

Structured Product Labeling and Supply Chain Integrity

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In This Presentation

- ⌘ Brief review transition to electronic format of data submission to FDA.
- ⌘ Structured Product Labeling (SPL) standard and integrity within the drug supply chain.
- ⌘ CDER Direct and common SPL documents used in Supply Chain Management.
- ⌘ Scenarios of SPL data use in management of supply chain integrity.



History of Electronic Submissions

- ⌘ The Paperwork Reduction Act of 1995
- ⌘ Image Solutions, Inc. first electronic submission to FDA in 1997 with Sandoz (Novartis)
- ⌘ Portable Document Format (PDF)
- ⌘ Extensible Markup Language (XML)



XML Language

```
directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</paragraph>
value="20121022"/>
</section>
</component>
<component>
<section ID="G81e48442-3c75-4441-8d7c-0a03266b696"/>
<code code="50565-1" codesystem="2.16.840.1.113883.6.1" displayName="OTC - KEEP OUT OF REACH OF CHILDREN SECTION"/>
<text>
<paragraph ID="Gde7a153c-f6bf-4652-8fd8-79347796fc08">In case of overdose, get medical help or contact a
Poison Control Center right away.</paragraph>
</text>
</section>
</component>
<component>
<section ID="G770a3473-1aea-48b3-b934-aec685c76bd3"/>
<id root="a40a840c-aa70-4999-bf21-cd7692f23716"/>
<code code="34068-7" codesystem="2.16.840.1.113883.6.1" displayName="DOSAGE & ADMINISTRATION SECTION"/>
<title>DIRECTIONS</title>
<list listType="unordered" ID="Ga2758bb7-fd11-4e70-9926-7649c955a44d" styleCode="Square">
<item>
<content styleCode="bold">do not take more than directed</content>
</item>
<item>
<content styleCode="bold">the smallest effective dose should be used</content>
</item>
<item>adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist</item>
<item>if pain or fever does not respond to 1 capsule, 2 capsules may be
used</item>
<item>children under 12 years: ask a doctor</item>
</list>
</text>
<effectiveTime value="20121022"/>
</section>
</component>
<component>
<section
ID="G0f6a3ea9-d168-4be8-a645-4ce9e6c3b940"/>
<id root="1e01a695-7d77-43ce-8741-a3f72950c707"/>
<code code="42229-5" codesystem="2.16.840.1.113883.6.1" displayName="SPL
UNCLASSIFIED SECTION"/>
<list listType="unordered" ID="G49c0009b-4161-4a8e-babc-c2f6d3aa2d94" styleCode="Square">
<item>
<content styleCode="bold">each capsule contains:</content> potassium 20 mg</item>
<item>read all warnings and directions before use. Keep
carton.</item>
<item>store at 20-25°C (68-77°F)</item>
<item>avoid excessive heat above 40°C (104°F)</item>
</list>
<effectiveTime value="20121022"/>
</section>
</component>
<component>
<section ID="G825e4ebb-6d09-41b2-8589-a8d1bd0f5a28"/>
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root="11cbe515-79f6-4fe7-a396-6df03bd7bc01"/>
<code code="51727-6" codesystem="2.16.840.1.113883.6.1" displayName="INACTIVE INGREDIENT SECTION"/>
<title>INACTIVE
INGREDIENTS</title>
<text>
<paragraph ID="G8410fc91-0741-4018-93a0-d25f6e34c5e0">FD&#x26; green no. 3, gelatin, light mineral oil, pharmaceutical ink, polyethylene glycol,
potassium hydroxide, purified water, sorbitan, sorbitol</paragraph>
</text>
</section>
</component>
<component>
<section ID="G73b44294-0ed6-40bd-83d2-250d51973814"/>
<id root="ed603046-8cab-4b11-9a56-63b3b39dad9e"/>
<code code="53413-1" codesystem="2.16.840.1.113883.6.1"
displayName="OTC - QUESTIONS SECTION"/>
<title>QUESTIONS OR COMMENTS</title>
<text>
<paragraph ID="Ge467ff10-18cf-4d6a-a9f8-aaa59c4c14be">call toll free
1-800-88-ADVIL</paragraph>
</text>
<effectiveTime value="20121022"/>
</section>
</component>
<component>
<section ID="G2ec33e3a-2763-4936-ba61-a1c75c9af72"/>
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<code code="51945-4"
codesystem="2.16.840.1.113883.6.1" displayName="PACKAGE LABEL, PRINCIPAL DISPLAY PANEL"/>
<title>PRODUCT PACKAGING</title>
<text>
<paragraph
ID="Gbeb77835-5a4a-4e0e-9a6f-32842f47ee1f">The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.</paragraph>
<paragraph ID="G0f32d34f-8af1-4187-85f7-f3ce8aa6bae0">
<content styleCode="bold">Advil Liqui-Gels</content>
</paragraph>
<paragraph
ID="G9ea87f8d-7697-499d-a9a0-76afaa70e231">solubilized Ibuprofen Capsules, 200 mg</paragraph>
<paragraph ID="G08de737a-95bf-48b3-8c5a-3a6aaa262401">Pain Reliever/Fever Reducer
(NSAID)</paragraph>
<paragraph ID="G9af288c4-88d8-464d-939e-0528dd54ace3">80 Liqui-Gels* *Liquid Filled Capsules</paragraph>
<paragraph
ID="G10fb614b-648b-4301-98fd-54fb7b0330d6">
<content styleCode="bold">Liquid Filled Capsules</content>
</paragraph>
<paragraph
ID="Ga9397d46-0ad2-47ca-98d6-3d4396d9d2f6">distributed by: Pfizer</paragraph>
<paragraph ID="Ga0cdfb5b-8f39-4a74-9972-7bb06fde874f">Madison, NJ 07940 USA
<paragraph ID="G53ff8af5-17af-4642-bac9-819fb6caf91d">LIQUI-GELS is a trademark or registered trademark of Catalent Pharma Solutions.
referencedObject="G69ec7423-075b-43ff-85bc-2e963ee2522e"/>
<text>
<text>Advil Liqui-Gels Packaging</text>
<value xsi:type="ED" mediaType="image/jpeg"/>
</text>
</section>
</component>
</structuredBody>
</component>
</document>
```

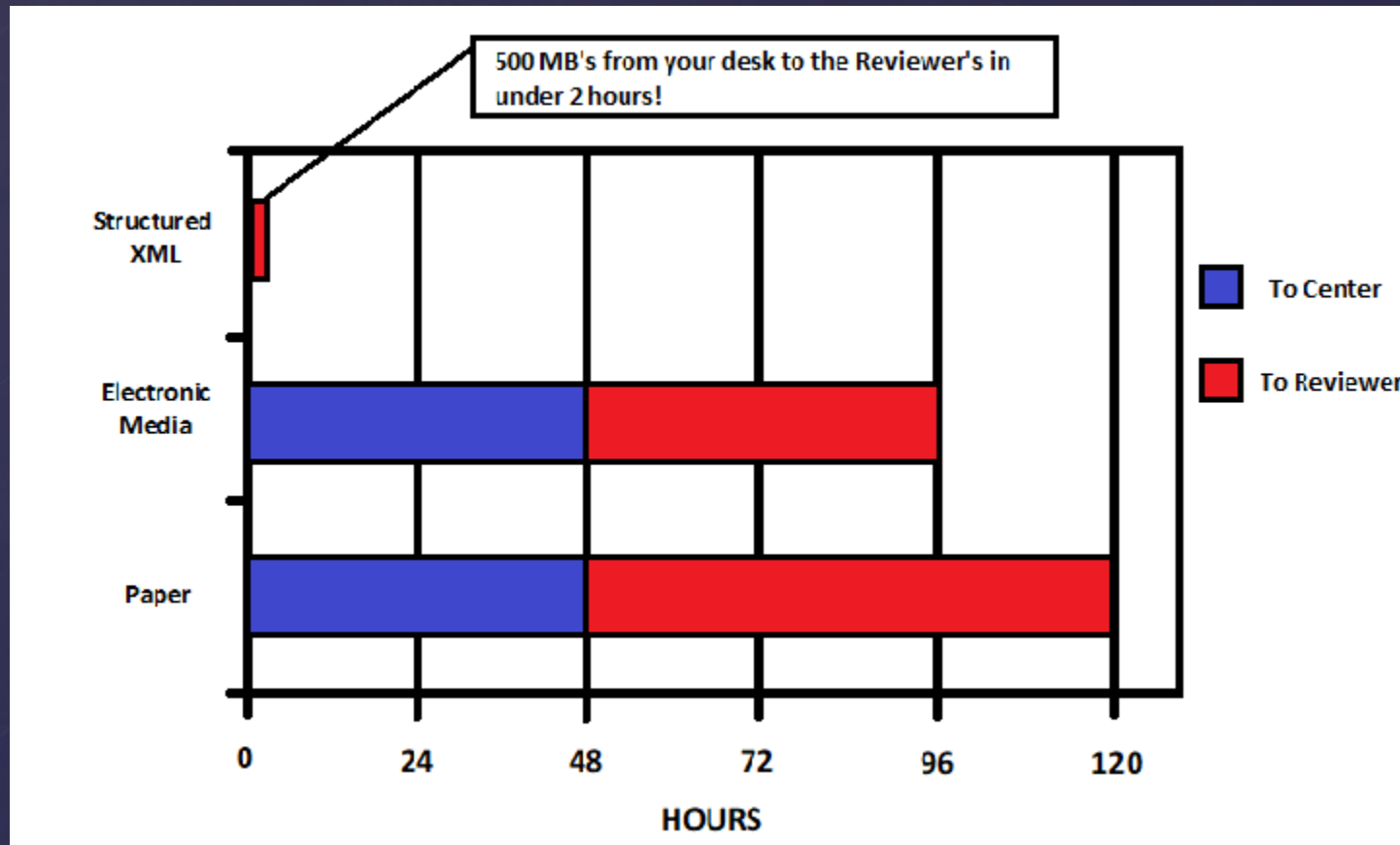


Benefits of Electronic Submission in XML Format

- ⌘ Paper -> Electronic Media -> XML
- ⌘ Automated/electronic processing – “computer-readable”
- ⌘ Electronic validation – validation procedures
- ⌘ Granular document approach
- ⌘ Moved between systems and combined with other data sources
- ⌘ Easy update/revision



Benefits of Structured XML Documents - Time



Health Information Management Technologies Supported by XML

- ⌘ Electronic Prescribing
- ⌘ Electronic Health Record (EHR)
- ⌘ National Library of Medicine (DailyMed) – populated by 101,896 current SPLs in XML
 - ⌘ Reimbursement
 - ⌘ Medicare
 - ⌘ Medicaid
- ⌘ Additional Downstream Users



Building a Structured XML Submission

- ⌘ FDA provided to industry as low cost options
 - ⌘ Pragmatic Structured Product Labeling Editor
 - ⌘ eSubmitter
 - ⌘ **CDER Direct**
- ⌘ Notepad
- ⌘ Commercially available customizable software
- ⌘ Conversion Vendors



Structured Product Labeling (SPL) and the Drug Supply Chain



What is Structured Product Labeling (SPL)?

- ⌘ Structure Product Labeling –
 - ⌘ Data standard for submitting, viewing, and exchanging information about products and facilities
 - ⌘ XML format – extensible mark-up language
- ⌘ Health Level Seven International (HL7)
- ⌘ SPL stands for “Structured Product Labeling” but covers product information beyond labeling



Document Types Currently in SPL

ANIMAL COMPOUNDED DRUG LABEL
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
BULK INGREDIENT
BULK INGREDIENT - ANIMAL DRUG
CELLULAR THERAPY
COSMETIC
DIETARY SUPPLEMENT
DRUG FOR FURTHER PROCESSING
ESTABLISHMENT DE-REGISTRATION
ESTABLISHMENT REGISTRATION
GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION
HUMAN COMPOUNDED DRUG LABEL
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG LABEL
IDENTIFICATION OF CBER-REGULATED GENERIC DRUG FACILITY



Document Types Currently in SPL

INDEXING - BILLING UNIT
INDEXING - BIOLOGICAL DRUG SUBSTANCE
INDEXING - INDICATION
INDEXING - PHARMACOLOGIC CLASS
INDEXING - PRODUCT CONCEPT
INDEXING - RISK EVALUATION & MITIGATION STRATEGIES
INDEXING - SUBSTANCE
INDEXING - WARNING LETTER ALERT
LICENSE BLOOD INTERMEDIATES/PASTE LABEL
LICENSED MINIMALLY MANIPULATED CELLS LABEL
LICENSED VACCINE BULK INTERMEDIATE LABEL
LOT DISTRIBUTION DATA
MEDICAL DEVICE
MEDICAL FOOD
NO CHANGE NOTIFICATION



Document Types Currently in SPL

NON-STANDARDIZED ALLERGENIC LABEL
NDC LABELER CODE INACTIVATION
NDC LABELER CODE INACTIVATION - ANIMAL DRUG
NDC LABELER CODE REQUEST - ANIMAL DRUG
NDC/NHRIC LABELER CODE REQUEST
OTC ANIMAL DRUG LABEL
OTC MEDICAL DEVICE LABEL
OTC TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL
OTC TYPE B MEDICATED FEED ANIMAL DRUG LABEL
OTC TYPE C MEDICATED FEED ANIMAL DRUG LABEL
OUT OF BUSINESS NOTIFICATION
PLASMA DERIVATIVE
PRESCRIPTION ANIMAL DRUG LABEL
PRESCRIPTION MEDICAL DEVICE LABEL
RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL



Document Types Currently in SPL

REMS CONVERSION TO SHARED SYSTEM
REMS RELEASE
RISK EVALUATION & MITIGATION STRATEGIES
STANDARDIZED ALLERGENIC
VACCINE LABEL
VFD TYPE A MEDICATED ARTICLE ANIMAL DRUG LABEL
VFD TYPE B MEDICATED FEED ANIMAL DRUG LABEL
VFD TYPE C MEDICATED FEED ANIMAL DRUG LABEL
WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT
WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT



Common SPLs for Drug Supply Chain

⌘ In the order of submissions, SPL in XML is the standard for:

⌘ NDC/NHRIC Labeler Code Request

⌘ Establishment Registration

⌘ Product Listing and Certification



Required by the Regulations

- ⌘ Establishment registration and drug listing:
 - ⌘ Section 510 of the Federal Food, Drug, and Cosmetic Act
 - ⌘ 207 of Title 21 of the Code of Federal Regulations (CFR)
- ⌘ What?
- ⌘ When?



Establishment Registration and Product Listing in SPL

- ⌘ List of all current drug manufacturers
- ⌘ Current inventory of all drugs in U.S. commercial distribution
- ⌘ Available to:
 - ⌘ FDA
 - ⌘ Public
 - ⌘ Health care professionals
 - ⌘ Healthcare industry access



SPL Data Received From Over 80 Countries



- ⌘ Each establishment in the supply chain registers
- ⌘ Business operations identified
- ⌘ Establishment linked to Product NDC



Specific FDA Use of Registration and Listing Data

- ⌘ Electronic Drug Registration and Listing Database
 - ⌘ Inspections
 - ⌘ Imports
 - ⌘ Post-marketing surveillance
 - ⌘ Recalls and shortage programs
 - ⌘ Adverse Event Reporting
- ⌘ Supply chain security
- ⌘ Counterterrorism
- ⌘ And many more



FDA Compliance Procedure for Registration and Listing Data

- & Surveillance
- & Compliance case
- & Deficiency letters
- & Data exclusion
- & Untitled Letters
- & Warning Letters



Supply Chain Integrity Summary

- ⌘ Current Registration and Listing via SPL provides visibility and traceability
- ⌘ Encourages interaction between supply chain participants
- ⌘ Quality Agreements/Defined responsibilities
- ⌘ Ingredient and product source



Supply Chain Integrity Summary

- ⌘ Minimize the end-user's exposure to products that are:
 - ⌘ adulterated in the traditional sense
 - ⌘ adulterated due to economic motivation
 - ⌘ misbranded containing unlabeled ingredients

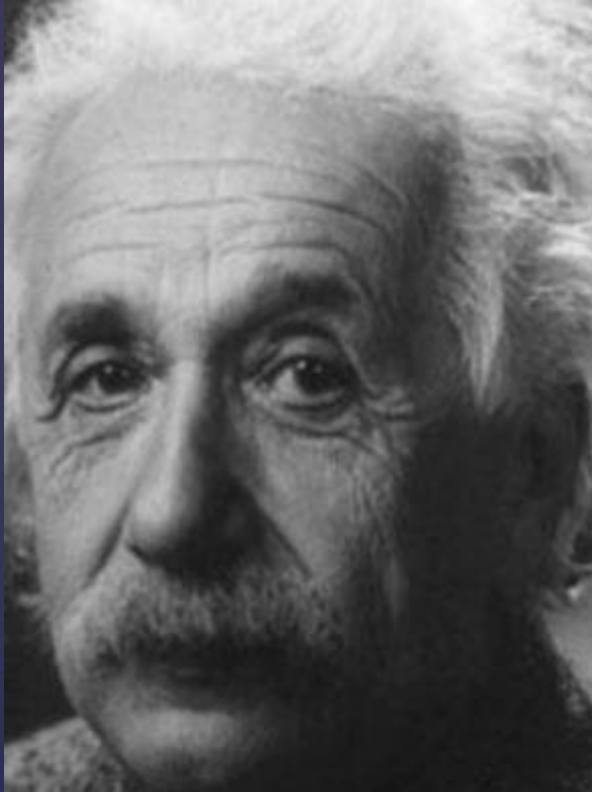


Supply Chain Integrity Summary

- ⌘ Minimize the end-user's exposure to products that are (continued):
 - ⌘ meant for destruction and stolen or diverted
 - ⌘ expired and relabeled to be sold to end-users
 - ⌘ not transported and stored according to the environmental conditions stated on the label



Integrity



Whoever is careless with the truth in
small matters cannot be trusted
with important matters.

— *Albert Einstein* —



CDER Direct and Common SPL Documents



CDER *Direct*

Electronic Submissions Portal



What is CDER Direct?

- ⌘ A web based tool for electronic registration and listing
- ⌘ Create, review, and send SPL submissions
- ⌘ User-friendly templates to build SPL in XML
- ⌘ Directly submit to FDA for internal processing
- ⌘ Initial validations and provides the FDA response to the user



Who Uses CDER Direct?

- ⌘ Individuals and Businesses responsible for:
 - ⌘ NDC Labeler Code Requests
 - ⌘ Establishment Registrations and annual updates
 - ⌘ GDUFA Facility self-identification
 - ⌘ Drug Listing
 - ⌘ Product Listing
 - ⌘ 503B outsourcing facility
 - ⌘ Registration
 - ⌘ Product reporting
 - ⌘ Wholesale Drug Distributors and Third Party Logistics Providers (WDD/3PL) Report – product transactions – product exchange



Available SPL Forms in CDER Direct

- ⌘ Labeler code Request
- ⌘ Establishment Registration/Update
- ⌘ GDUFA Self ID
- ⌘ 503B Outsourcing Facility Registration
- ⌘ 503B Outsourcing Facility Product Reporting
- ⌘ Wholesale Drug Distributors and Third Party Logistics Providers (WDD/3PL) Report – transactions and product exchange
- ⌘ Product Listing and Certification



Product Listing and Certification SPLs in CDER Direct

- ⌘ Bulk Ingredient
- ⌘ Cellular Therapy
- ⌘ Drug for Further Processing
- ⌘ Human Compounded Drug Label
- ⌘ Human OTC Drug Label
- ⌘ Human Prescription Drug Label
- ⌘ Non-Standardized Allergenic Label
- ⌘ Plasma Derivative
- ⌘ Standardized Allergenic
- ⌘ Vaccine Label
- ⌘ Blanket No Changes Certification of Product Listings (October 1st and December 31st.)



CDER Direct Log-In

← → ↻ Secure | https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP:104841793868729::::

U.S. Department of Health & Human Services

FDA **CDER Direct**
Electronic Submissions Portal

LOGIN

Username:

Password:

Under [18 U.S.C. 1001](#), anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I Understand.

LOGIN [Forgot your password?](#)

QUICK LINKS

- [Create Account](#)
- [Resources](#)
- [Tutorials](#)
- [Help Desk](#)
- [FAQs](#)

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your Username and Password.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording. Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

Browser Compatibility: The CDER Direct portal currently works best with the following browsers:

- Microsoft Internet Explorer 8 (IE8) and above
- Firefox version 28 and above
- Google Chrome 44.0.2403.130
- Safari 10.0.1 and above

NOTIFICATIONS

FDA

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[A to Z Index](#) | [Follow FDA](#) | [FDA Voice Blog](#) | [Privacy](#)



CDER Direct NDCLCR

Home > NDC/NHRC Labeler Code Request > SPL Submission

[SAVE AS DRAFT](#) [<< RETURN](#)

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: *	<div>NDC/NHRC LABELER CODE REQUEST --Select One-- NDC/NHRC LABELER CODE REQUEST Generate New NDC LABELER CODE INACTIVATION Generate New 00a30001-200a-c2ea-8053-2a91a00a73da</div>	Version Number: *	<input type="text" value="1"/>
Set ID: *		Effective Date: *	<input type="text" value="05-07-2018"/>
Root ID: *			

LABELER DETAILS

Labeler Name: *	<input type="text"/>	Labeler Code: *	<input type="text"/>
Labeler DUNS: *	<input type="text"/>		

LABELER CONTACT DETAILS

Contact Name: *	<input type="text"/>
Contact Email: *	<input type="text"/>
Contact Phone: *	<input type="text"/> Format
Phone Extension: *	<input type="text"/>

LABELER CONTACT ADDRESS

Country: *	<div>-Select Country-</div>
Street Address: *	<input type="text"/>
City: *	<input type="text"/>
State/Province: *	<input type="text"/>
Postal Code: *	<input type="text"/>



CDER Direct NDCLCR

— ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABEL	U.S. AGENT
<input type="checkbox"/> San	Agent Name: <input type="text"/>
Country	Agent DUNS: <input type="text"/>
Street A	Agent Email: <input type="text"/>
City: *	Agent Phone: <input type="text"/> Format
State/Pr	Phone Extension: <input type="text"/>
Postal C	
BUSI	
<input type="checkbox"/> +	
<input type="checkbox"/> *	

API/FDF ANALYTICAL TESTING
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY
FDF MANUFACTURE
CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY
IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING
ANALYSIS
DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE LABEL
API MANUFACTURE
MANUFACTURE
MEDICATED ANIMAL FEED MANUFACTURE
PACK
PARTICLE SIZE REDUCTION
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION
RELABEL
REPACK
STERILIZE
LABEL

QUALIFIER



CDER Direct ER

[Home](#) > [Establishment Registration](#) > [SPL Submission](#)

[SAVE AS DRAFT](#) [<< RETURN](#)

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

— HEADER DETAILS

Document Type: *

ESTABLISHMENT REGISTRATION

Set ID: *

6b5443ce-fc1d-04e3-e053-2991aa0a5ab6

[Generate New](#)

Version Number: *

1

Root ID: *

6b5443ce-fc1e-04e3-e053-2991aa0a5ab6

[Generate New](#)

Effective Date: *

05-03-2018

— REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: *

[Format](#)

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: *

-Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

— ESTABLISHMENTS

None

[ADD ESTABLISHMENT](#)

CDER Direct ER

ESTABLISHMENT DETAILS		ESTABLISHMENT ADDRESS	
Establishment Name: *	<input type="text"/>	Country: *	<input type="text" value="-Select Country-"/>
Establishment DUNS: *	<input type="text"/>	Street Address: *	<input type="text"/>
Establishment FEI:	<input type="text"/>	City: *	<input type="text"/>
		State/Province:	<input type="text"/>
		Postal Code:	<input type="text"/>

ESTABLISHMENT CONTACT DETAILS		ESTABLISHMENT CONTACT ADDRESS	
<input type="checkbox"/> Same as Registrant Contact Details and Address			
Contact Name: *	<input type="text"/>	Country: *	<input type="text" value="-Select Country-"/>
Contact Email: *	<input type="text"/>	Street Address: *	<input type="text"/>
Contact Phone: *	<input type="text"/>	City: *	<input type="text"/>
Phone Extension:	<input type="text"/>	State/Province:	<input type="text"/>
		Postal Code:	<input type="text"/>

U.S. AGENT	
Agent Name: *	<input type="text"/>
Agent DUNS: *	<input type="text"/>
Agent Email: *	<input type="text"/>
Agent Phone: *	<input type="text"/>
Phone Extension:	<input type="text"/>

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

IMPORTERS					
	NAME	DUNS	EMAIL	PHONE	EXTENSION
<input type="button" value="+"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

BUSINESS OPERATION(S)		
	BUSINESS OPERATION	QUALIFIER
<input type="button" value="+"/>	<input type="text" value="-Select One-"/>	<input type="text" value="-Select One-"/>



CDER Direct Product Listing

CREATE NEW PRODUCT LISTING

☒ Create a New Product Listing or Certification using a blank form
☐ Import an existing Product Listing or Certification SPL

Product Document Type: *
.....

Note: To update an existing submission, click
Dashboard.

MISSION ACCEPTED from the table in the prior page /

CONTINUE **CANCEL**

-- Select Document Type --

-- Select Document Type --
BULK INGREDIENT
CELLULAR THERAPY
DRUG FOR FURTHER PROCESSING
HUMAN COMPOUNDED DRUG LABEL
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG LABEL
NON-STANDARDIZED ALLERGENIC LABEL
PLASMA DERIVATIVE
STANDARDIZED ALLERGENIC
VACCINE LABEL



CDER Direct Product Listing

Home Product Listing and Reporting Products **Establishment Details**

SAVE ESTABLISHMENT DELETE ESTABLISHMENT << RETURN

ESTABLISHMENT DETAILS

Establishment Name: * Establishment DUNS: *

☒ Confidential

BUSINESS OPERATION(S) ⓘ

+	BUSINESS OPERATION	PRODUCT NDC
✖	MANUFACTURE ▼	<input type="text"/>



CDER Direct Product Listing

SAVE PRODUCT << RETURN

PRODUCT DATA ELEMENTS

NDC Product Code: *	<input type="text"/>	Proprietary Name: *	<input type="text"/>	Suffix: *	<input type="text"/>
Non Proprietary Name: *	<input type="text"/>	DEA Schedule: *	-Select DEA Schedule- ▼		
Dosage Form: *	-Select Dosage Form- ▼				
Route of Administration: *	<div><div>AURICULAR (OTIC) BUCCAL CONJUNCTIVAL CUTANEOUS DENTAL ELECTRO-OSMOSIS</div><div><div>▶▶▶▶▶▶</div><div>◀◀◀◀◀◀</div></div><div><div>▶▶▶▶▶▶</div><div>◀◀◀◀◀◀</div></div></div>				
Source NDC: *	<input type="text"/>				

MARKETING DETAILS

Marketing Status: *	--Select One-- ▼
Marketing Start Date: *	<input type="text"/>
Marketing Category: *	-Select Marketing Category- ▼
Application Number/Regulatory Citation: *	<input type="text"/>

ADD INGREDIENT

INGREDIENTS

None

UPLOAD IMAGE

PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)

Note: JPG files only. Package Images and other labeling should be uploaded under the Content of Labeling tab.

Select a File: **Choose File**



CDER Direct Product Listing

[Home](#) > [Product Listing and Reporting](#) > [Products](#) > [Product Details](#) > **Ingredient Details**

SAVE INGREDIENT << **RETURN**

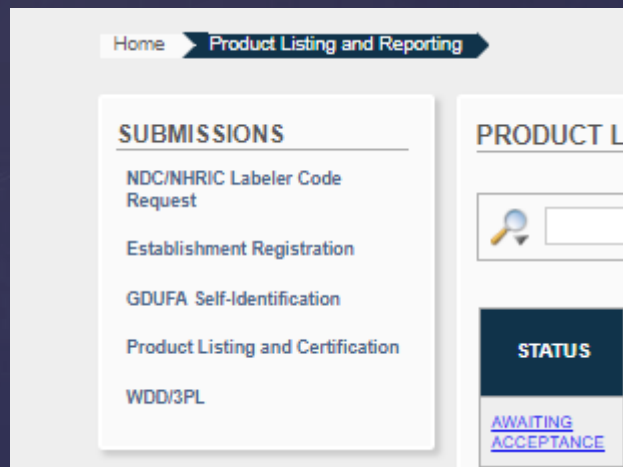
Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Denominator Strength: *	<input type="text"/>	Unit of Measure: *	-- Select One -- ▼
Type: *	<div>-- Select One -- -- Select One -- Active Ingredient, Ingredient is Basis of Strength Active Ingredient, Moiety is Basis of Strength Active Ingredient, Reference Ingredient is Basis of Strength Inactive Ingredient</div>		
Ingredient UNII - Name: *		Unit Of Measure: *	-- Select One -- ▼
Strength: *			
Active Moiety: *	<input type="text"/>		
ADD ACTIVE MOIETY			
Reference Ingredient: *	<input type="text"/>		



CDER Direct Submission



<u>SUBMISSION</u> <u>ACCEPTED</u>	8b400b 75-e05 850f
<u>SUBMISSION</u> <u>FAILED</u>	8b3210 8b-e05 8b4



CDER Direct Errors

12 ERRORS HAVE OCCURRED

- Enter Establishment Name. ([Go to error](#))
- Enter Establishment DUNS. ([Go to error](#))
- Select Establishment Country. ([Go to error](#))
- Enter Establishment Address. ([Go to error](#))
- Enter Establishment City. ([Go to error](#))
- Enter Establishment Contact Name. ([Go to error](#))
- Enter Establishment Contact Email. ([Go to error](#))
- Enter Establishment Contact Phone. ([Go to error](#))
- Select Establishment Contact Country. ([Go to error](#))
- Enter Establishment Contact Address. ([Go to error](#))
- Enter Establishment Contact City. ([Go to error](#))
- Select at least one Business Operation. ([Go to error](#))

Home Establishment Registration SPL Submission **Establishment**

SAVE ESTABLISHMENT << RETURN

ESTABLISHMENT DETAILS	ESTABLISHMENT ADDRESS
Establishment Name: * <input type="text"/>	Country: * <input type="text" value="-Select Country-"/>
Establishment DUNS: * <input type="text"/>	Street Address: * <input type="text"/>
Establishment FEI: <input type="text"/>	



Scenarios of SPL use in management of supply chain integrity



Inaccurate SPL Information

- ⌘ Missing/Incorrect establishment info
- ⌘ Additional review of ingredients
 - ⌘ Missing ingredients
 - ⌘ Strength
 - ⌘ Application number or monograph
- ⌘ Comparison of submitted representative package image
- ⌘ Possibly misbranded



Refusal of Import

- ⌘ Product held at the port
- ⌘ Database used by FDA compliance not updated
- ⌘ Failure of foreign supply chain entity to list under the appropriate marketing category
- ⌘ Product registered by domestic labeler



Compounding Pharmacy

- ⌘ 503B reporting
- ⌘ Validation errors
- ⌘ Source - active/bulk or finished product used in a compounded product not listed





Questions?