CDER SBIA Webinar Series

U.S. FOOD & DRUG ADMINISTRATION

Identification of Medicinal Products (IDMP): What is IDMP and Why Should I Care?

Ron Fitzmartin, PhD, MBA
Sr. Project Manager
Review Management | Office of the Director
Center for Biologics Evaluation and Research (CBER) | FDA

Ta-Jen (TJ) Chen, MS
Project Management Officer
Office of Strategic Programs (OSP) | Center for Drug Evaluation and Research (CDER) | FDA

Larry Callahan, PhD
Global Substance Registration System (G-SRS) | Office of Health Informatics
Office of Chief Scientist (OCS) | FDA

FDA Webinar
June 13, 2019

Identification of Medicinal Products (IDMP) Update:

Ron Fitzmartin, PhD, MBA
Sr. Project Manager
Review Management | Office of the Director
Center for Biologics Evaluation and Research (CBER) | FDA

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What is IDMP?

- IDMP is a suite of five standards developed (2012) within the International Organization for Standardization (ISO) which will create an internationally-accepted framework to uniquely identify and describe medicinal products.
- FDA is a member of ISO and has participated in the development of these five standards.
- The 5 Standards include data elements and structures for identification for
  - ISO 11615 - medicinal product information (MPID)
  - ISO 11616 - pharmaceutical product information (PhPID)
  - ISO 11238 - substances (Substance ID)
  - ISO 11239 - pharmaceutical dose forms, units of presentation and routes of administration
  - ISO 11240 - unique identification and exchange of units of measurement

Potential Benefits of IDMP

Safety Surveillance

- Unambiguous global identification will improve pharmacovigilance by uniquely identifying specific medicinal products in ICSRs.
- Globally detect safety signals from medicinal products referenced in adverse events.

Transparency

- Communicate medicinal product data globally.
- Opportunity to communicate and build trust with the public and other stakeholders about medicinal product quality and safety.

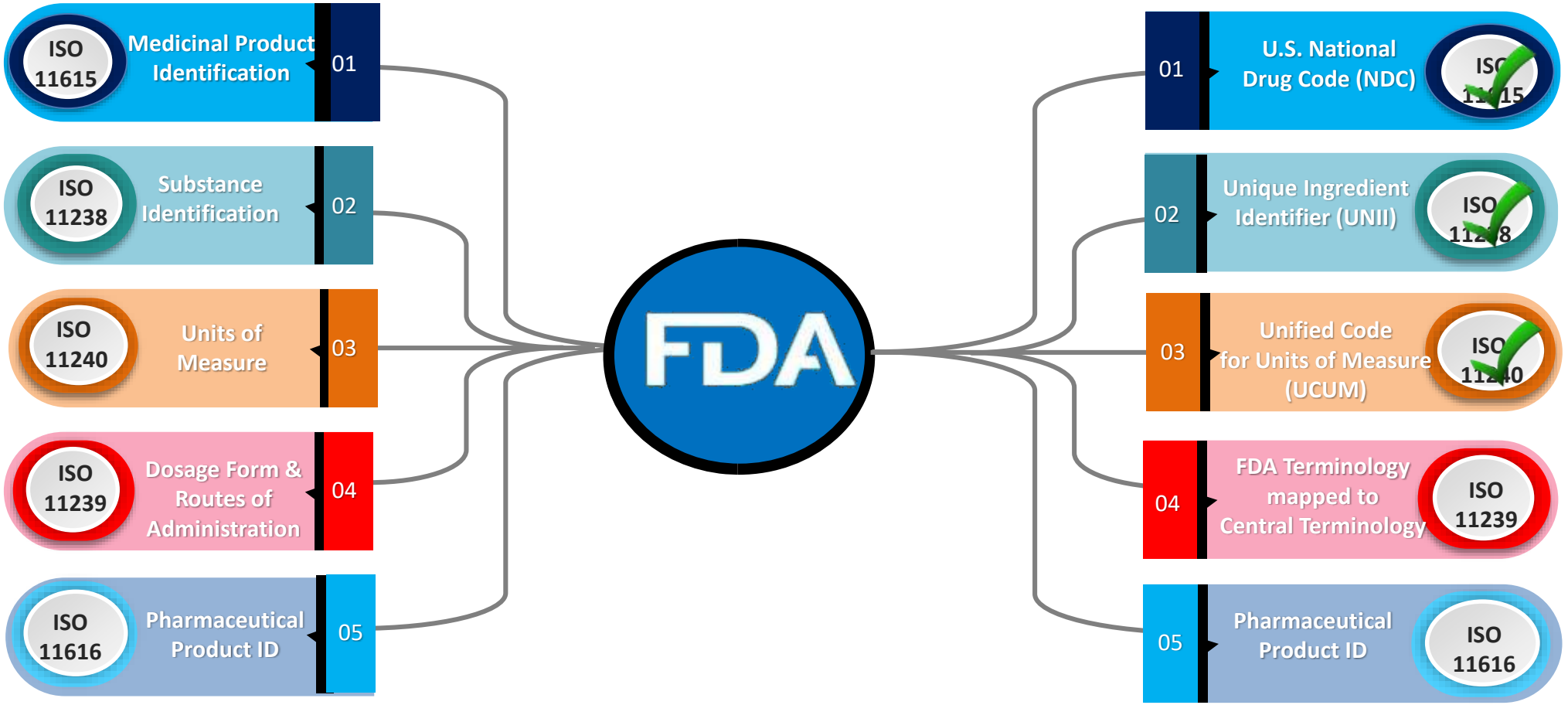
Mitigation of Drug Shortages

- Standard allows us to identify pharmaceutically equivalent products across regions, to support mitigation of drug shortages.

Interoperability

- Harmonized source for product information based on globally controlled vocabularies and standards
- Support the exchange of medicinal product information between companies and regulators.

FDA's Approach to ISO IDMP Standards



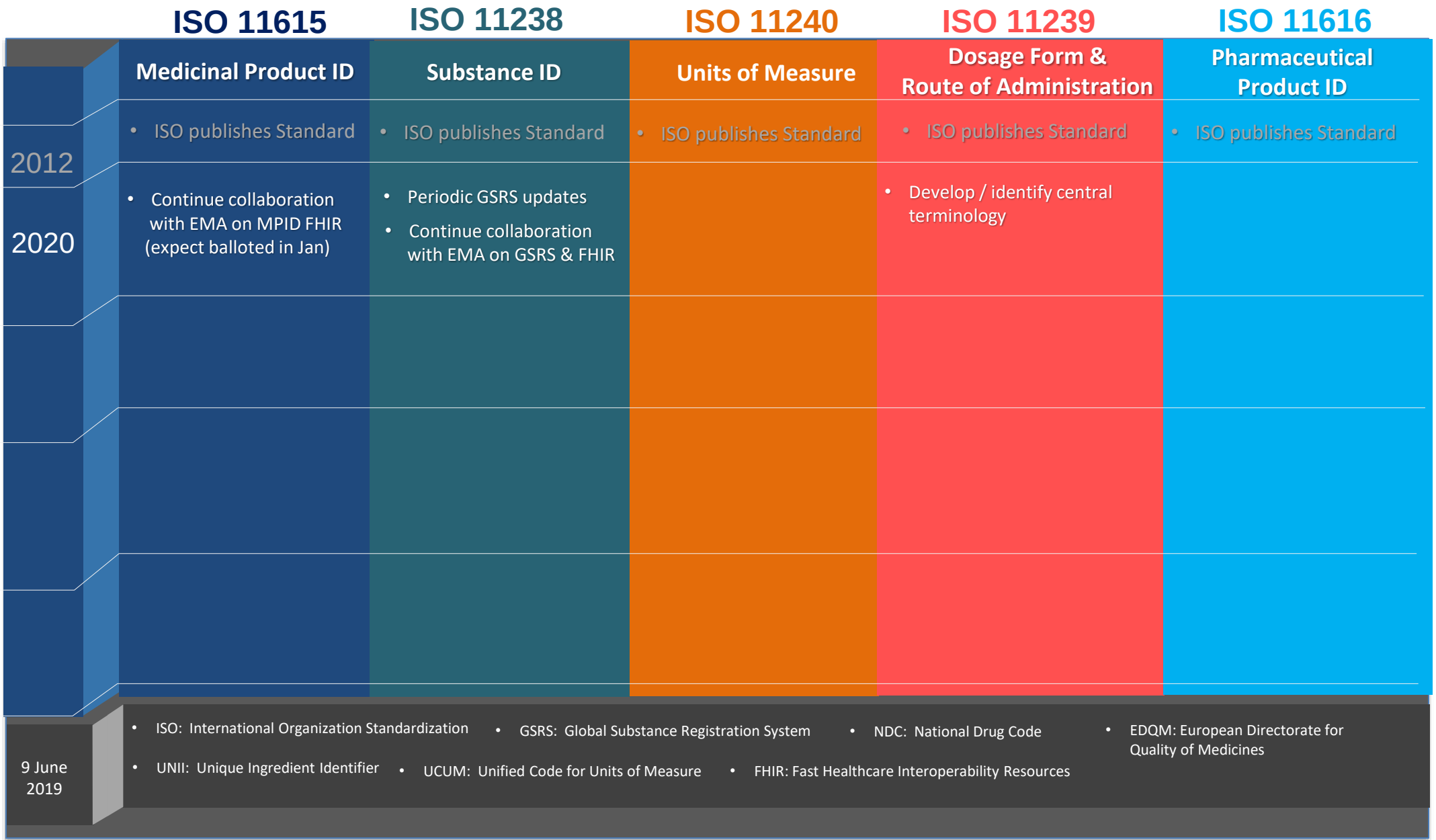
FDA IDMP Roadmap (1)

	ISO 11615 Medicinal Product ID	ISO 11238 Substance ID	ISO 11240 Units of Measure	ISO 11239 Dosage Form & Route of Administration	ISO 11616 Pharmaceutical Product ID
2012	• ISO publishes Standard	• ISO publishes Standard	• ISO publishes Standard	• ISO publishes Standard	• ISO publishes Standard
2016		• GSRS Project Initiated • UNII conforms to ISO 11238 • EMA-FDA Collaboration	• UCUM conforms to ISO 11240		
2017	• Initiate evaluation of NDC conformance • NDC Conforms to ISO 11615	• GSRS in production • Collaborate on FHIR Exchange Standard		• Initiate evaluation of FDA Terminology for SPL conformance	• Test FDA / Regional PhPIDs
2018		• Periodic GSRS updates		• Determined FDA Terminology does not conform to ISO 11239 • Analysis to assess mapping to EDQM standard terms	
2019	• Collaboration with EMA on MPID FHIR (development)	• Continue collaboration with EMA on GSRS and FHIR • Periodic GSRS updates		• Determined mapping must be to a central terminology • Planned update to the ISO TS 20440 and development of central terms	• Proposed meeting WHO / UMC on PhPID validation/ maintenance

9 June 2019

- ISO: International Organization Standardization
- GSRS: Global Substance Registration System
- NDC: National Drug Code
- EDQM: European Directorate for Quality of Medicines
- UNII: Unique Ingredient Identifier
- UCUM: Unified Code for Units of Measure
- FHIR: Fast Healthcare Interoperability Resources

FDA IDMP Roadmap (2)



Identification of Medicinal Products (IDMP): Update on MPID, PhPID, SubID & Units

Ta-Jen (TJ) Chen, MS
Project Management Officer
Office of Strategic Programs (OSP) | Center for Drug Evaluation and Research (CDER) | FDA

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ISO 11615 Medicinal Product Identification (MPID)

- **MPID Description**
  - Data elements and structures for unique identification and exchange of regulated medicinal product information
- **U.S. National Drug Code (NDC)** is FDA's regional MPID
  - First two segments of the NDC code will be used to represent MPID
  - The full NDC will be used to represent the medicinal product at the package level (known as the PCID)
    - **Example:**

National Drug Code (NDC)

US FDA Identifiers

MPID = Labeler and Product Codes

ISO 11615 Medicinal Product Identification (MPID)

ISO 11615:2017

8.2.1 General considerations

For each authorized Medicinal Product, a unique MPID shall be assigned. The MPID … supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a region. This is … and to contribute to improving patient safety by allowing for the unique identification of Medicinal Products worldwide.

The MPID shall use a common segment pattern … define a specific MPID concept. The pattern is:

a) country code segment (ISO 3166-1 alpha-2 code elements);
b) marketing authorization holder (organization identifier) code segment; Labeler Code
c) Medicinal Product code segment. Product Code

Any change of the values related to these three code segments shall result in the assignment of a new MPID.

ISO 11615 Medicinal Product Identification (MPID)

- **ISO 11615:2017**

  3.1.41 marketing authorisation holder

  – organisation that holds the authorisation for marketing a *Medicinal Product* (3.1.50) in a *region* (3.1.73)

- **CFR 21 Part 207 Subpart C—National Drug Code**

  §207.33 (c) Who must obtain an NDC labeler code …

  – (1) Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under this part must apply for an NDC labeler code , by providing …

ISO 11615 Medicinal Product Identification (MPID)

ISO 11615:2017

8.2.2.4 Medicinal Product code segment

This code segment shall reflect a Medicinal Product code assigned to the Medicinal Product. It utilises defining attributes to determine a single Medicinal Product to which a code is assigned. A different Medicinal Product code segment shall be assigned, leading to a unique MPID, (subject also to the notes below) whenever any of the following items of information for a Medicinal Product are modified, as applicable, per a Medicines Regulatory Agency process(es):

a) marketing authorization in relation to the jurisdiction;

b) legal status of supply (e.g. prescription only or “over the counter” sale);

c) Medicinal Product name;

d) pharmaceutical dose form;

e) active ingredient(s)/active moieties and their corresponding strength;

f) device(s) where a Medicinal Product is combined with a medical Device;

g) therapeutic indication(s) as authorized for the Medicinal Product

ISO 11615 Medicinal Product Identification (MPID)

CFR 21 Part 207 Subpart C—National Drug Code

§207.35 What changes require a new NDC?

(b) The proposed new NDC must include a new product code when there is a change to any of the following information:

(1) The drug's established name or proprietary name, if any;

(2) Any active pharmaceutical ingredient or the strength of any active pharmaceutical ingredient;

(3) The dosage form;

(4) A change in the drug's status, between prescription and nonprescription

(5) A change in the drug's intended use between human and animal

(6) The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any).

(c) When there is a change only to the package size or type, including the immediate unit-of-use container the proposed new NDC must include only a new package code and retain the existing product code unless all available package codes have already been combined with the existing product code in NDCs assigned by FDA.

ISO 11615 Medicinal Product Identification (MPID)

- **MPID Exchange Standard (ISO/TS20443)**
  - ISO 11615:2017
    - *"This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7."*
  - FDA uses SPL (HL7 v3 message) for labeling and drug listing and registration submissions, and does not currently have plans to change
    - FDA determined that the MPID required components are captured in the SPL label
    - Indication will be captured prospectively via regulatory submissions
  - FDA is collaborating with EMA to develop and test HL7 Fast Healthcare Interoperability Resource (FHIR) for information exchange
    - Test will ensure adherence to the ISO (TS20443) technical specification, *and*
    - FDA will evaluate and determine steps necessary to accept FHIR messages as well as SPL

ISO 11616 Pharmaceutical Product Identification (PhPID)

- **PhPID Description -** *PhPID is a code generated by an algorithm based on substance, strength, and dose form. PhPID can be used to associate products with same or similar pharmaceutical composition.*

PhPID_SUB_L1 → Substance Term(s)

PhPID_SUB_L2 → Substance Term(s)+ Strength+ reference strength

PhPID_SUB_L3 → Substance Term(s) + Dose Form

PhPID_SUB_L4 → Substance Term(s) + Strength + reference strength + Dose Form

NOTE 1 The substance(s) within the ingredient role "active" and "adjuvant" is utilised to define the PhPID.

- FDA is currently testing the generation of regional PhPIDs
- In May 2018, WHO/ UMC presented a conceptual proposal for validation and maintenance of global PhPIDs.
- Planning to participate at a technical and policy working group meeting in August 2019.

Substance Identification (SubID)

- **SubID Description**
  - Data elements and structures for unique identification and exchange of regulated information on substances

- **Unique Ingredient Identifier (UNII),** ISO 11238 compatible, used by FDA for many years to uniquely and unambiguously identify substances

- The Open Source Global Substance Registration System (GSRS) has been developed and is available at https://tripod.nih.gov/ginas/#/
  - **FDA-GSRS is in production** (approx. 180,000 entries)

IDMP on FHIR

- In January 2018, the EU endorsed* using FHIR as the basis for the API for the Product Management Service
  - Makes FHIR the data standard that supports the exchange of information about medicinal products, substances, and related reference data in the EU
- HL7's BR&R workgroup presently sponsors the development of ISO IDMP 11238 (Substance Specification) and IDMP 11615 (Medicinal Product) resources
  - Medicinal Product resource development takes place in collaboration with HL7's Pharmacy work group
  - IDMP resources are expected to be balloted by January 2020 meeting

* https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/substance-product-data-management-services

Units of Measurement

- **Units of Measurement Definition**
  - Data elements and structures for unique identification and exchange of units of measurement

- The ***Unified Code for Units of Measure*** (**UCUM**) was selected as the ISO 11240 compliant standard
  - UCUM is a system intended to include all units of measures being contemporarily used in international science, engineering, and business
  - Currently, FDA receives submissions that use the UCUM syntax standard for dosage strength in both content of product labeling and drug establishment registration and drug listing.

Identification of Medicinal Products (IDMP): Update on Dosage Form and Route of Administration

Ron Fitzmartin, PhD, MBA
Sr. Project Manager
Review Management | Office of the Director
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ISO 11239 Dosage Form (DF) & Route of Administration (RoA)

- **DF & RoA Description**
  - Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

- Based on review of ISO 11239's technical specification (20440:2016), the terminology of the European Directorate for the Quality of Medicines (EDQM) conforms to the ISO 11239 standard.
  - European Directorate for the Quality of Medicines, under the authority of the Council of Europe, maintains the terminology.
  - EDQM terminology can be found at: https://standardterms.edqm.eu/

ISO 11239 Dosage Form (DF) & Route of Administration (RoA)

- **FDA Terminology for SPL is used in**
  - Content of drug and biologics labeling
    - https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm
  - Drug establishment registration and listing
    - https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm
  - CDISC controlled terminology for SDTM used in clinical trials
    - https://www.cancer.gov/research/resources/terminology/cdisc
- **National Cancer Institute / Enterprise Vocabulary Service (NCI /EVS) maintains the FDA terminology as part of the larger NCI terminology**
  - https://evs.nci.nih.gov/ftp1/FDA/SPL/About.html
- Based on review of TS20440:2016 and analysis of EDQM, the *FDA Terminology for SPL* **does not** conform to the ISO 11239 standard for international IDMP.

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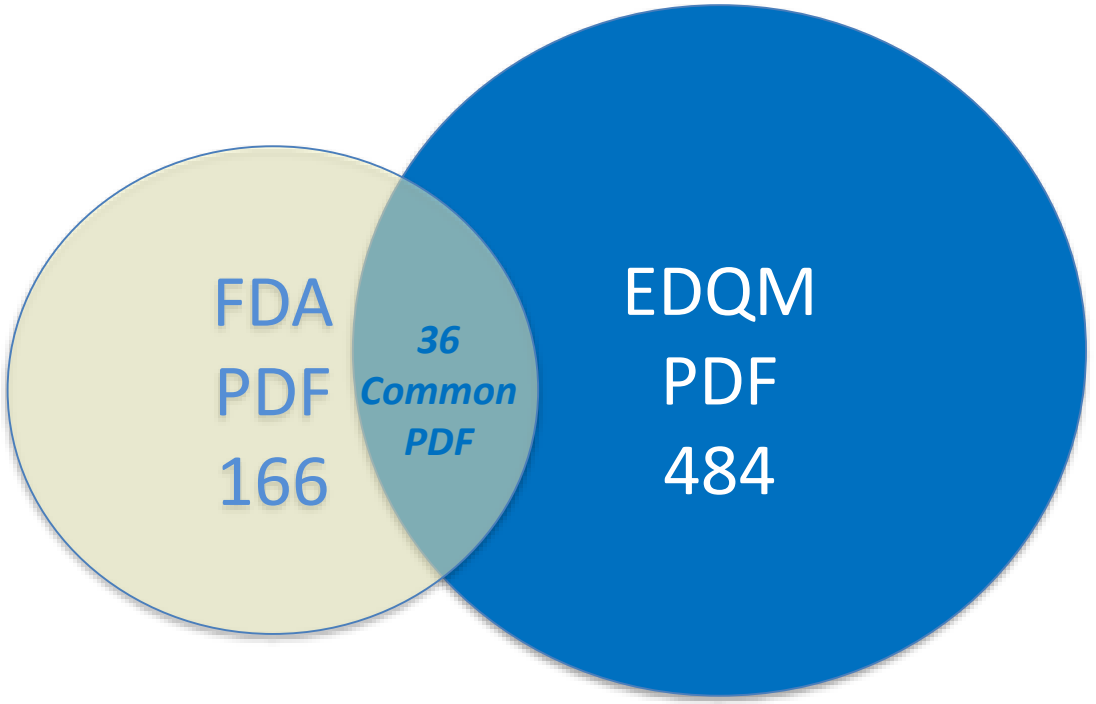
ISO 11239 Dosage Form (DF) & Route of Administration (RoA)

Mapping Results of FDA Terminology to EDQM PDFs

- FDA Terminology has **166** Pharmaceutical Dosage Forms (PDF)
- EDQM has **~484** PDFs
- FDA Terminology & EDQM share **36** common / mapped dose forms



ISO 11239 Dosage Form (DF) & Route of Administration (RoA)

FDA Terminology Capsule Types Without a 1:1 Map to EDQM Standard Term Capsule Types

B	E	F
Source PT	NCIt Conce	EDQM-HC Preferred Term
capsule	C149582	Inhalation vapour, capsule
capsule, COATED	C149872	Prolonged-release capsule, soft
capsule, COATED PELLETS	C150008	Vaginal capsule, soft
capsule, COATED, EXTENDED RELEASE	C149882	Rectal capsule
capsule, DELAYED RELEASE	C149664	Modified-release capsule, soft
capsule, DELAYED RELEASE PELLETS	C64904	capsule, hard
capsule, EXTENDED RELEASE	C64909	capsule, soft
capsule, FILM COATED, EXTENDED RELEASE	C149531	Gastro-resistant capsule, hard
capsule, GELATIN COATED	C149613	Intrauterine capsule
capsule, LIQUID FILLED	C149368	Chewable capsule, soft
	C149732	Oromucosal capsule
	C149663	Modified-release capsule, hard
	C149871	Prolonged-release capsule, hard
	C149532	Gastro-resistant capsule, soft
	C150007	Vaginal capsule, hard

ISO 11239 Dosage Form (DF) & Route of Administration (RoA)

- If EDQM (standard terms) is considered the IDMP central terminology, international PhPID Levels 3 and 4 may not be possible for some regions.

- For FDA, using EDQM, an international PhPID may not be possible for the highlighted levels below:

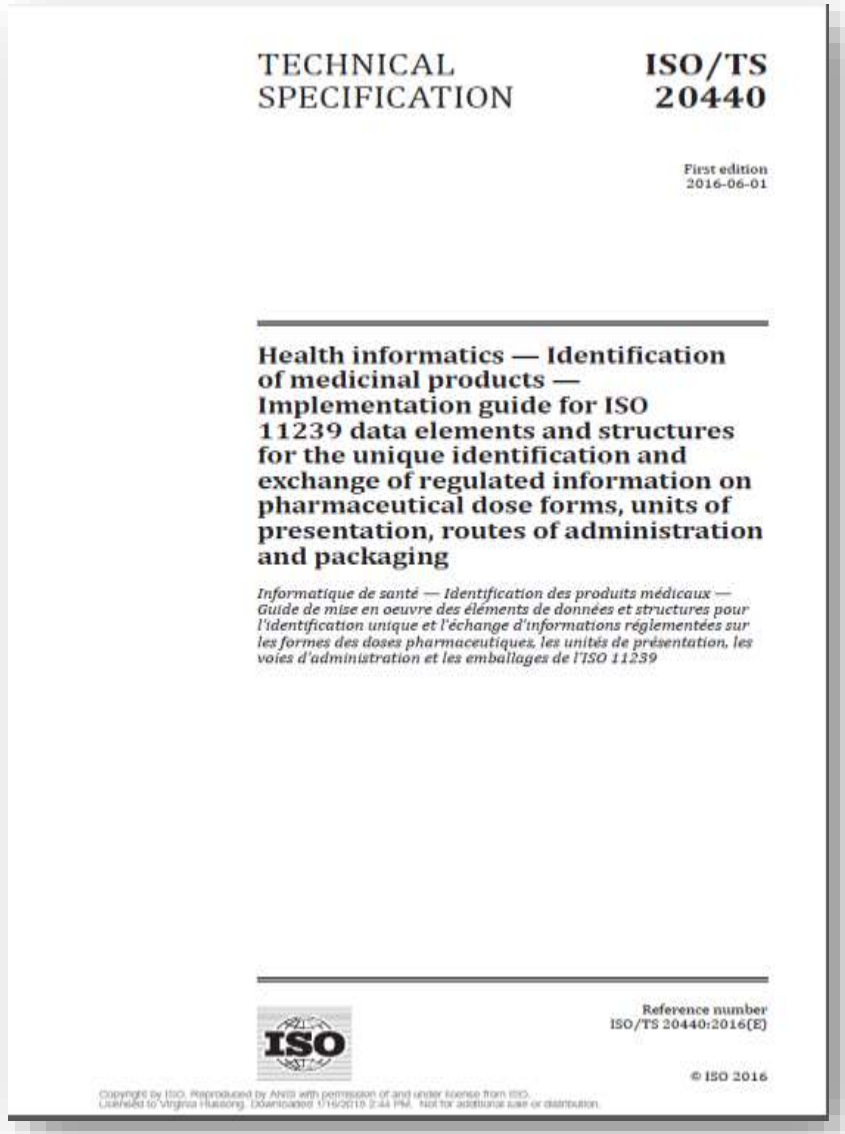
1. PhPID_Substance Level_L1 → Substance(s) Term

2. PhPID_Substance Level_L2 → Substance Term(s) +Strength+ reference strength

~~3. PhPID_Substance Level_L3 → Substance Term(s) + Administrable Dose Form~~

~~4. PhPID_Substance Level_L4 → Substance(s) Term+ Strength + reference strength + Administrable Dose Form~~

ISO 11239 Dosage Form (DF) & Route of Administration (RoA)


TECHNICAL SPECIFICATION

ISO/TS 20440

First edition
2016-06-01

Health informatics — Identification of medicinal products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Informatique de santé — Identification des produits médicaux — Guide de mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages de l'ISO 11239

ISO

Reference number
ISO/TS 20440:2016(E)

© ISO 2016

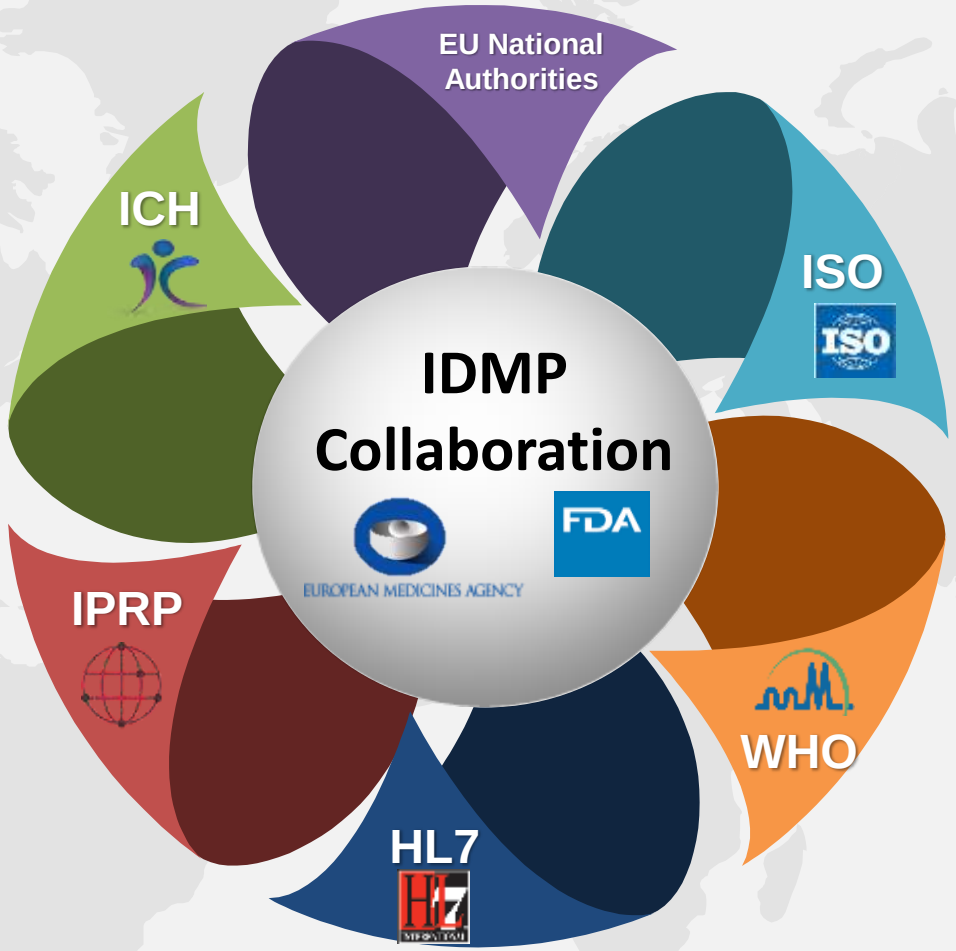
- **ISO TS 20440 Systematic Review Cycle**
  - As of 15 April, TS 20440 is scheduled for systematic review cycle
  - ISO ballot process underway to open for review: August 2019
  - If approved for systematic review, working group formed to update the Technical Specification 20440.
  - Goal: to ensure all parties can conform to a central set of dosage form terms.

Examples of EMA - FDA IDMP Collaboration

- Related to IDMP activities:
  - EWG E2B, ICH M2/M8
  - eCTD
  - CTD M2.3, 3 /PQ/CMC

- Develop & disseminate information on conformance to IDMP standards

- ISO IDMP underlying messaging infrastructure. FHIR resources for substance and medicinal product via HL7 Biomedical Research & Regulation workgroup (BR&R).



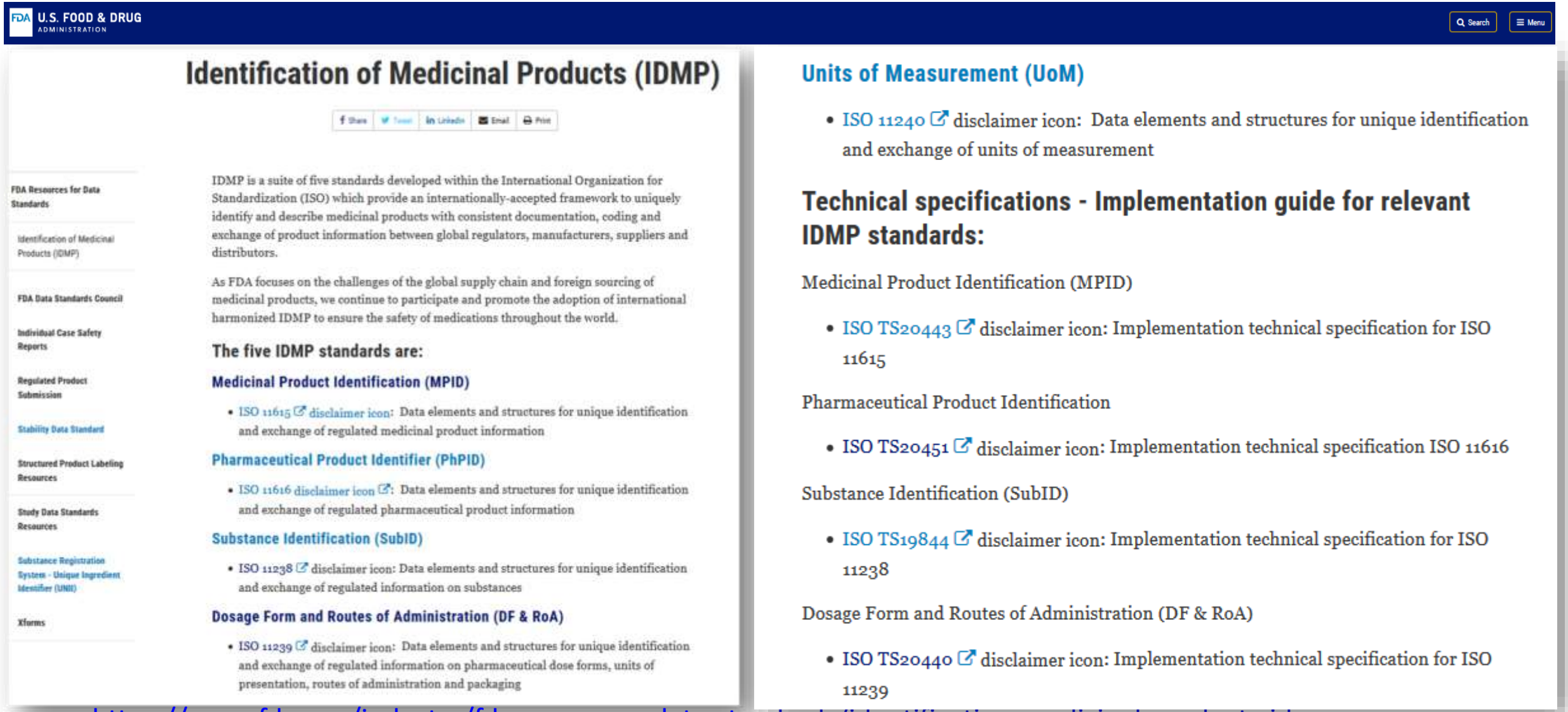
- Implementation of the EU Substance Registration System and Integration of GSRS and data exchange between regions to support EMA and FDA applications.

- Implementation of the ISO IDMP suite and information exchange between the regions.

- Enhance, review and maintenance of the ISO IDMP standards & technical specifications via ISO/TC 215, CEN/TC 251.

- Proposed maintenance of IDMP global identifiers and terminology (substance IDs, PhPIDs, Org IDs, etc.).

Resources



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Study Data Standards Resources

Substance Registration System - Unique Ingredient Identifier (UNII)

Xforms

IDMP is a suite of five standards developed within the International Organization for Standardization (ISO) which provide an internationally-accepted framework to uniquely identify and describe medicinal products with consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors.

As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, we continue to participate and promote the adoption of international harmonized IDMP to ensure the safety of medications throughout the world.

The five IDMP standards are:

Medicinal Product Identification (MPID)

- ISO 11615 disclaimer icon: Data elements and structures for unique identification and exchange of regulated medicinal product information

Pharmaceutical Product Identifier (PhPID)

- ISO 11616 disclaimer icon: Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

Substance Identification (SubID)

- ISO 11238 disclaimer icon: Data elements and structures for unique identification and exchange of regulated information on substances

Dosage Form and Routes of Administration (DF & RoA)

- ISO 11239 disclaimer icon: Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Units of Measurement (UoM)

- ISO 11240 disclaimer icon: Data elements and structures for unique identification and exchange of units of measurement

Technical specifications - Implementation guide for relevant IDMP standards:

Medicinal Product Identification (MPID)

- ISO TS20443 disclaimer icon: Implementation technical specification for ISO 11615

Pharmaceutical Product Identification

- ISO TS20451 disclaimer icon: Implementation technical specification ISO 11616

Substance Identification (SubID)

- ISO TS19844 disclaimer icon: Implementation technical specification for ISO 11238

Dosage Form and Routes of Administration (DF & RoA)

- ISO TS20440 disclaimer icon: Implementation technical specification for ISO 11239

https://www.fda.gov/industry/fda-resources-data-standards/identification-medicinal-products-idmp

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International Pharmaceutical Regulators Programme

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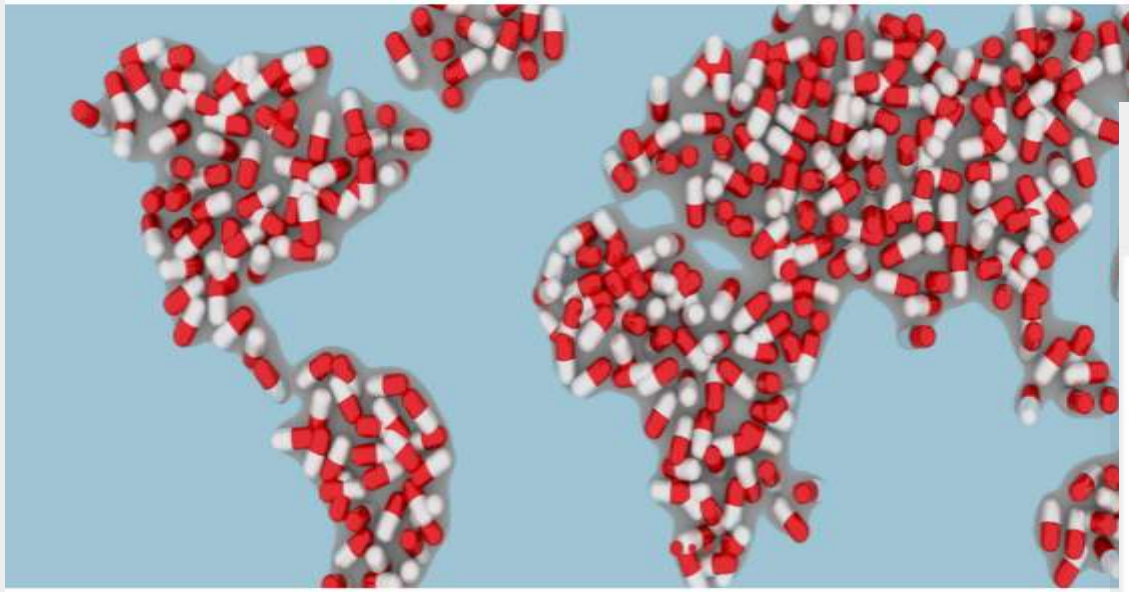


International Pharmaceutical Regulators Programme

IPRP was created to establish a forum for its regulatory members and observers to exchange information on issues of mutual interest and enable regulatory cooperation. This dedicated venue will assist in maximising potential efficiencies in addressing the increasingly complex global regulatory environment, facilitate the implementation of ICH and other internationally harmonised technical guidelines for pharmaceuticals for human use, promote collaboration and regulatory convergence, and contribute to the coordination of a range of international efforts

Identification of Medicinal Products

The Identification of Medicinal Products Working Group (IDMPWG)'s work is to ensure the awareness and understanding of the IDMP standards by pharmaceutical regulators, to clarify how and why these standards can add value to regulator business processes to improve the quality and effectiveness of shared regulatory functions, and to share strategies and experiences for their successful and consistent implementation.

Mandate

1. General considerations

The international community in the health domain identified a need for the development of international standards, via the International Organization for Standardization (ISO), for the global identification of medicinal products (IDMP). This includes the development of both ISO standards and corresponding ISO Technical Specifications for use as implementation guides. The standards provide definitions and conceptual models for the unique identification of medicinal products throughout the product lifecycle for improved regulatory and clinical activities. Although the application of the standards is broader than the regulatory domain, there is a unique role for regulators in implementing the standards with potential value not only to regulatory business processes, but more broadly to healthcare systems.

To optimize the utility of the standards in the regulatory domain, broader regulatory uptake is desirable. However, outside of the early adopters of the standards, there is limited awareness of what the standards are, what the regulatory use-cases are (the value of the standards to regulators), and what resources exist to facilitate the implementation of the standards. There is a need for a venue in which regulators can exchange information around the implementation of the standards. The IPRP IDMP Working Group provides such a venue for regulators to learn about the IDMP standards.

2. Objectives

Objectives of the IDMP Working Group are to ensure the awareness and understanding of the standards of the IDMP standards more globally by pharmaceutical regulators to clarify how and why these standards can add value to regulator business processes to improve the quality and effectiveness of shared regulatory functions, and to share strategies and experiences for their successful and consistent implementation.

3. Scope

Provide an understanding/comprehension of the ISO IDMP standards and their implementation by:

- Sharing strategies around implementation approaches such as limited, phased, or more fully across the product lifecycle
- Clarifying the use cases (i.e., the regulatory and public health value), e.g., in the areas of pharmacovigilance, compliance, clinical decision support, e-prescribing/dispensing, risk management and lifecycle management activities (from investigational phase through product registration)
- Updating members of on the status, progress, and challenges of implementation activities by early adopters

Members list

IDMPWG - Members & Observers list, dated 10 May 2019

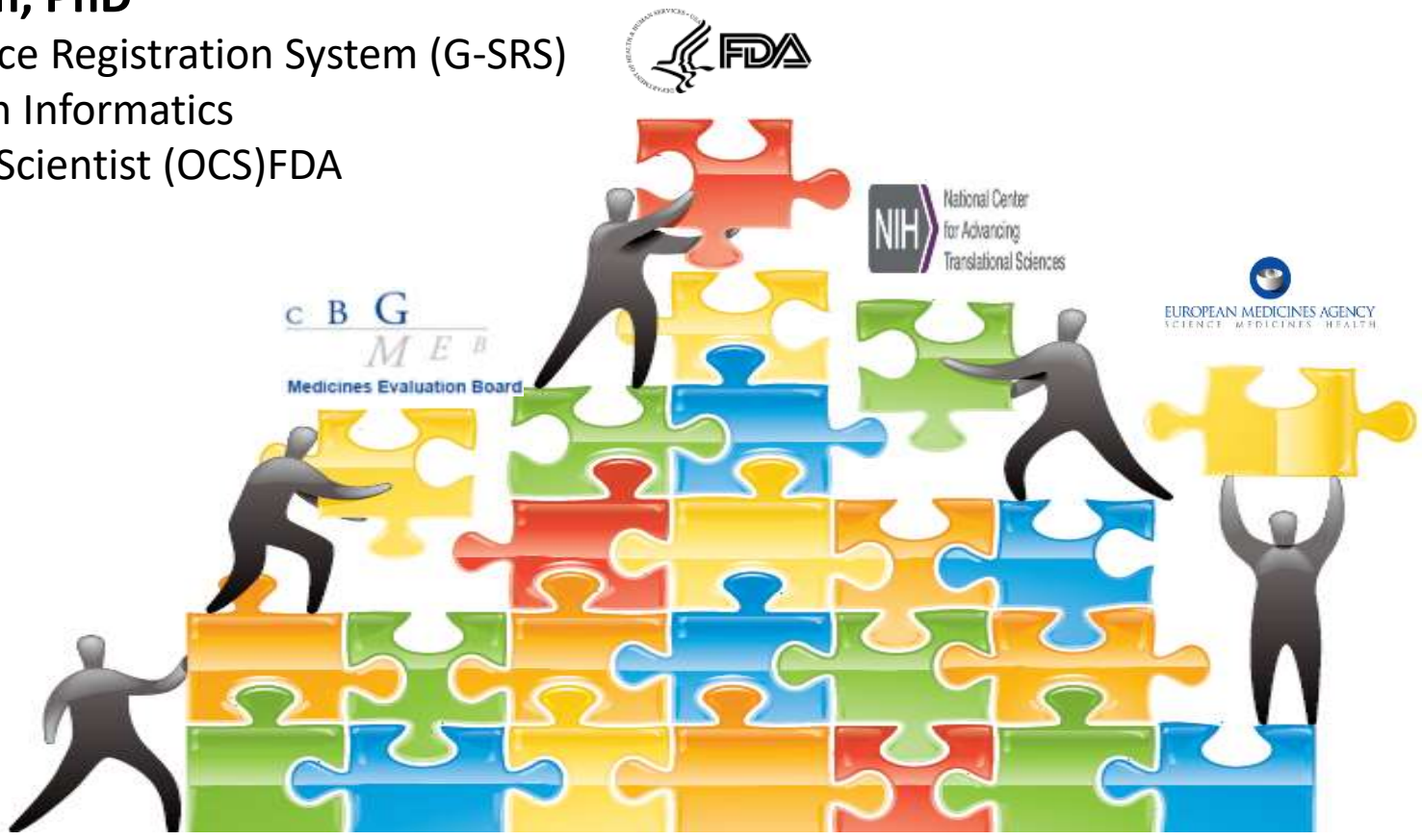
File(s)

IDMPWG Work plan, dated 21 May 2018

http://www.iprp.global/home

Overview of Global Substance Registration System (GSRS), Identification of Medicinal Products (IDMP)

Larry Callahan, PhD
Global Substance Registration System (G-SRS)
Office of Health Informatics
Office of Chief Scientist (OCS)FDA



Outline of Talk

- Organizing Information
- IDMP Standard
- What is a substance
- GInAS/GSRS
- Status of Development
- Adverse Event Data

Organizing Information

- FDA has the most important/valuable repository of human biological and product data but limited integration.
  - Submission process
    - Paper
    - PDF's
  - Organizational
    - Different Centers
    - Different Contractors
    - Business Process
- The amount of information is increasing
  - Rapid Screening Methods
  - Enzyme and Receptor Profiling
    - Cyp , Transporter and Receptor
  - Genomics
  - Epigenomics
  - Electronic Health Records
  - Many CMC changes
- Substances
  - A key lynchpin for organizing scientific and regulatory information
  - GSRS attempts to define substances consistently and unambiguously based on scientific principles
  - UNII permanently assigned ties an identifier to actual entities independently of nomenclature

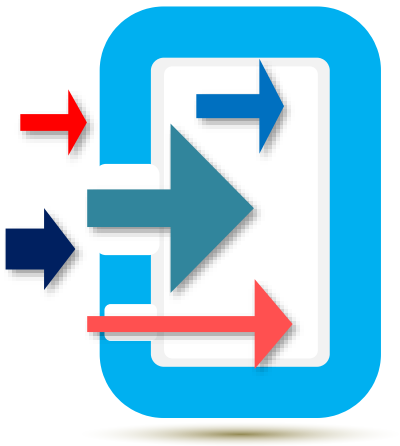
Organizing Information

- Identification of Medicinal Products (IDMP)
  - ISO project; 5 standards
- Approach of the IDMP to organizing information
  - Goal is to get data organized prior to submission
  - Fielded data is better than non-fielded Data
  - Controlled vocabulary is better that non-controlled vocabulary
  - Codes are better than names in electronic systems particularly relevant to substances
  - Substance terminology on definitions (truth) not hierarchy
  - All substances in medicinal products should be defined and assigned a permanent unique ID

Goals of IDMP Project

- Develop a common data structure and terminology for the description of medicinal products
  - Facilitate data exchange
    - Pharmacovigilance
    - Quality of pharmaceutics/detect/prevent counterfeiting
    - Predict/prevent drug-drug food-drug interactions
    - Incorporation of diverse data into databases
    - Prevent drug shortages
    - Promote Drug Development
  - Consistent review
  - Enter once use many (substances, organizations)
  - Assist in mining of EHRs (Effectiveness. Safety, Better Dosing)
  - Global ID for substances and pharmaceutical products (ie 200 mg ibuprofen tablets)

Global Health Benefits of IDMP



- **Improve Pharmacovigilance**
  - Globally detect safety signals from medicinal products referenced in adverse events
- **Support Mitigation of Drug Shortages**
  - Allows the identification of pharmaceutically equivalent products across regions
- **Promote Greater Understanding and Sharing**
  - Supports the exchange of post-market medicinal product information between companies and regulators

What is a Substance: ISO 11238

- ARISTOTLE (Metaphysics)...the generally recognizable substances... are the sensible substances, and sensible **substances all have matter...,** and in another sense the formula or form..., and thirdly the complex of matter and form, which alone is generated and destroyed, and is, without qualification, **capable of separate existence**
- **A unit of matter that can be quantitatively measured**
- **Five types of substances**
  - Chemicals, Proteins, Nucleic Acids, Polymers, and Structurally Diverse Material
  - Mixtures
- **Substance are not defined based on use**
- **The same substance can be manufactured or isolated using different methods**

Substances (ISO IDMP)

- Five groups of elements are used to describe single substances.
  - Monodisperse
    - Chemicals
      - Defined primarily by molecular structure (connectivity and stereochemistry)
    - Proteins
      - Amino Sequence, type of glycosylation, modifications
    - Nucleic Acids
      - Sequence, type of sugar and linkage, modifications

Substances (ISO IDMP)

- Polydisperse
  - Polymers (Synthetic or biopolymers)
    - Structural repeating units, type, geometry, type of copolymer (block or random), ratio of monomers, modifications, molecular weight or properties related to molecular weight, biological source for many biopolymers
  - Structurally Diverse Substances (viruses, cells, tissues, complex materials)
    - Taxonomic, anatomical, fractionation, physical properties, modifications

Why Register Substances

Need to tie substances to regulatory submissions

- Enhance review and drug development
  - Active substance and inactive substances under review
  - Biomarkers can be defined and tracked
  - Use substances and related substance information to structure submissions
    - Quality
    - Manufacturing
    - In-vitro data
    - Clinical Information
      - » Clinical trial registration
      - » ICSR
  - Starting materials
  - Processing materials I
  - Impurities

Need to tie substances to other substances

- Relationships between substances
  - Active Moiety
  - Salt/Solvate-> Parent relationships
  - Metabolites
  - Impurities
  - Drug target
  - Metabolic Enzymes (substrate, inhibitor, inducer)
  - Transporters (substrate, inhibitor, inducer)
  - Off target enzymes and receptors

Why Register Substances?

Need to tie substances to products

- Quality perspective
  - Change in substance can lead to a change in product
  - Find all products that could contain a "bad" ingredient (heparin, diethylene glycol)
  - Consistent specifications
- Safety perspective
  - Track adverse events based on substances
  - Tie substances to targets and pathways
- Drug Utilization
  - Predict and prevent shortages
  - Global marketplace need a global systems

Need to tie substances to manufacturer

- Quality
  - Who makes it
  - Where they make it
  - How they make it
  - Coordinate Inspections and testing

Tie Substances to other Information

Need to tie substances to other information

- Quality
  - Characterization
  - Specifications
  - Stability
- Physical Properties
  - Molecular weight
  - Solubility
  - pKa or pKb
  - Partition coefficients
  - Polymorph (crystal, amorphous)
- Toxicology and Animal Pharmacology
  - Genotoxicity
  - Cellular Cytoxicity
  - Summary Animal Toxicology
- Acute , Subchronic and Chronic
  - NOAEL, tissue distribution
  - Environmental Fate
  - Lab on a Chip results
- Clinical Pharmacology (LADMER)
  - Dissolution Data
  - Pharmacokinetics (Cmax, Tmax, Half-life, Vd, etc.)
  - Metabolism
  - Excretion
  - Pharmacodynamics
- Health and Disease
  - Indications (treatment, prevention, causative)
  - Adverse Events
  - Drug-Drug Interactions
  - Drug-Food Interactions
  - Health Outcomes
  - - omics

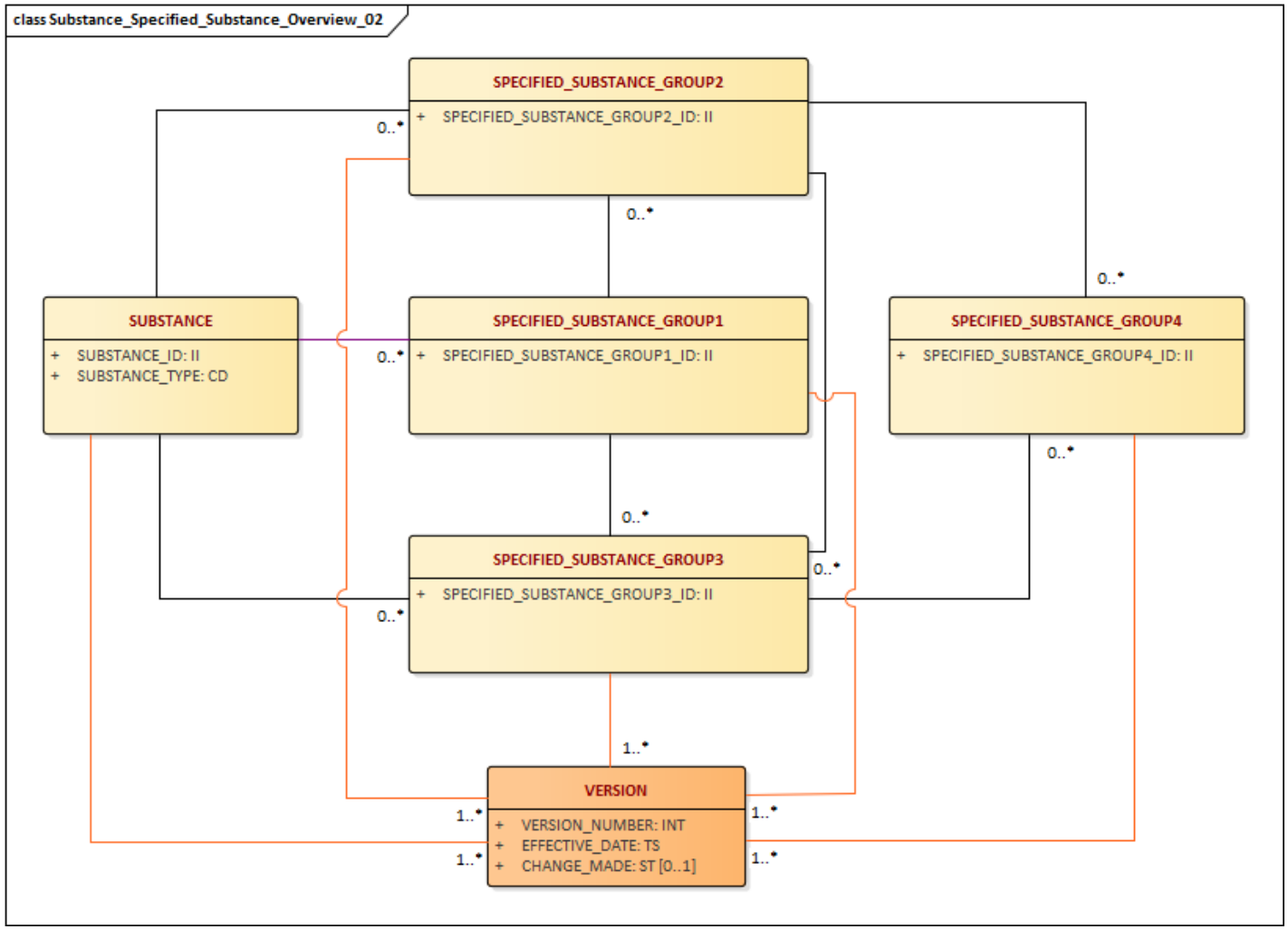
Need for Specified Substance

- Organize additional information on ingredients (SSG1).
  - Need to describe multiple substance ingredients (Simethicone, Colorants, Flavors)
  - Need to describe extracts (allergenic and herbal extracts, tinctures)
  - Need to distinguish materials that differ by physical form or critical properties (Polymorphs, Flowability, Compressibility)
  - Just starting to implement this at FDA

Need for Specified Substance

- Need to tie material to a manufacturer and a process (SSG2 and SSG4)
- Need to tie material to a specific grade (SSG3)
- Need to obtain specification information (SSG4)
- Need to obtain information about processing materials (SSG4)
- Need to establish and monitor the supply chain (SSG2)
- Manufacturing and specifications were separated out in ISO version 2

Specified Substance



UNIIs, SPL, Orange Book, Purple Book, Green Book, INDs

- GSRS currently implemented at FDA at the substance level
- UNIIs are required for all ingredients listed in SPL
- Nearly all drug targets have UNII codes
- UNII codes assigned when INDs come in (CDER)
- Companies will eventually preregister or obtain UNII shortly after submission
- UNIIs not explicitly listed in Orange Book, Purple Book or Green Book

What is the GSRS?

Assigns permanent UNII code to each substance

Compliant with the ISO IDMP Standard

Ties substances to:

- ✓ Products
- ✓ applications (Integrity, CFSAN and GSRS)
- ✓ clinical trials (CT.gov and EUCT)
- ✓ Adverse events counts
- ✓ Drug targets

Limited quality information

- ✓ Limited LADMER data (metabolites, cyp, transporter info)

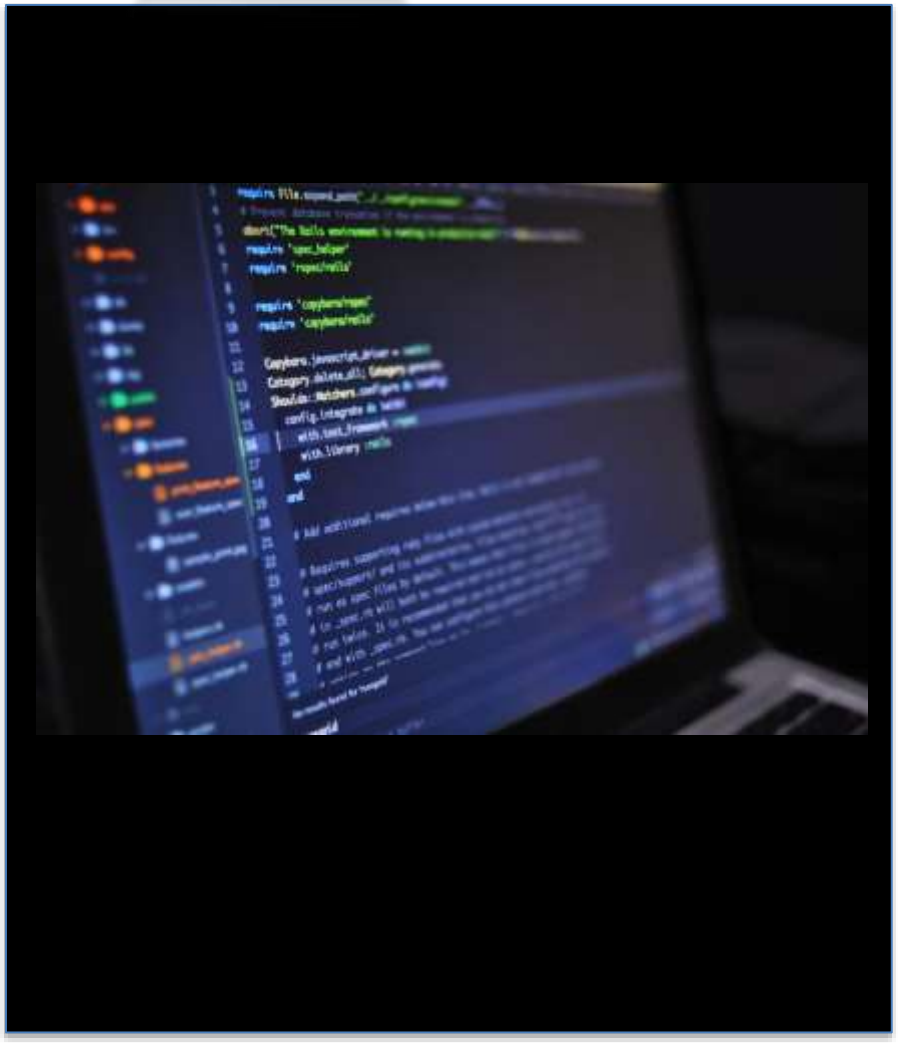
Registers and defines

GSRS is part of the IDMP effort

Global Substance Registration System

- Global marketplace for ingredients requires a global system to monitor the global supply chain
- A Global Repository of Regulatory Information and Data on Ingredients (Shortages, substandard and counterfeit ingredients, coordinate inspections)
- Standard is complex, difficult and expensive to implement
- Data abstraction and curation is very expensive
- Global database means better data, less redundancy, more data, less mapping

GSRS is a Software Application



- ❑ Freely distributable (NCATS version, substance only)
- ❑ Predominantly open source
- ❑ Data accessed and entered through an API
- ❑ Backend Java, Oracle
- ❑ Works with Oracle, PostgreSQL, MySQL has built-in H2 database
- ❑ Has native JSON message can be adapted to HL7-FHIR
- ❑ UI development Angular 1.0, Scala, Play framework, upgrating to angular 2.6
- ❑ Extensive use of Lucene Indexes
- ❑ Implemented Substance, Specified Substance Groups 1, 2, 3 and part of Specified Substance Group 4
- ❑ Excel tools for batch updating and queries

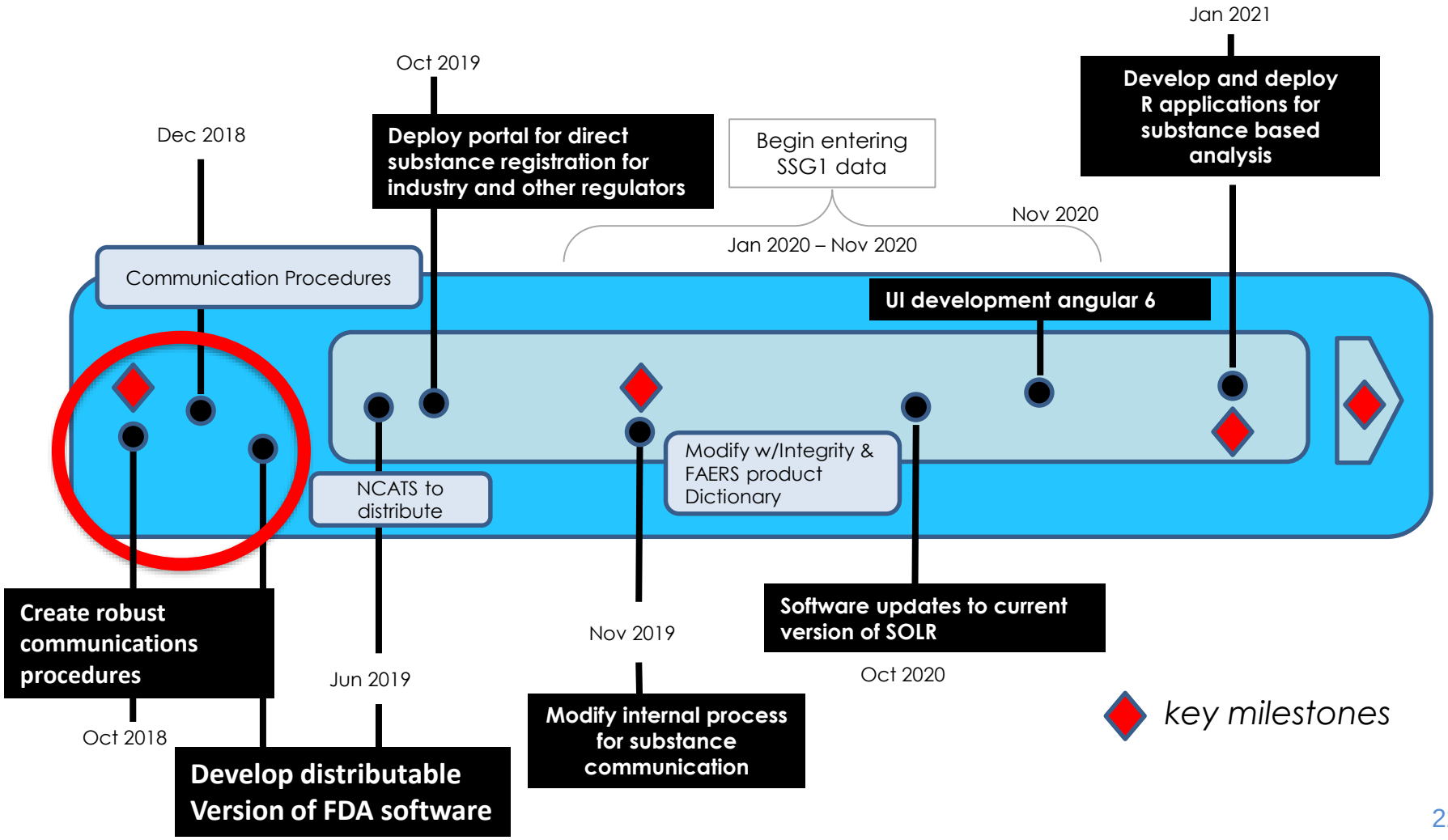
How it's used at FDA

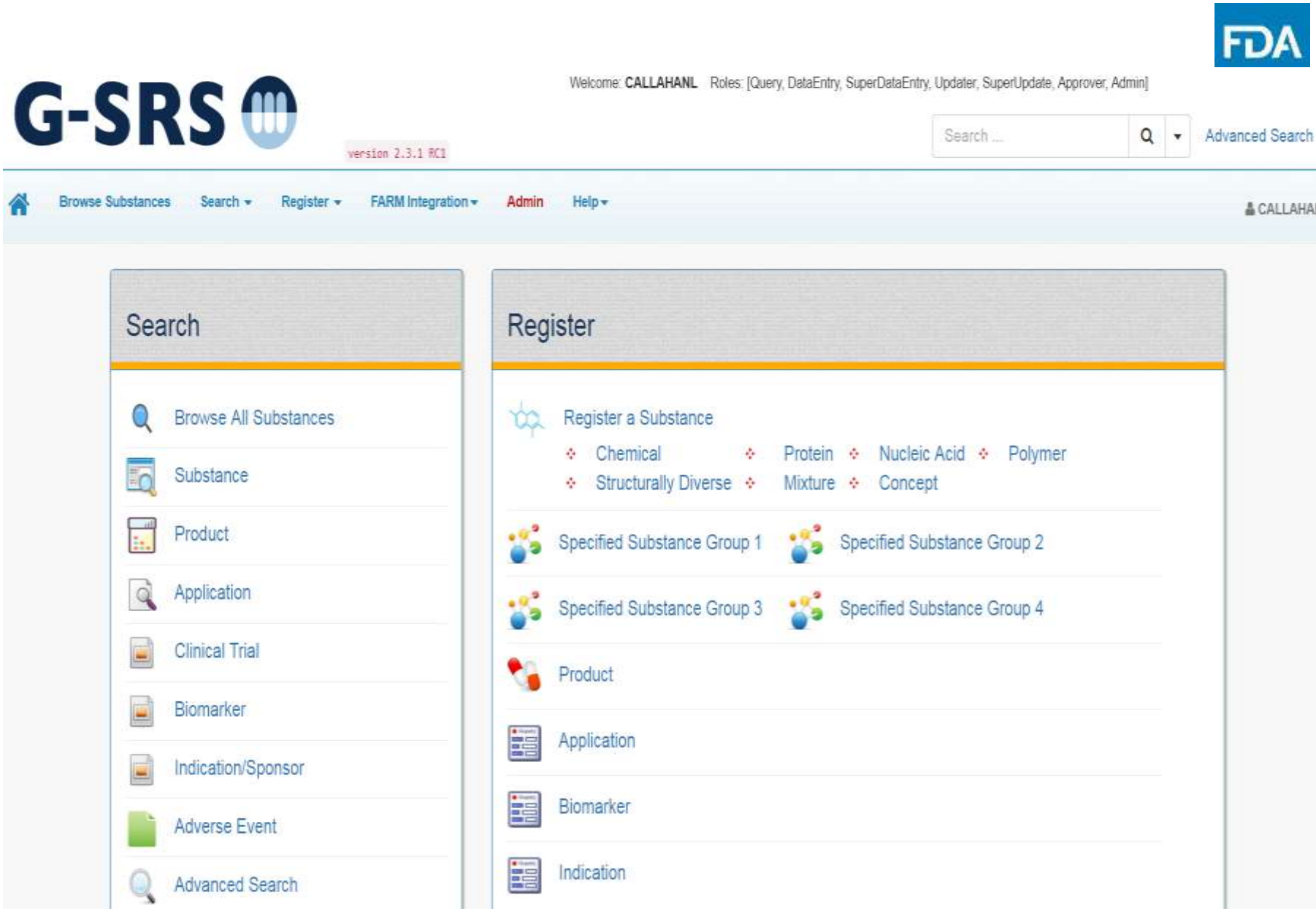
- FDA has adapted GSRS to integrate with existing internal databases and systems.
  - Adverse events
  - Products
  - Applications (INDs, NDAs)
  - Clinical Trials
- Industry uses the data from GSRS to find the UNII codes for their substances, which are submitted to the FDA.
  - In the future, they will be able to create a JSON message defining their substance to the FDA
  - Change submission process and eCTD

GSRS Software Current Status

- Works in all modern browsers: IE, Chrome, and Firefox
- System will be distributed with a large set of curated public domain data and updated periodically
  - Over 180,000 substances or concepts
  - Over 900,000 names, 800,000 codes (CAS numbers, WHO-ATC, etc), 150,000 relationships between substances (targets, metabolites, metabolic enzymes, transporters)
  - Links to many outside resource (Chemid, Pubchem, Drug Bank, Orphan Drug etc)
  - Mapped to both CTGOV and EUCT
  - Structure and sequence based searching
  - Faceted and advanced field-based searching
  - Data downloadable in a variety of formats JSON, Text, Excel
  - Attempts to tie indication-target-intervention

Where we are going?




G-SRS
version 2.3.1 RC1
Welcome: CALLAHANL Roles: [Query, DataEntry, SuperDataEntry, Updater, SuperUpdate, Approver, Admin]
Search ...
Advanced Search
Browse Substances
Search
Register
FARM Integration
Admin
Help
CALLAHANL
Search
Browse All Substances
Substance
Product
Application
Clinical Trial
Biomarker
Indication/Sponsor
Adverse Event
Advanced Search
Register
Register a Substance
Chemical
Protein
Nucleic Acid
Polymer
Structurally Diverse
Mixture
Concept
Specified Substance Group 1
Specified Substance Group 2
Specified Substance Group 3
Specified Substance Group 4
Product
Application
Biomarker
Indication

Show Deprecated Records

- Record Status
- Substance Type
- Source Tag
- Relationships
- Code System
- ATC Level 1
- ATC Level 2
- ATC Level 3
- ATC Level 4
- Application Status
- Application Type
- DME Reactions
- Moiety Type
- Stereochemistry
- Last Validated

185,804 « ‹ 1 2 3 4 5 6 7 8 ··· 11612 11613 › »

Sort By: Sort By

LISINOPRIL ANHYDROUS

UNII:7Q3P4BS2FD

ABSOLUTE

Names: LISINOPRIL ANHYDROUS ✔
L-PROLINE, 1-(N(SUP 2)-(1-CARBOXY-3-PHEN...
1-(N(SUP 2)-((S)-1-CARBOXY-3-PHENYLPROP...
LISINOPRIL [INN]
LISINOPRIL [MI]

Codes: BDNUM: *0335557AA*
CAS: *76547-98-3*
WHO-ATC: *C09AA03*
EVMPD: *SUB23348 SUB08533MIG*

Relationships: 4

Formula: C21H31N3O5

Mol Weight: 405.49

Date validated: 10 years ago
Created: 14 years ago
Last modified: a minute ago
Status: Validated (UNII)
Version: 8

Substance Hierarchy

▷ LISINOPRIL ANHYDROUS 7Q3P4BS2FD

Product Count:	Application Count:	Clinical Trial Count:	Adverse Event Count:
Active: 0	CDER: 0	0	47533
Inactive: 0	SRS: 0		

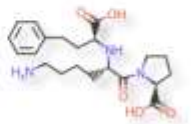
Validated (UNII) 8

Show All Records Matching Search

LISINOPRIL ANHYDROUS

UNII:7Q3P4BS2FD

ABSOLUTE



Names: LISINOPRIL ANHYDROUS ✔
L-PROLINE, 1-(N(SUP 2)-(1-CARBOXY-3-PHEN...
1-(N(SUP 2)-((S)-1-CARBOXY-3-PHENYLPROP...
LISINOPRIL [INN]
LISINOPRIL [MI]

Codes: BDNUM: *0335557AA*
CAS: *76547-98-3*
WHO-ATC: *C09AA03*
EVMPD: *SUB23348 SUB08533MIG*

Relationships: 4

Formula: C21H31N3O5

Mol Weight: 405.49

Date validated: 10 years ago
Created: 14 years ago
Last modified: 13 hours ago
Status: Validated (UNII)
Version: 8

Substance Hierarchy

- LISINOPRIL ANHYDROUS — 7Q3P4BS2FD
  - LISINOPRIL ANHYDROUS — 7Q3P4BS2FD *{ACTIVE FORM}*
  - LISINOPRIL — E7199S1YWR *{SALT/SOLVATE}*

Product Count:	Application Count:	Clinical Trial Count:	Adverse Event Count:
Active: 0	CDER: 0	0	47533
Inactive: 0	SRS: 0		

Substance Type

- Chemical 7
- Protein 1

Source Tag

Search GInAS Tag...

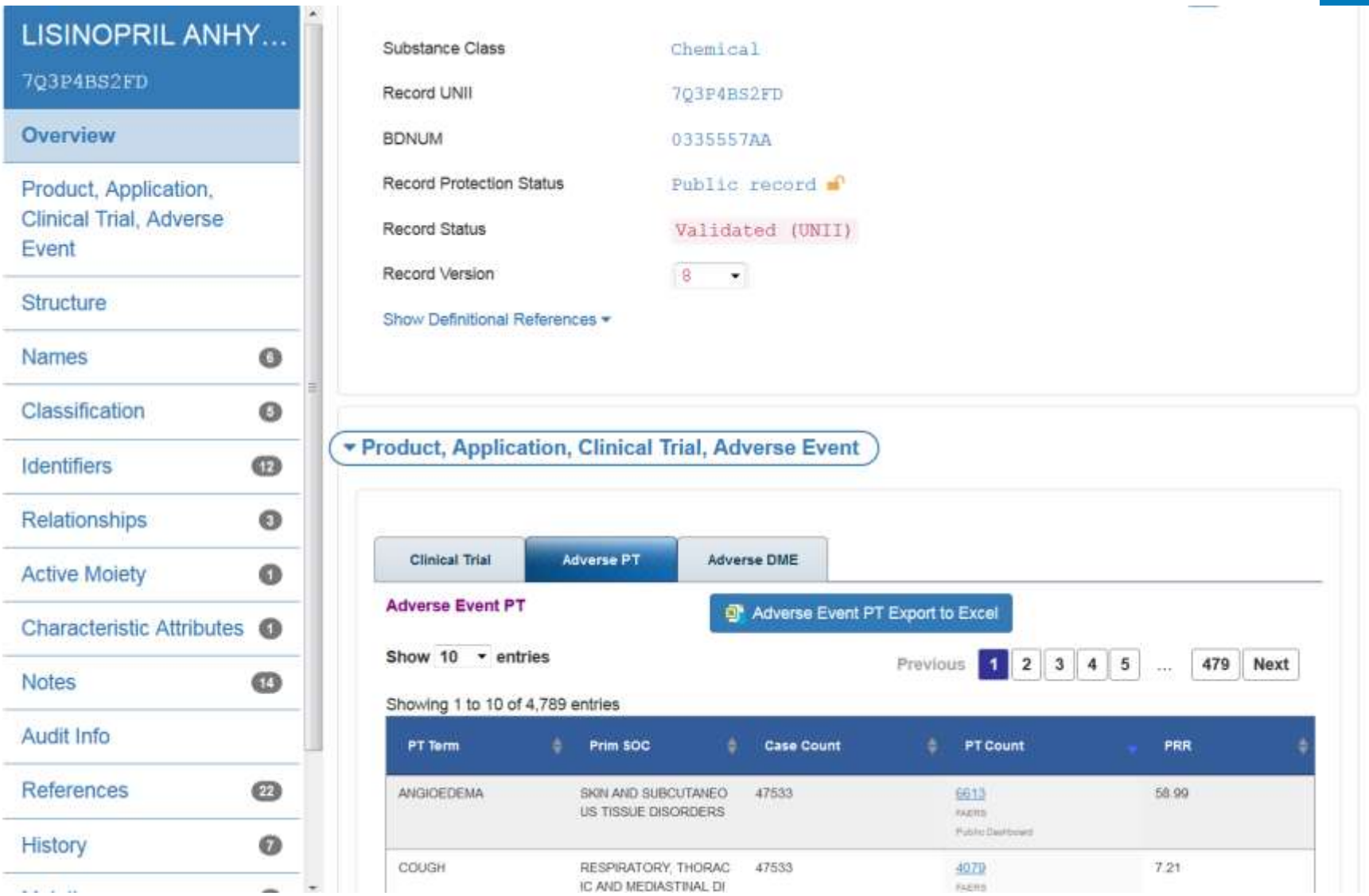
- MI 6
- WHO-DD 6
- INN 5
- VANDF 5
- MART. 4

More ...

Relationships

Code System

ATC Level 1


LISINOPRIL ANHY...
7Q3P4BS2FD
Overview
Product, Application, Clinical Trial, Adverse Event
Structure
Names 6
Classification 5
Identifiers 12
Relationships 3
Active Moiety 1
Characteristic Attributes 1
Notes 14
Audit Info
References 22
History 7
Substance Class Chemical
Record UNII 7Q3P4BS2FD
BDNUM 0335557AA
Record Protection Status Public record
Record Status Validated (UNII)
Record Version 8
Show Definitional References
Product, Application, Clinical Trial, Adverse Event
Clinical Trial
Adverse PT
Adverse DME
Adverse Event PT
Adverse Event PT Export to Excel
Show 10 entries
Previous 1 2 3 4 5 ... 479 Next
Showing 1 to 10 of 4,789 entries
PT Term
Prim SOC
Case Count
PT Count
PRR
ANGIOEDEMA
SKIN AND SUBCUTANEOUS TISSUE DISORDERS
47533
6613
58.99
COUGH
RESPIRATORY, THORACIC AND MEDIASTINAL DI
47533
4079
7.21

LISINOPRIL [MI]	Common Name	English	view	view

Showing 1 to 5 of 6 entries

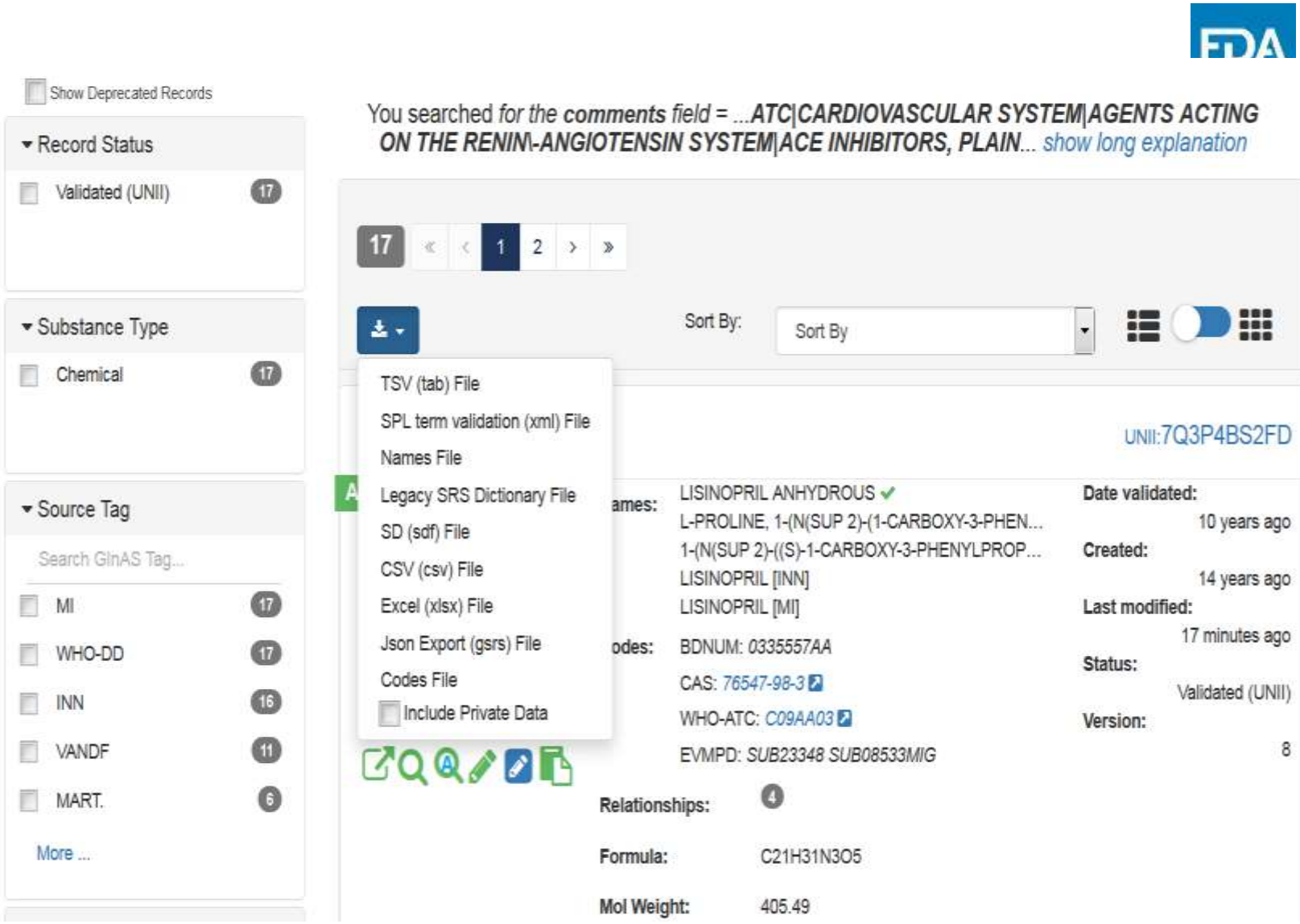
Previous 1 2 Next

Classification

Show 5 entries

Search ...

Classification Tree	Code System	Code	References
WHO-SDG Antihypertensives(49) Angiotensin converting enzyme (ACE) inhibitors(53)	WHO-SDG	53	view
Pharmacologic Substance[C1909] Agent Affecting Cardiovascular System[C78274] Antihypertensive Agent[C270] ACE Inhibitor	NCI_THESAURUS	C247	view
Cellular or Molecular Interactions [MoA] Enzyme Interactions [MoA] Enzyme Inhibitors [MoA] Protease Inhibitors [MoA] Angiotensin-converting Enzyme Inhibitors [MoA]	NDF-RT	N0000000181	view
Established Pharmacologic Class [EPC] Angiotensin Converting Enzyme Inhibitor [EPC]	NDF-RT	N0000175562	view
ATC CARDIOVASCULAR SYSTEM AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM ACE INHIBITORS, PLAIN ACE inhibitors, plain lisinopril	WHO-ATC	C09AA03	view


Show Deprecated Records
Record Status
Validated (UNII) 17
Substance Type
Chemical 17
Source Tag
Search GInAS Tag...
MI 17
WHO-DD 17
INN 16
VANDF 11
MART. 6
More ...
You searched for the comments field = ...ATC|CARDIOVASCULAR SYSTEM|AGENTS ACTING ON THE RENIN\-ANGIOTENSIN SYSTEM|ACE INHIBITORS, PLAIN... show long explanation
17
1
2
Sort By:
Sort By
TSV (tab) File
SPL term validation (xml) File
Names File
Legacy SRS Dictionary File
SD (sdf) File
CSV (csv) File
Excel (xlsx) File
Json Export (gsrs) File
Codes File
Include Private Data
UNII:7Q3P4BS2FD
LISINOPRIL ANHYDROUS
L-PROLINE, 1-(N(SUP 2)-(1-CARBOXY-3-PHEN...
1-(N(SUP 2)-((S)-1-CARBOXY-3-PHENYLPROP...
LISINOPRIL [INN]
LISINOPRIL [MI]
BDNUM: 0335557AA
CAS: 76547-98-3
WHO-ATC: C09AA03
EVMPD: SUB23348 SUB08533MIG
Relationships: 4
Formula: C21H31N3O5
Mol Weight: 405.49
Date validated:
10 years ago
Created:
14 years ago
Last modified:
17 minutes ago
Status:
Validated (UNII)
Version:
8

ZIDOVUDINE

4B9XT59T7S

- Overview
- Product, Application, Clinical Trial, Adverse Event
- Structure
- Names 37
- Classification 24
- Identifiers 20
- **Relationships 13**
- Metabolites 6
- Impurities 19
- Characteristic Attributes 12
- Notes 44
- Audit Info
- References 111

optical activity: (+)

ZIDOVUDINE

0M77W789J  URIDINE DIPHOSPHATE GLUCURONOSYLTRANSFERASE 2B7	METABOLIC ENZYME -> SUBSTRATE	*none*	view 2 reference(s)
I81U7H57XI  OAT-1	TRANSPORTER -> SUBSTRATE	*none*	view 1 reference(s)
22ES734693  MULTIDRUG RESISTANCE PROTEIN 1	TRANSPORTER -> SUBSTRATE	*none*	view 1 reference(s)

ZIDOVUDINE

4B9XT59T7S

- Overview
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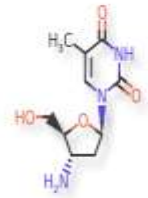
- Classification 24
- Identifiers 20
- Relationships 13
- **Metabolites 6**
- Impurities 19
- Characteristic Attributes 12
- Notes 44
- Audit Info

Related Record	Type	Details	References
K7ZG448V5M  ZIDOVUDINE DIPHOSPHATE	METABOLITE ACTIVE -> PARENT	*none*	view 2 reference(s)
6RGF96R053  ZIDOVUDINE TRIPHOSPHATE	METABOLITE ACTIVE -> PRODRUG	*none*	view 1 reference(s)
7W21N8C25B  3'-AMINO-3'-DEOXYTHYMIDINE	METABOLITE TOXIC -> PARENT	*none*	view 2 reference(s)

Amount:
RELATIONSHIP_AMOUNT

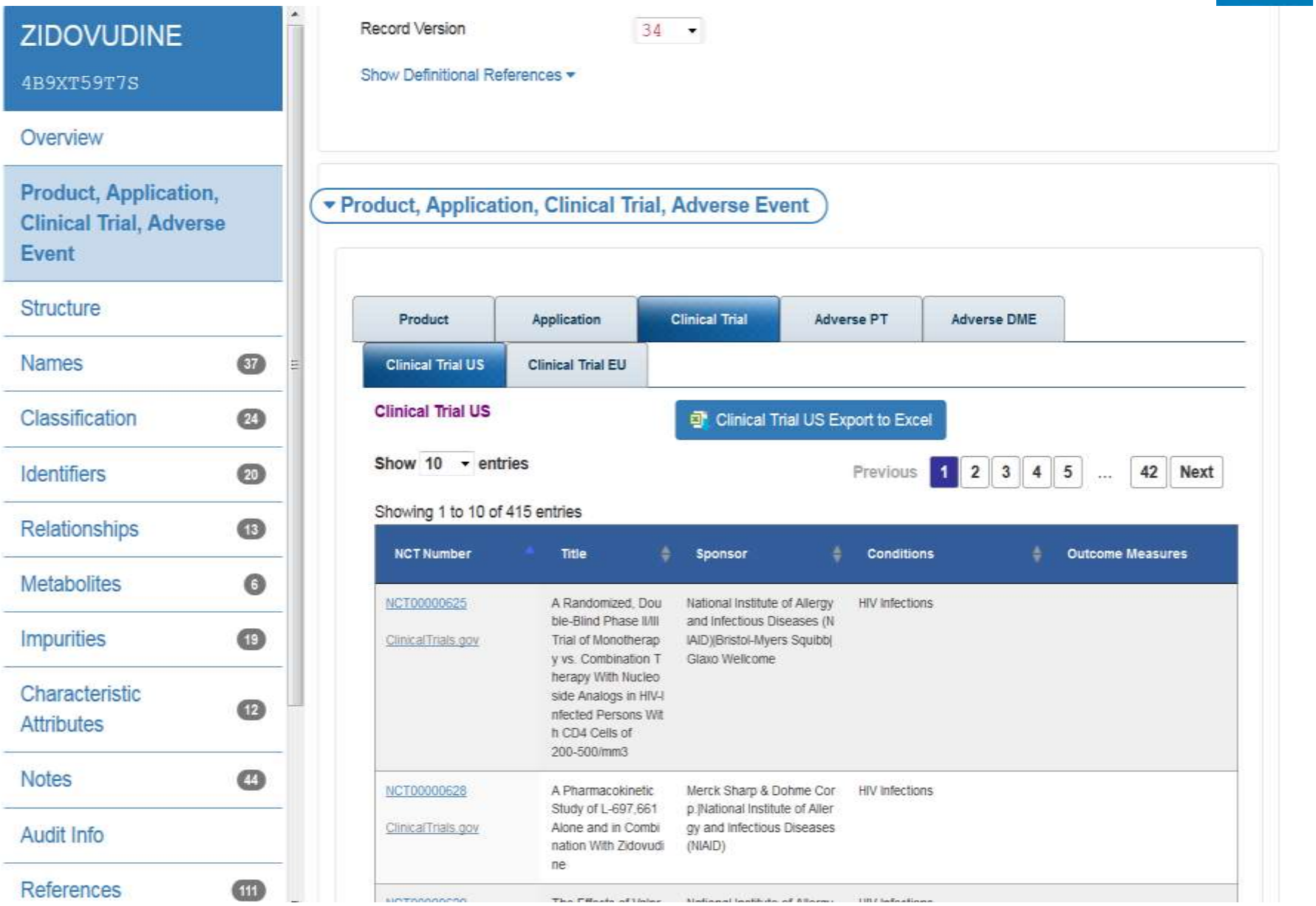
8GQZ0LXH8C IMPURITY -> PARENT hide hide 2 reference(s)

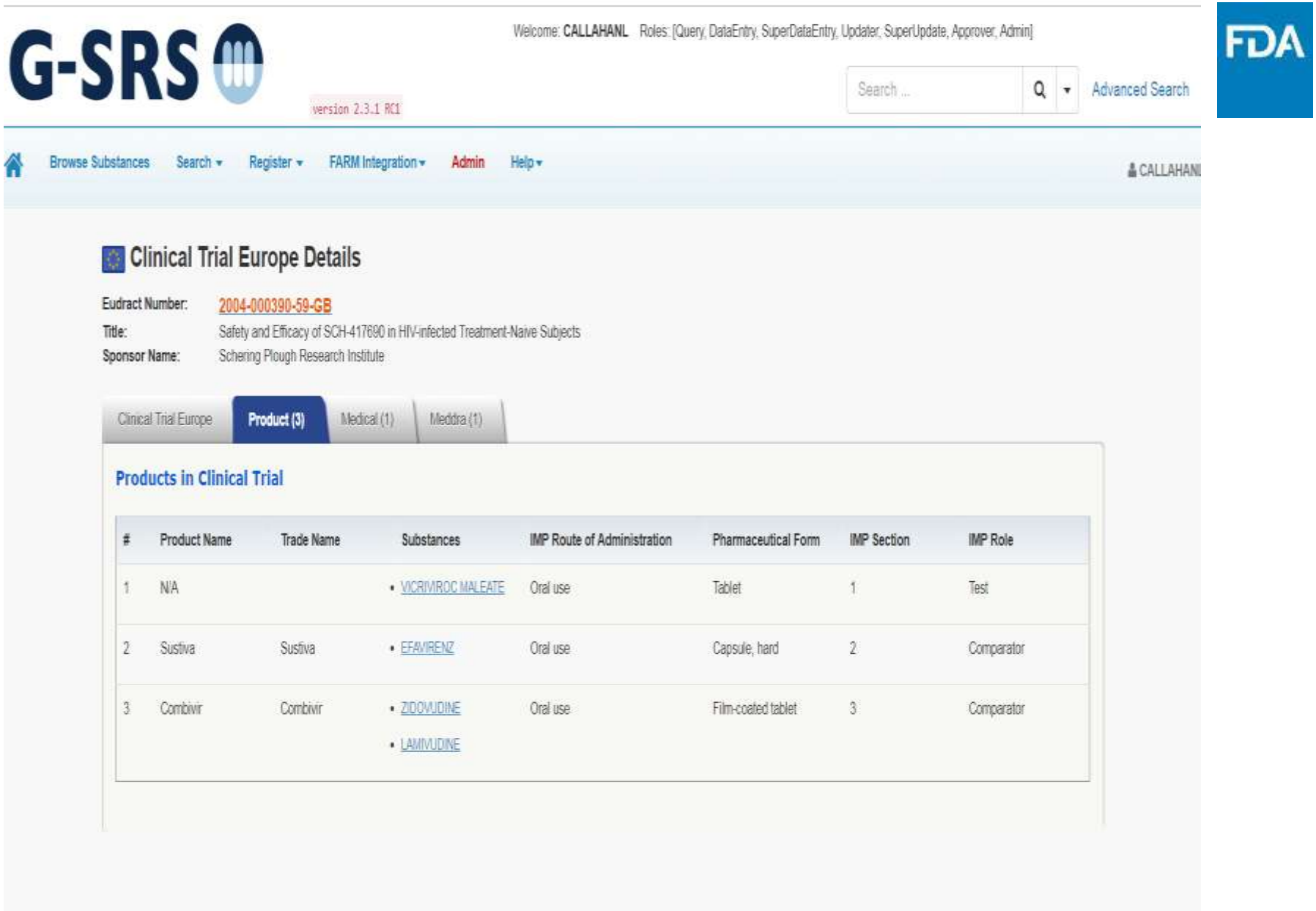
3'-CHLORO-3'-DEOXYTHYMIDINE

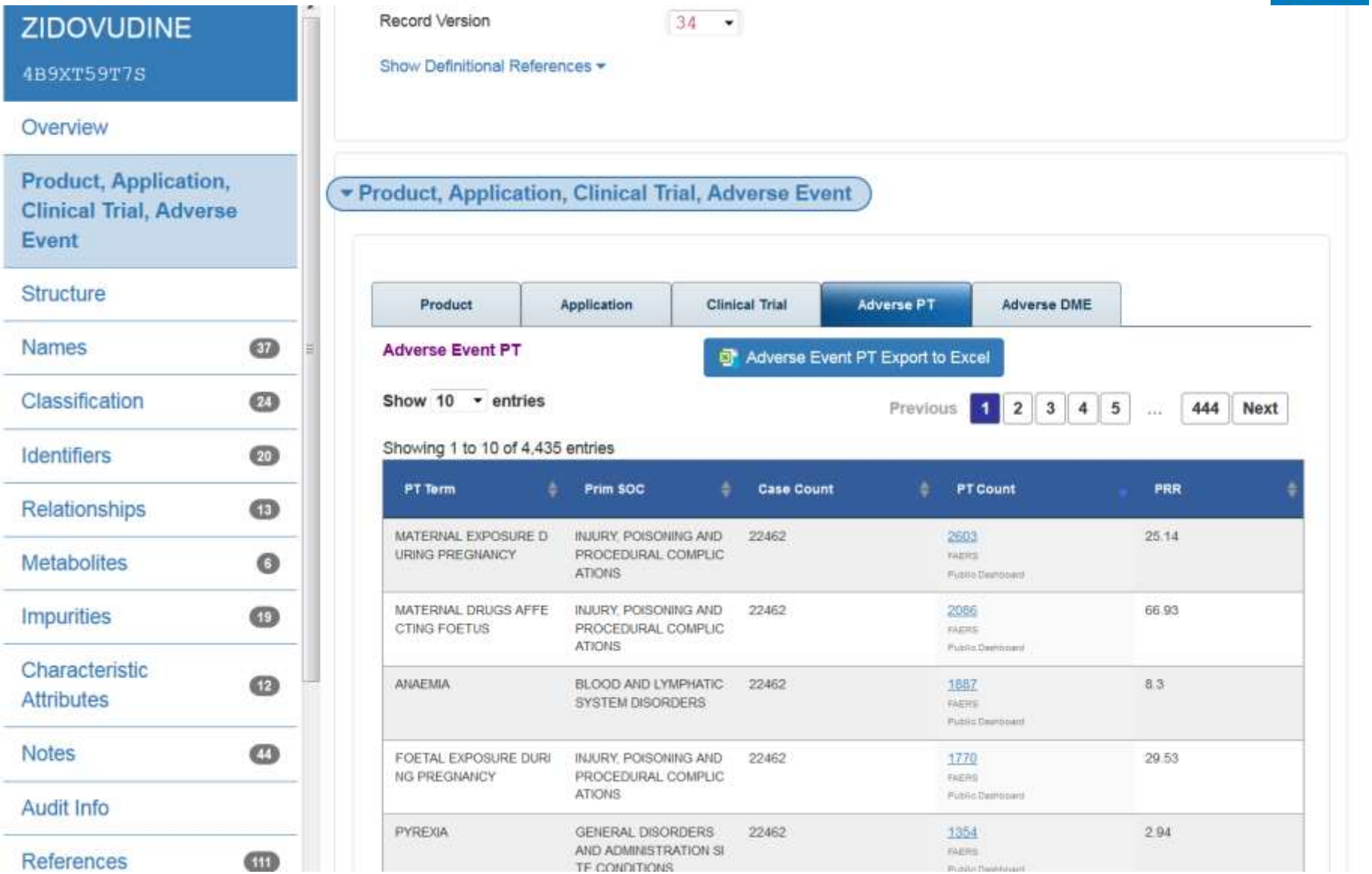
Mediator Substance	Details
none	**Interaction Type** CHROMATOGRAPHIC PURITY (HPLC/UV) **Amount:** RELATIONSHIP_AMOUNT [<1] PERCENT PEAK AREA (limits)

Index	Source Text / Citation	Source Type	Tags	Document	Date Accessed
38	ZIDOVUDINE MONOGRAPH [EP 7.6]	EUROPEAN PHARMACOPEIA	NOMEN		
39	0148163AA->[]->0769357AA	BDNUM	NOMEN		

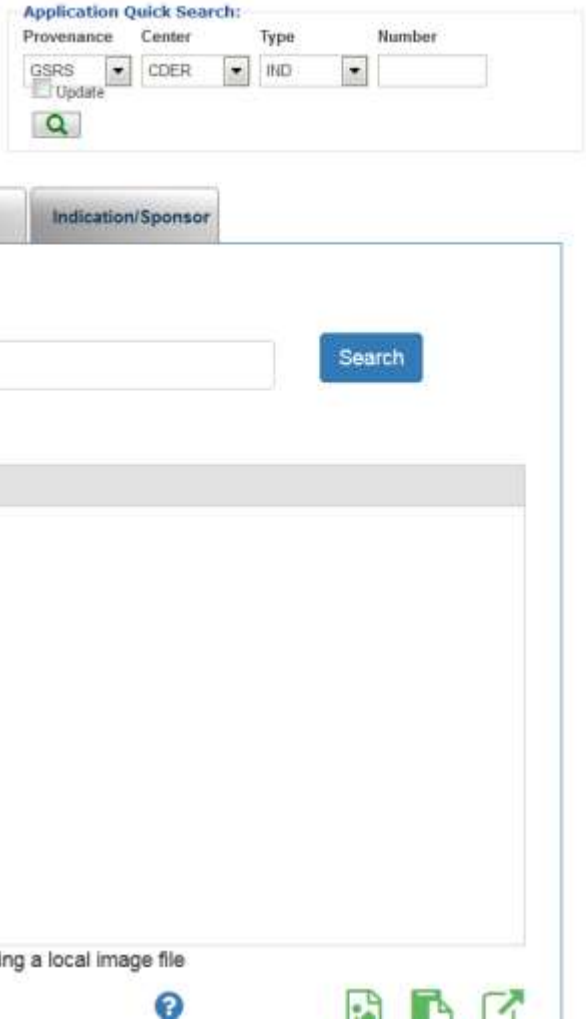
8GQZ0LXH8C IMPURITY -> PARENT hide view 2 reference(s)


ZIDOVUDINE
4B9XT59T7S
Overview
Product, Application, Clinical Trial, Adverse Event
Structure
Names 37
Classification 24
Identifiers 20
Relationships 13
Metabolites 6
Impurities 19
Characteristic Attributes 12
Notes 44
Audit Info
References 111
Record Version 34
Show Definitional References
Product, Application, Clinical Trial, Adverse Event
Product
Application
Clinical Trial
Adverse PT
Adverse DME
Clinical Trial US
Clinical Trial EU
Clinical Trial US
Clinical Trial US Export to Excel
Show 10 entries
Previous 1 2 3 4 5 ... 42 Next
Showing 1 to 10 of 415 entries
NCT Number
Title
Sponsor
Conditions
Outcome Measures
NCT00000625
ClinicalTrials.gov
A Randomized, Double-Blind Phase II/III Trial of Monotherapy vs. Combination Therapy With Nucleoside Analogs in HIV-Infected Persons With CD4 Cells of 200-500/mm3
National Institute of Allergy and Infectious Diseases (NIAID)|Bristol-Myers Squibb|Glaxo Wellcome
HIV Infections
NCT00000628
ClinicalTrials.gov
A Pharmacokinetic Study of L-697,661 Alone and in Combination With Zidovudine
Merck Sharp & Dohme Corp.|National Institute of Allergy and Infectious Diseases (NIAID)
HIV Infections


G-SRS
version 2.3.1 RC1
Welcome: CALLAHANL Roles: [Query, DataEntry, SuperDataEntry, Updater, SuperUpdate, Approver, Admin]
Search ...
Advanced Search
FDA
Browse Substances
Search
Register
FARM Integration
Admin
Help
CALLAHANL
Clinical Trial Europe Details
Eudract Number: 2004-000390-59-GB
Title: Safety and Efficacy of SCH-417690 in HIV-infected Treatment-Naive Subjects
Sponsor Name: Schering Plough Research Institute
Clinical Trial Europe
Product (3)
Medical (1)
Meddra (1)
Products in Clinical Trial
Product Name Trade Name Substances IMP Route of Administration Pharmaceutical Form IMP Section IMP Role
1 N/A • VICRIVIROC MALEATE Oral use Tablet 1 Test
2 Sustiva Sustiva • EFAVIRENZ Oral use Capsule, hard 2 Comparator
3 Combivir Combivir • ZIDOVUDINE Oral use Film-coated tablet 3 Comparator
• LAMIVUDINE


ZIDOVUDINE
4B9XT59T7S
Overview
Product, Application, Clinical Trial, Adverse Event
Structure
Names 37
Classification 24
Identifiers 20
Relationships 13
Metabolites 6
Impurities 19
Characteristic Attributes 12
Notes 44
Audit Info
References 111
Record Version 34
Show Definitional References
Product, Application, Clinical Trial, Adverse Event
Product
Application
Clinical Trial
Adverse PT
Adverse DME
Adverse Event PT
Adverse Event PT Export to Excel
Show 10 entries
Previous 1 2 3 4 5 ... 444 Next
Showing 1 to 10 of 4,435 entries
PT Term
Prim SOC
Case Count
PT Count
PRR
MATERNAL EXPOSURE DURING PREGNANCY
INJURY, POISONING AND PROCEDURAL COMPLICATIONS
22462
2603
25.14
MATERNAL DRUGS AFFECTING FOETUS
INJURY, POISONING AND PROCEDURAL COMPLICATIONS
22462
2086
66.93
ANAEMIA
BLOOD AND LYMPHATIC SYSTEM DISORDERS
22462
1687
8.3
FOETAL EXPOSURE DURING PREGNANCY
INJURY, POISONING AND PROCEDURAL COMPLICATIONS
22462
1770
29.53
PYREXIA
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
22462
1354
2.94

Advanced Search



Register a Chemical

Register a Protein

Register a Structurally Diverse Substance

Register a Polymer

Register a Nucleic Acid

Register a Mixture

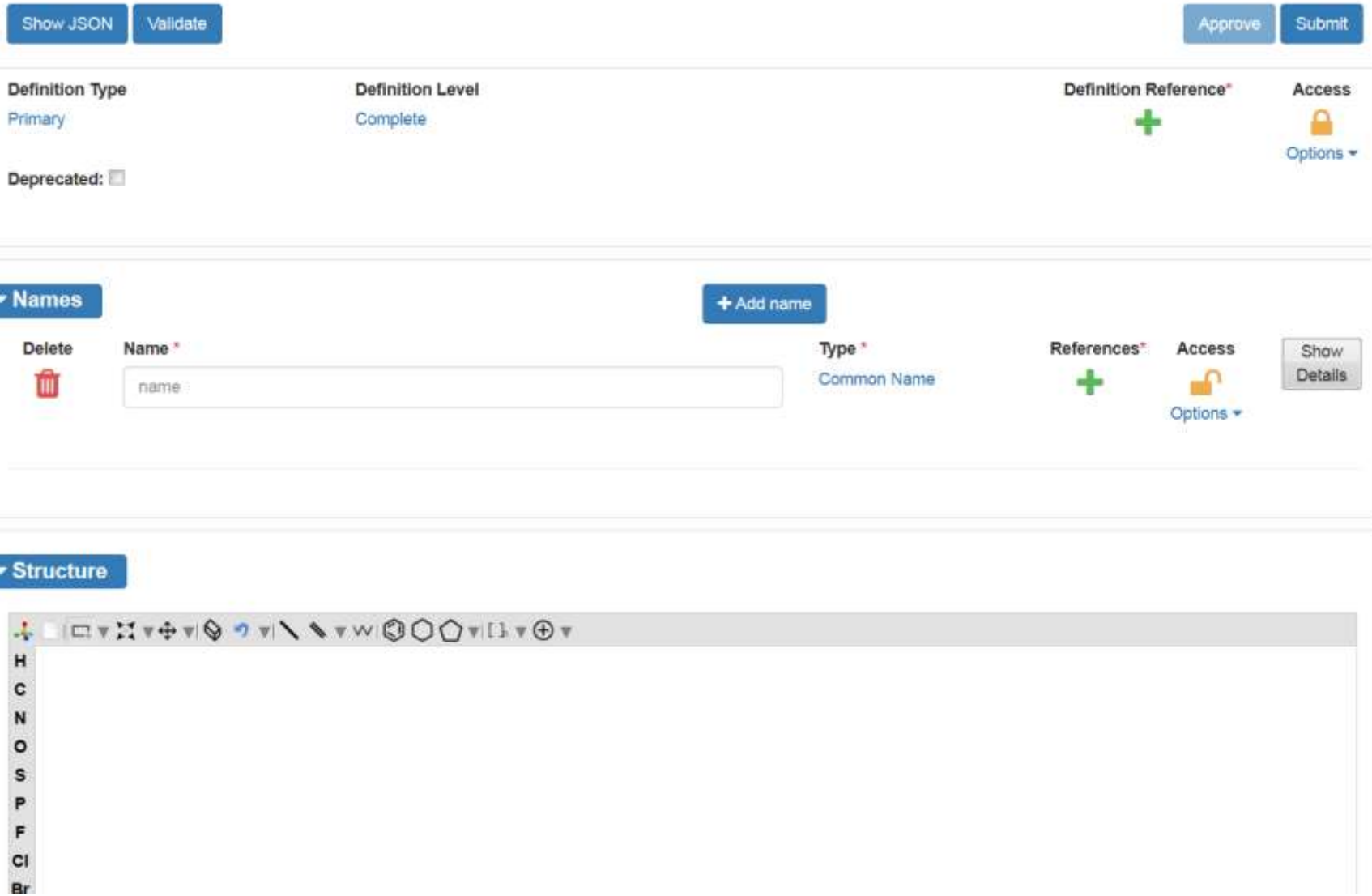
Register a Concept

Register a Group 1 Specified Substance

Register a Group 2 Specified Substance

Register a Group 3 Specified Substance

Register a Group 4 Specified Substance


Show JSON
Validate
Approve
Submit
Definition Type
Primary
Definition Level
Complete
Definition Reference*
Access
Options
Deprecated:
Names
+ Add name
Delete
Name *
name
Type *
Common Name
References*
Access
Options
Show Details
Structure
H
C
N
O
S
P
F
Cl
Br

Submit

Register Product

* = Required field

Full Product Name
Full Product Name

Product Name Type
Product Name Type...

Add More Product Name

Add Term and Term Part

Non Proprietary Name/INN/USAN Name/Generic Name
Non Proprietary Name/INN/USAN Name/Generic Name

Proprietary Name/Invented Name
Proprietary Name/Invented Name

Dosage Form/Pharmacedical Dosage Form
Dosage Form/Pharmacedical Dosage Form...

Compose Product Name
Compose Product Name

Release Characteristic
Release Characteristic...

Strength Characteristic
Strength Characteristic

Country Code
Country Code...

Language
English

Product Code
Product Code

Product Code Type
Product Code Type...

Add More Code

Product Type
Product Type...

Status
Status...

Public Domain
Public Domain...

Source
source

Source Type
Source Type...

Unit Of Presentation
Unit of Presentation...

Route Of Administration
Route of Administration...

Application Type
Application Type...

Application Number
Application Number

Company Name
Company Name

Company Address
Company Address

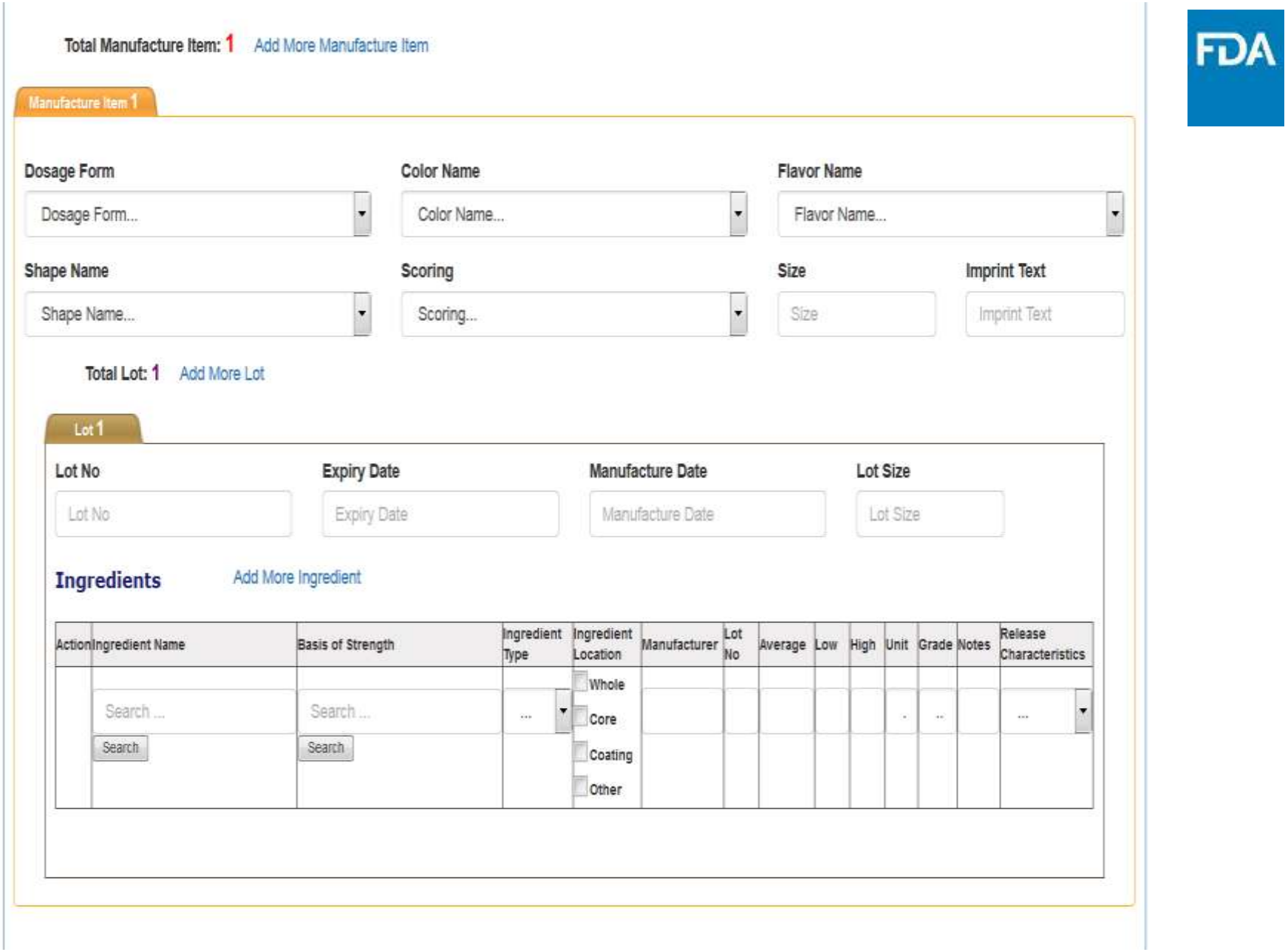
Company Role
Company Rol

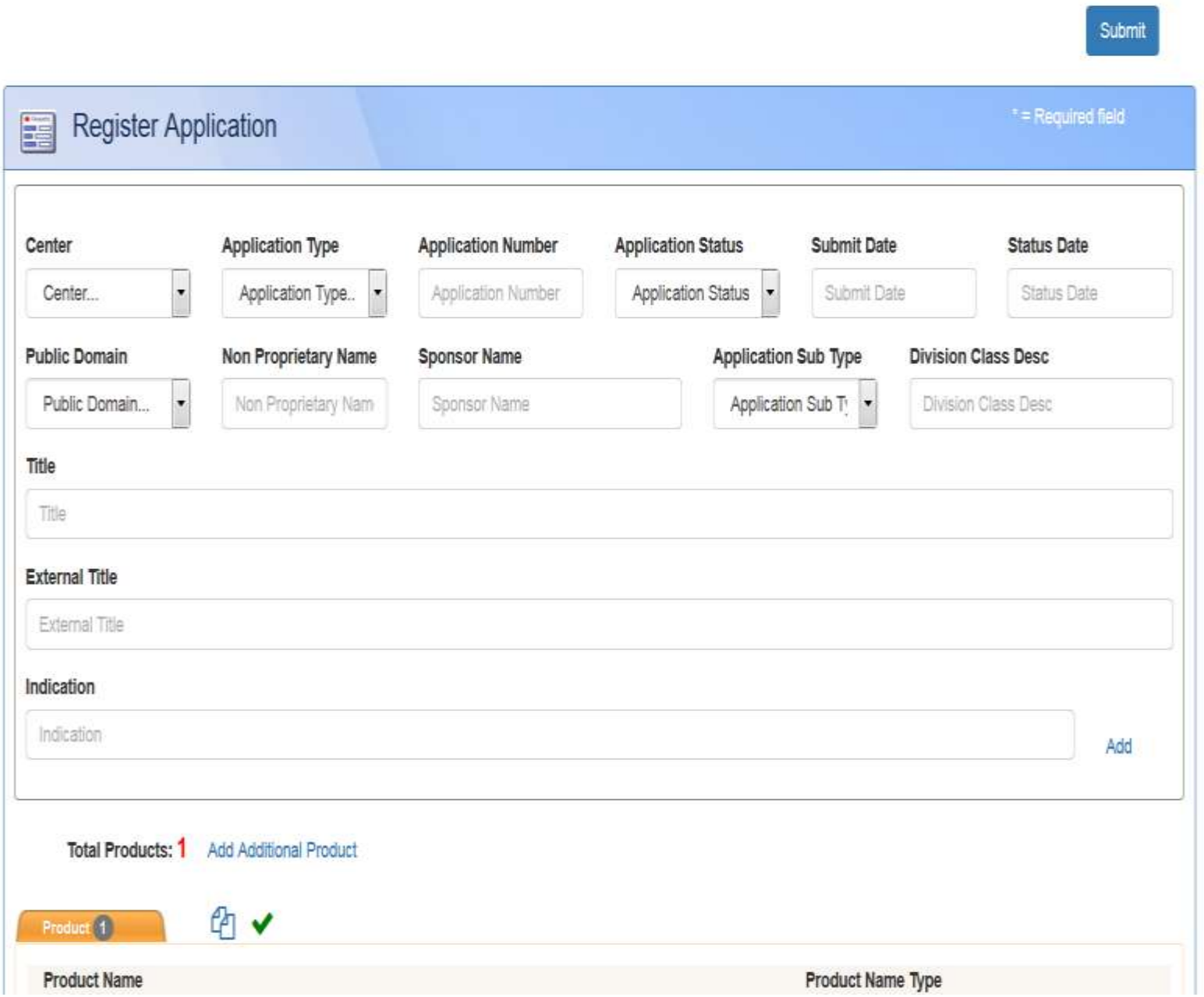
Company Code
Company Code

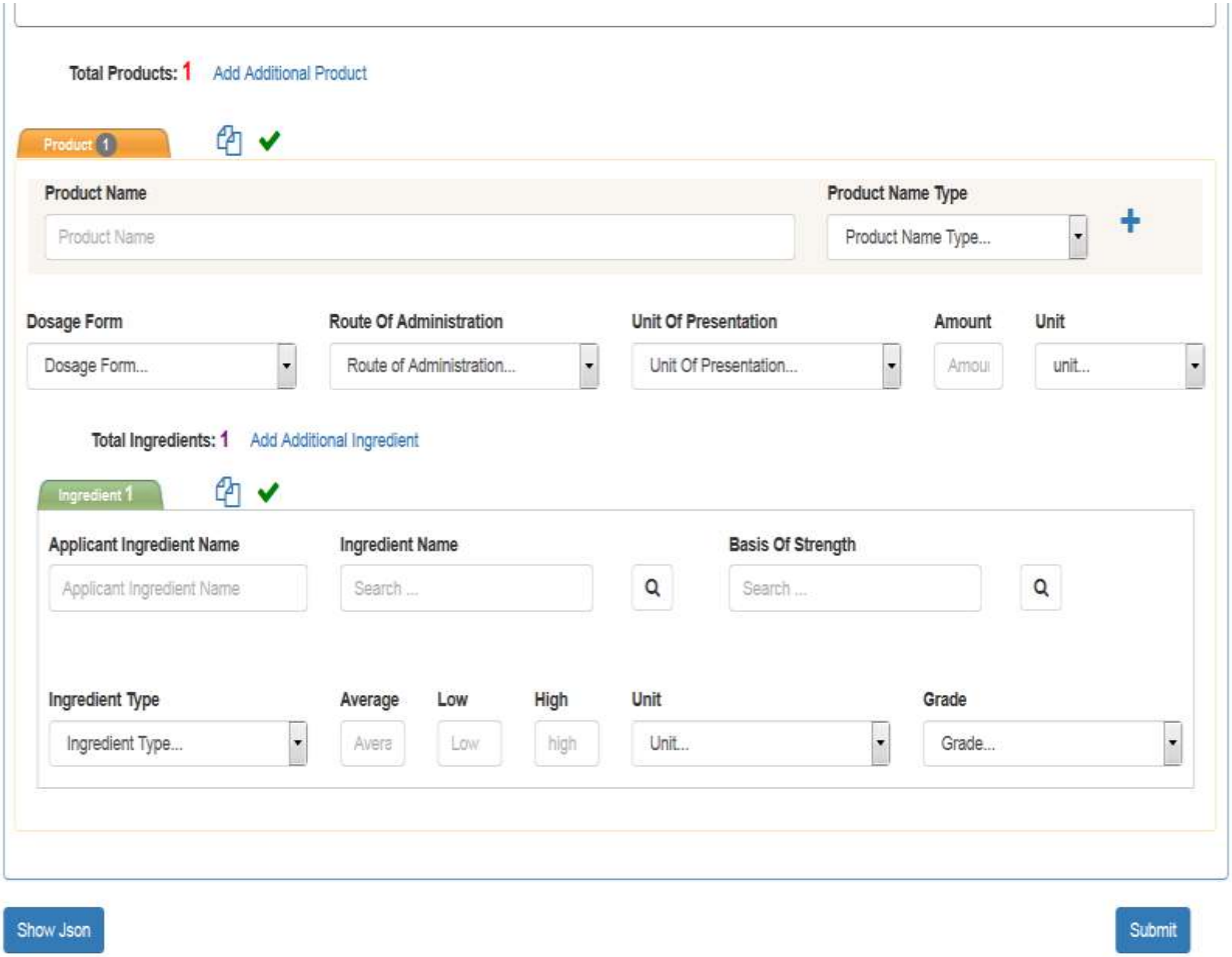
Company Code Type
Company Coc

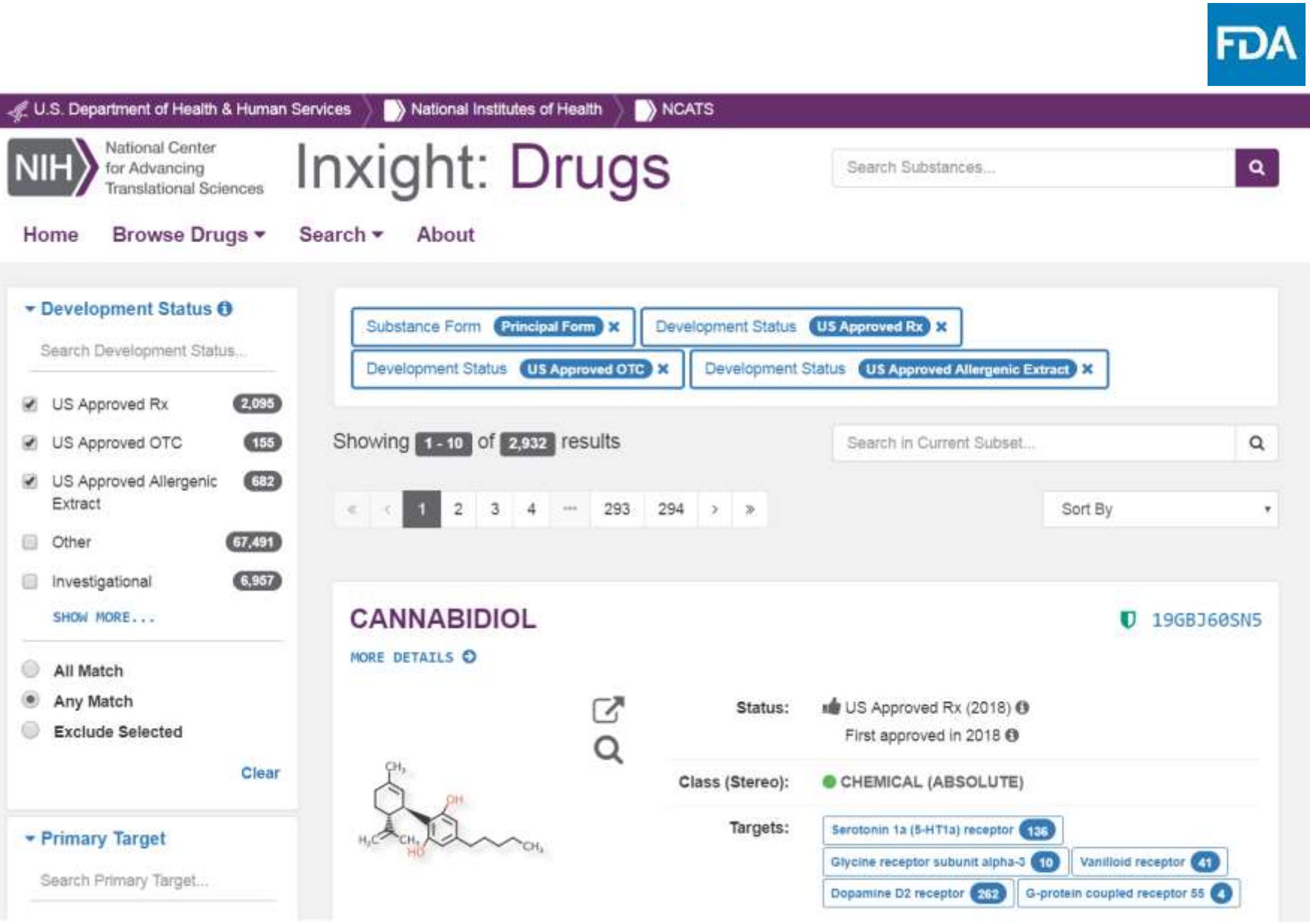
Add More

Total Manufacture Item: 1 Add More Manufacture Item

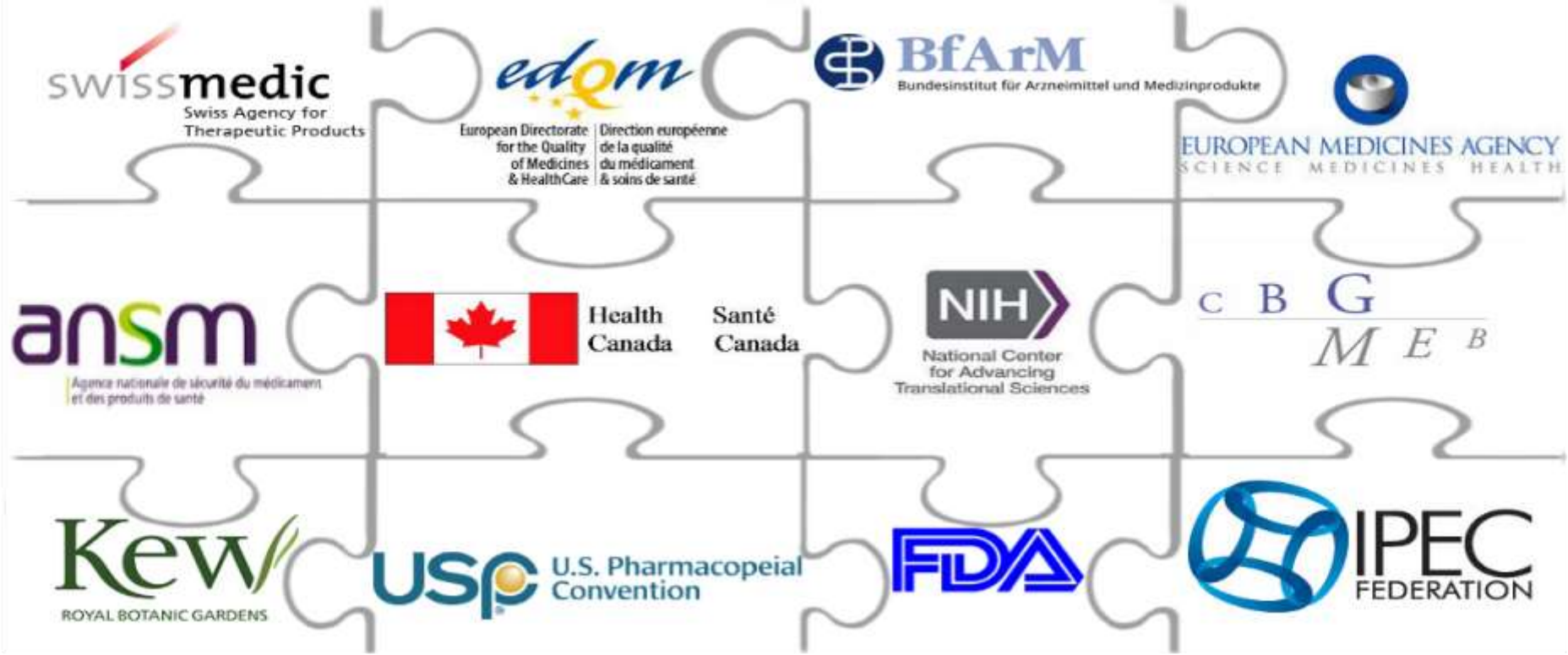

Total Manufacture Item: 1
Add More Manufacture Item
Manufacture Item 1
Dosage Form
Dosage Form...
Color Name
Color Name...
Flavor Name
Flavor Name...
Shape Name
Shape Name...
Scoring
Scoring...
Size
Size
Imprint Text
Imprint Text
Total Lot: 1
Add More Lot
Lot 1
Lot No
Lot No
Expiry Date
Expiry Date
Manufacture Date
Manufacture Date
Lot Size
Lot Size
Ingredients
Add More Ingredient
Action
Ingredient Name
Basis of Strength
Ingredient Type
Ingredient Location
Manufacturer
Lot No
Average
Low
High
Unit
Grade
Notes
Release Characteristics
Search ...
Search
Search ...
Search
Whole
Core
Coating
Other


Submit
Register Application
* = Required field
Center
Center...
Application Type
Application Type..
Application Number
Application Number
Application Status
Application Status
Submit Date
Submit Date
Status Date
Status Date
Public Domain
Public Domain...
Non Proprietary Name
Non Proprietary Nam
Sponsor Name
Sponsor Name
Application Sub Type
Application Sub T
Division Class Desc
Division Class Desc
Title
Title
External Title
External Title
Indication
Indication
Add
Total Products: 1
Add Additional Product
Product 1
Product Name
Product Name Type


Total Products: 1
Add Additional Product
Product 1
Product Name
Product Name
Product Name Type
Product Name Type...
Dosage Form
Dosage Form...
Route Of Administration
Route of Administration...
Unit Of Presentation
Unit Of Presentation...
Amount
Amoui
Unit
unit...
Total Ingredients: 1
Add Additional Ingredient
Ingredient 1
Applicant Ingredient Name
Applicant Ingredient Name
Ingredient Name
Search ...
Basis Of Strength
Search ...
Ingredient Type
Ingredient Type...
Average
Avera
Low
Low
High
high
Unit
Unit...
Grade
Grade...
Show Json
Submit


FDA
U.S. Department of Health & Human Services
National Institutes of Health
NCATS
NIH
National Center for Advancing Translational Sciences
Inxight: Drugs
Search Substances...
Home
Browse Drugs
Search
About
Development Status
Search Development Status...
US Approved Rx 2,095
US Approved OTC 155
US Approved Allergenic Extract 682
Other 67,491
Investigational 6,957
SHOW MORE...
All Match
Any Match
Exclude Selected
Clear
Primary Target
Search Primary Target...
Substance Form Principal Form
Development Status US Approved Rx
Development Status US Approved OTC
Development Status US Approved Allergenic Extract
Showing 1 - 10 of 2,932 results
Search in Current Subset...
1 2 3 4 293 294
Sort By
CANNABIDIOL
19GBJ60SN5
MORE DETAILS
Status: US Approved Rx (2018)
First approved in 2018
Class (Stereo): CHEMICAL (ABSOLUTE)
Targets:
Serotonin 1a (5-HT1a) receptor 136
Glycine receptor subunit alpha-3 10
Vanilloid receptor 41
Dopamine D2 receptor 262
G-protein coupled receptor 55 4

Working Collaboratively



GInAS Meetings

- To get the software and data from NCATS
  - https://tripod.nih.gov/ginas
- Meetings and Teleconferences
  - Free and Open to Public
- To Get on the GInAS Notification List
  - Sign-up at https://tripod.nih.gov/ginas
- NCATS Inxight Link
  - https://drugs.ncats.io/
- NLM-FDA Link
  - https://fdasis.nlm.nih.gov/srs/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