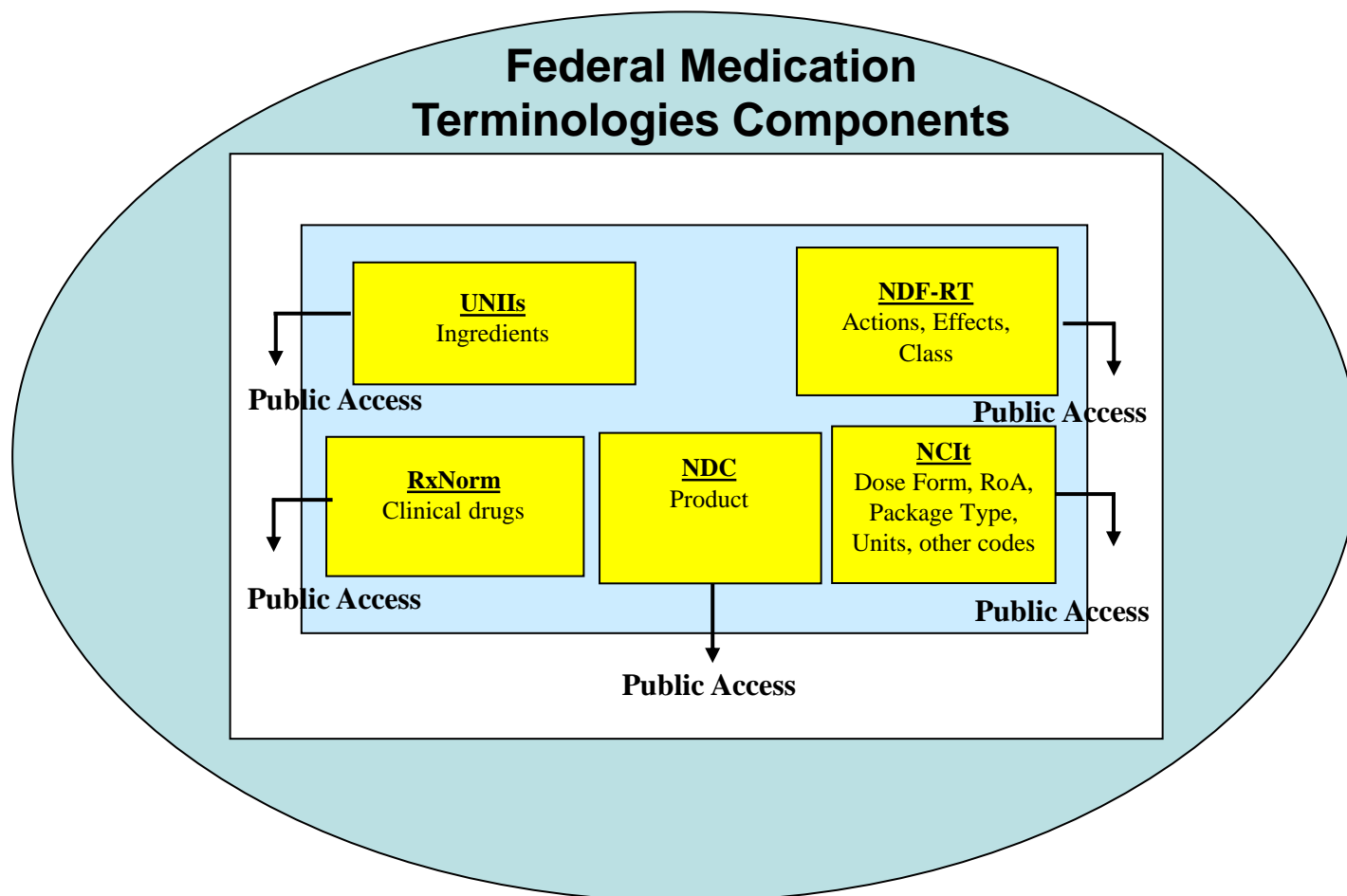
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Accessibility Options

All Components are accessible from: FMT Web Portal

<http://www.cancer.gov/cancertopics/terminologyresources/FMT>



Federal Medication Terminologies Website

Terminology Resources - National Cancer Institute - Windows Internet Explorer provided by MITRE

http://www.cancer.gov/cancertopics/terminologyresources/page4

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Terminology Resources - National Cancer Institute

National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov

NCI Home Cancer Topics Clinical Trials Cancer Statistics Research & Funding News About NCI

Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, and CDISC Terminology

Federal Medication Terminologies

The Federal Medication (FedMed) Interagency collaboration is organizing an agreed set of standard, comprehensive, freely and easily accessible Federal Medication Terminologies (FMT) to improve the exchange and public availability of medication information. FedMed is a joint effort of these Federal partner agencies:

- Food and Drug Administration (FDA)
- National Library of Medicine (NLM)
- Veterans Health Administration (VHA)
- National Cancer Institute (NCI)
- Agency for Healthcare Research and Quality (AHRQ)

The FedMed resources and related standards encompass medication and ingredient names, codes, routes of administration, dosage forms, units of presentation, mechanisms of action, physiologic effects, and structure. Participating agencies currently provide the following FMT components and related products:

- FDA's [Unique Ingredient Identifier \(UNII\) codes](#) for drug ingredients (see [FDA Terminology](#) Web page) and [National Drug Codes \(NDC\)](#) for prescription medications.
- NLM's [RxNorm](#) for clinical drug names, and [DailyMed](#) for viewing and downloading SPL-encoded drug labels.
- VHA's National Drug File Reference Terminology (NDF-RT) formulary. Three FMT-related SPL subsets of NDF-RT are described and accessible on the [FDA Terminology](#) Web page. Terminology for the full public release version of NDF-RT is available here in two versions: [all data zipped XML](#) and [terms and codes \(text\)](#).
- NCI Thesaurus (NCIT) for a range of supporting terminology sets and investigational agents. The FedMed-related SPL subsets of NCIT are described and accessible on the [FDA Terminology](#) Web page. NCIT as a whole is available via [browser](#), [file downloads](#), and application programming interfaces.

The Initial FMT terminology set has been endorsed by U.S. Federal standards efforts including the National Committee on Vital and Health Statistics (NCVHS), Consolidated Health Informatics (CHI), and the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS). An overview of the FMT goals, directions, and components is available in a jointly developed [PowerPoint presentation](#). The FedMed partners are working with ONC to develop an Interagency Coordination Group that can support coordination, development, and use of the FMT standards.

Please send questions and support requests to: FedMedHelp@hhs.gov

NCI Enterprise Vocabulary Services (EVS)
NCI Dictionaries
Federal Medication Terminologies
FDA Terminology
CDISC Terminology

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Quick Links

Director's Corner
Dictionary of Cancer Terms
NCI Drug Dictionary
Funding Opportunities
NCI Publications
Advisory Boards and Groups
NIE Calendar of Events
Español

Questions about cancer?

1-800-4-CANCER
LiveHelp® online chat

NCI Highlights

NCI Launches Community Cancer Centers Pilot
Researchers Discover Genes in Blood Vessels
New Study Shortens Timeline for Drug Development
The Nation's Investment in Cancer Research FY 2009

Drinking Water | Next Section

Internet 70%

FDA Terminologies

* On NCI Website (include NCIt code sets)

The screenshot shows a Windows Internet Explorer browser window displaying the National Cancer Institute (NCI) Terminology Resources page. The browser's address bar shows the URL: <http://www.cancer.gov/cancertopics/terminologyresources/page5>. The page features a red header with the NCI logo and navigation links. The main content area is titled "Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, and CDISC Terminology". On the left, there is a sidebar with various links and a "Page Options" section. The main content area is titled "FDA Terminology" and contains a paragraph explaining the FDA's work with EVS to develop controlled terminology. It lists four main areas of focus: 1. Structured Product Labeling (SPL), 2. Unique Ingredient Identifier (UNII), 3. Individual Case Safety Report (ICSR), and 4. Center for Devices and Radiological Health (CDRH). Each area is described with its purpose and the formats available for download. The page also includes a search bar and a "Live Search" button.

Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, and CDISC Terminology

FDA Terminology

The FDA is working with EVS to develop and support controlled terminology in several areas. More than 10,000 FDA terms and codes are stored in NCI Thesaurus (NCIt). This and other terminology used by FDA is updated and made available for download from an [NCI File Transfer Protocol \(FTP\) site](#). Listings of all FDA subsets in NCIt are available in [tab-delimited text](#), [Excel spreadsheet](#), and [zip-compressed Excel](#) formats. Relevant subsets are also available in each of these four main areas:

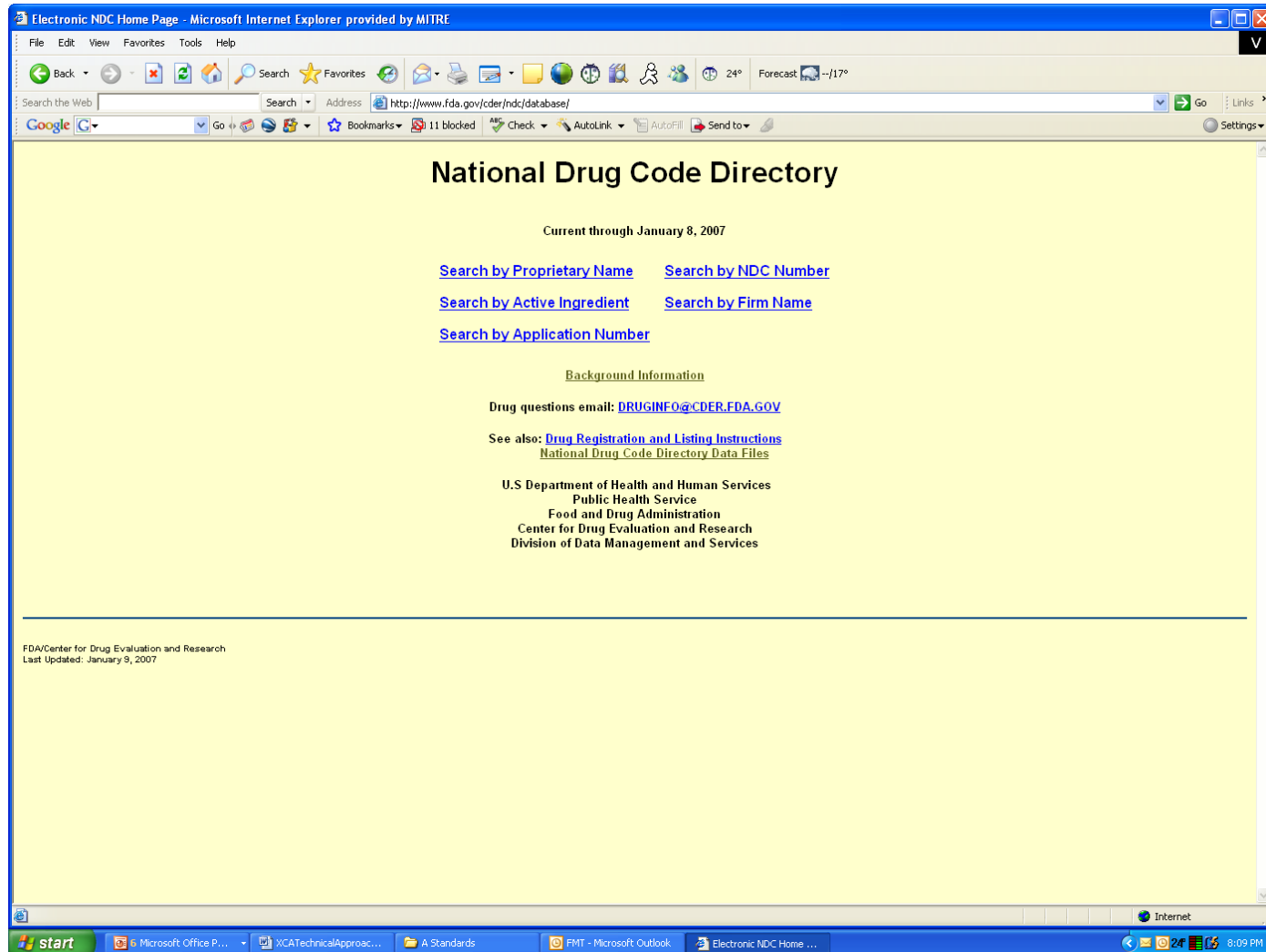
1. **Structured Product Labeling (SPL)** is a document markup standard approved by [Health Level Seven \(HL7\)](#), an international medical standards organization, and used by FDA to exchange medication information. The SPL standard specifies use of some 30 sets of controlled terminology. The NCI FTP site provides these SPL resources:
 - **NCIt SPL Subsets:** Eleven sets of SPL terminology are maintained in NCIt and available for download in [Excel](#) or [text](#) formats.
 - **NDF-RT SPL Subsets:** The VHA National Drug File Reference Terminology (NDF-RT) maintains terminology used to code these medication properties:
 - Mechanism of Action ([Excel](#) or [text](#)), and
 - Physiologic Effect ([Excel](#) or [text](#)), and
 - Structural Class ([Excel](#) or [text](#)).
 - **Problem List Subset:** The Medical Condition component of SPL is coded with the VHA and Kaiser Permanente (VAKP) Problem List Subset of the Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT). This set of SNOMED terms and codes is freely reusable worldwide without licensing or intellectual property restrictions. It is available in [Excel](#), [zipped Excel](#), and [text](#) formats, as well as through a specialized [browser application](#).
2. **Unique Ingredient Identifier (UNII)** codes are being developed by FDA to uniquely identify all ingredients used in marketed medications in the United States. Each UNII is assigned based on molecular structure, manufacturing process, or other characteristics. A full set of UNII codes is maintained in NCI Thesaurus, and is available for download in [Excel](#) and [text](#) formats.
3. **Individual Case Safety Report (ICSR)** terminology is used to encode adverse event information for reporting purposes. Fifteen ICSR term sets are maintained in NCI Thesaurus, and are available for download in [Excel](#) and [text](#) formats.
4. **Center for Devices and Radiological Health (CDRH)** terminology is under development to encode reporting of medical device problems. Three CDRH term sets, covering Patient Problem Codes, Device Component Codes, and Device Problem Codes, are maintained in NCIt and available for download in [Excel](#) and [text](#) formats.

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Only a
portion of
NCIt is
included
in the
FMT

<http://www.cancer.gov/cancertopics/terminologyresources/FDA>

NDC



<http://www.cancer.gov/cancertopics/terminologyresources/FMT>

<http://www.fda.gov/cder/ndc/database/>

FDA SRS - Microsoft Internet Explorer provided by MITRE

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Back Forward Stop Home Search Favorites

Search the Web Search Address <http://www.fda.gov/oc/datacouncil/SRS.htm> Go Links

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FDA **U.S. Food and Drug Administration** U.S. Department of Health and Human Services

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Substance Registration System - Unique Ingredient Identifier (UNII)

The overall purpose of the joint FDA/USP Substance Registration System (SRS) is to support health information technology initiatives by generating unique ingredient identifiers (UNIs) for substances in drugs, biologics, foods, and devices. The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.

The procedures and management of the SRS is provided by the SRS Board. The SRS Board includes experts from both FDA and USP. The SRS operating procedures defined by the SRS Board are detailed in the SRS Manual.

The UNII is:

- One of the core components of the United States Federal Medication Terminology.
- Used in the FDA's Structured Product Labeling
- Used to assist in the generation of the National Library of Medicine's (NLM's) RxNorm.
- A US government standard for drug ingredient and food allergen identifiers
- A component of the Environmental Protection Agency's Substance Registry System (future)

The UNII may be found in:

- NLM's Unified Medical Language System (UMLS)
- National Cancer Institutes Enterprise Vocabulary Service
- USP Dictionary of USAN and International Drug Names (future)
- FDA Data Standards Council website
- VA National Drug File Reference Terminology (NDF-RT)

Questions about the UNII should be directed to fda-srs@fda.hhs.gov

SRS Resources

[FDA Substance Registration System User's Guide Version 5b](#)

[Released UNIs and their Preferred Terms](#)

[Data Council Home Page](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

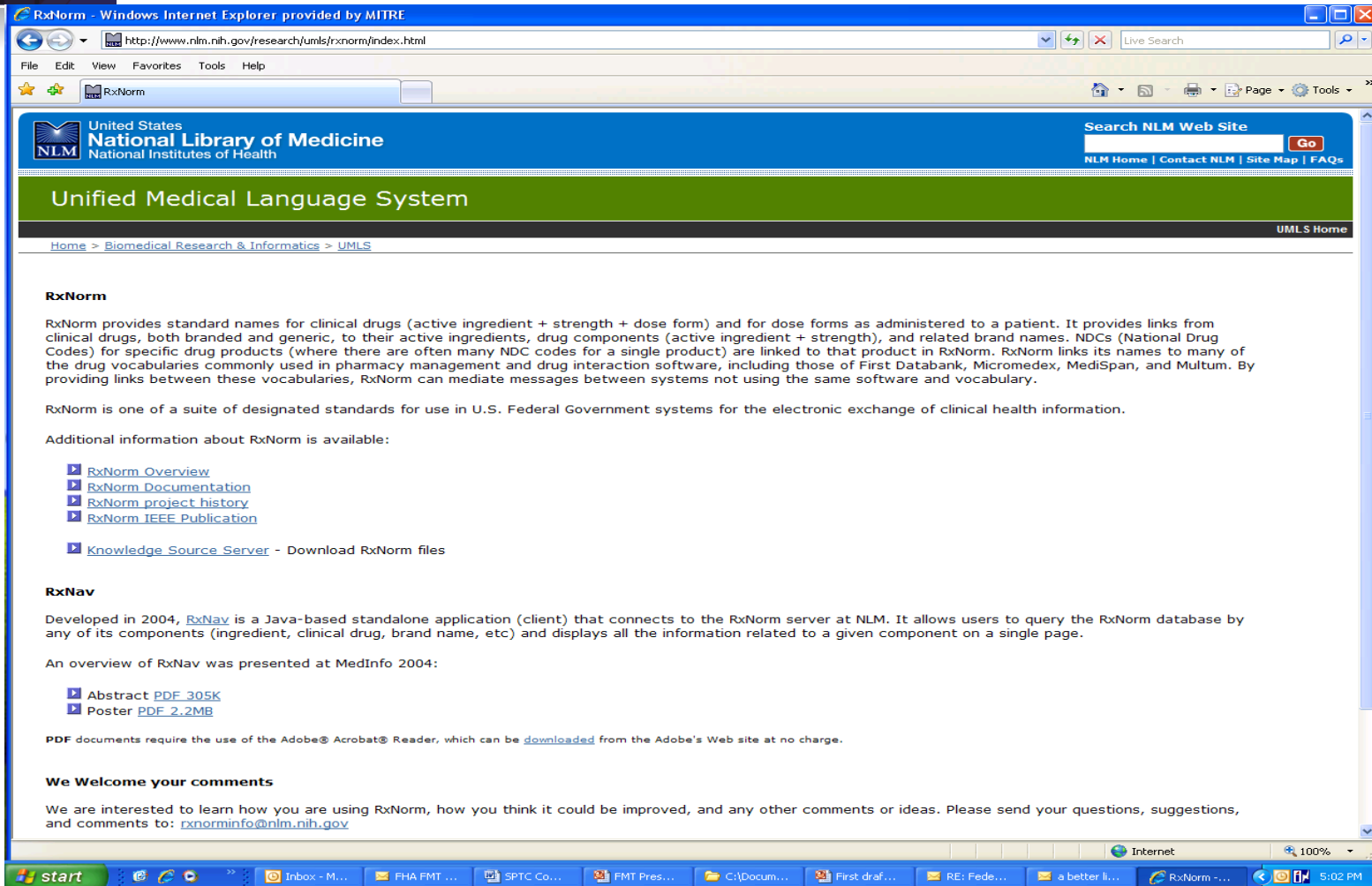
[FDA Website Management Staff](#)

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<http://www.cancer.gov/cancertopics/terminologyresources/FMT>

<http://www.fda.gov/oc/datacouncil/SRS.htm>

RxNORM



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portion of
RxNorm
is
included
in the
FMT

<http://www.cancer.gov/cancertopics/terminologyresources/FMT>

<http://www.nlm.nih.gov/research/umls/rxnorm/index.html>

NDF-RT

SPL Terminology - Microsoft Internet Explorer provided by MITRE

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Search the Web Search Address <http://www.fda.gov/oc/datacouncil/term.html#term1> Go Links

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FDA **U.S. Food and Drug Administration** U.S. Department of Health and Human Services

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [FDA Centennial](#)

Terminology

Pharmacological Class - Physiologic Effect: Display name and VA identifiers

Source: Department of Veterans Affairs National Drug File Reference Terminology

National Drug File Reference Terminology OID: 2.16.840.1.113883.3.26.1.5

The NDF-RT codes can be found on the NCI web site at: <ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/ndfirt/>

Pharmacological Class - Mechanism of Action: Display name and VA identifiers

Source: Department of Veterans Affairs National Drug File Reference Terminology

National Drug File Reference Terminology OID: 2.16.840.1.113883.3.26.1.5

The NDF-RT codes can be found on the NCI web site at: <ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/ndfirt/>

Pharmacological Class - Structural Class

Source: Department of Veterans Affairs National Drug File Reference Terminology

National Drug File Reference Terminology OID: 2.16.840.1.113883.3.26.1.5

The NDF-RT codes can be found on the NCI web site at: <ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/ndfirt/>

Intent of Use: FDA Preferred Name and HL7 Codes

Source: Health Level Seven

FDA Preferred Name	Code
TREATMENT	TREAT
PROPHYLAXIS	PRYLX
DIAGNOSTIC	DIAG

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<http://www.cancer.gov/cancertopics/terminologyresources/FMT>

<ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/ndfirt/>



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Collaboration/Coordination

- Fed Med Collaboration efforts:
 - NCI EVS
 - SPL
 - FMT, SNOMED, LOINC
 - HITSP
 - Consumer Empowerment Medication History Use Case
 - Care Delivery Medication Management Use Case
 - NIST HCSL, USHIK
 - CHDR
 - SDO efforts: NCPDP, HL7, ICH, ISO
 - Regulatory submissions, Discovery research, Clinical data, Billing, Statistics, Administration
 - Industry agreements, nationally accredited, global standardization
 - ePrescribing
 - SNOMED Mappings
- Fed Med Coordination efforts
 - Authoritative Source
 - Terminology Development
 - Maintenance, Distribution and Accessibility Planning





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U.S. Department of Health
and Human Services



U.S. Food and Drug Administration

