SPL Data Challenges with Medication Guide Extraction and Data Mining

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Disclaimer Slide

The views and opinions expressed in the following PowerPoint and accompanying oral presentation should not be construed as official or unofficial FDA position.

Objectives

- **Learn about Medication Guides sourced from FDA Structured Product Labeling (SPL)**
- Discuss issues regarding incorrect SPL Section LOINC codification or missing Medication Guides
- Review issues with bulleted lists and formatting of content
- Review Feedback to the FDA
- Discuss the benefits of SPL and the importance of careful coding and content review

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My Background and AHFS Drug Information

- **Pharmacist and Clinical Informaticist**
- **Early 2000's – Converted *AHFS Patient Medication Information* (PMI) and the *Handbook on Injectable Drugs* from text files to eXtensible Markup Language (XML)**
- **2005 – 1ST SPL released on DailyMed (XML format)**
- **2005 – Internal mapping for internal drug information updating via extracting SPL NDC and Product Information**
- **2010 – Client need for Medication Guides**
  - Familiar with SPL at DailyMed
  - Suitable format to extract Medication Guides for XML and PDF generation

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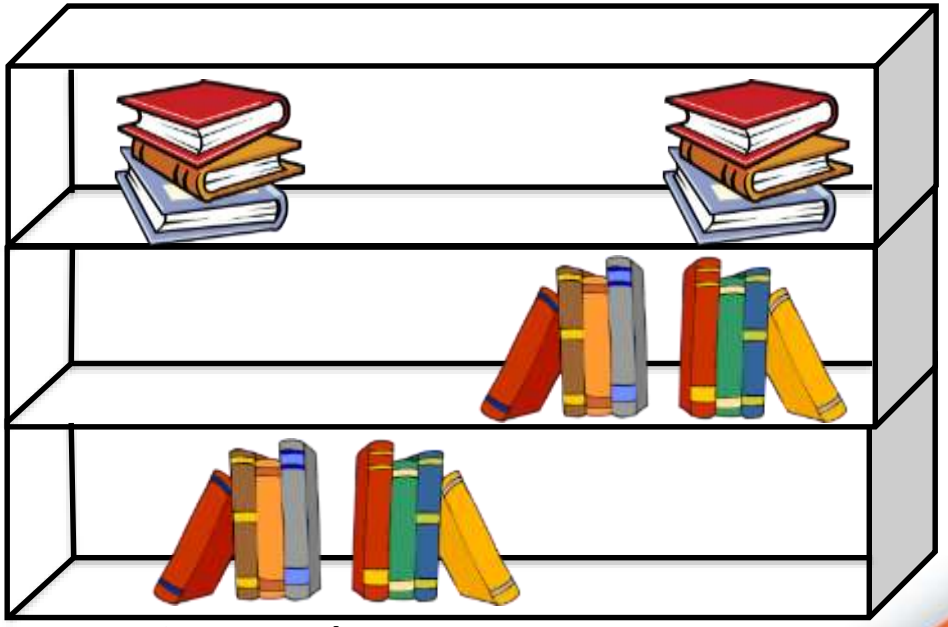
Raise your hand if you have ever bought a piece of furniture to put together?

- Have you ever been at the end and are missing a bolt, screw, washer?
- Had mislabeled pieces?
- Had missing pieces?

X 24

X 30 (only 29 included)



Part B

X 4 (only 3 included)

Structured Product Labeling

- Remember the frustration of missing an item or a mislabeled piece?
- Contains important clinical information that a healthcare provider and patient needs to know
- Content that needs to be updated and correct for public consumption
- Importance of current and correctly codified SPL

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FDA Medication Guide Website

https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Medication Guides

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Drugs@FDA and DailyMed also contain medication guides as part of drug labeling.

Get email alerts when the Medication Guides page is updated.

Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.

FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that:

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product are essential to its effectiveness.

Information Update (3/2017)

Medication Guides are updated as they appear in new drug labeling. Please note that we link directly into the drug label to the first page of the medication guide.

Medication Guides may or may not be at the end of the label. Before printing check the number of pages of the Medication Guide.

The newest labeling may contain a Medication Guide, but this is not necessarily reflective of the date of the label.

Medication Guides are available for these products:

*biologic or drug/biologic combination

- Abilify (aripiprazole) [8/2016 version]
- Abilify Maintena (aripiprazole) [1/2016 version]
- Absorica (isotrentinoin) [2014 version]
- Abstral (fentanyl) [2016 version]
- Aciphex Sprinkles (rabeprazole sodium) [7/2017 version]
- Aciphex DR (rabeprazole sodium) [4/2016 version]
- Accutane (isotretinoin) [2010 version]
- Actemra (tocilizumab) [8/2017 version]
- Nalfon (fenoprofen calcium) [5/2016 version]
- Naprelan (naproxen sodium) [2011 version]
- Naprosyn (naproxen) [3/2017 version]
- Nardil (phenelzine sulfate) [2007 version]
- Natpara (parathyroid hormone) for injection [12/2015 version]
- Nesina (alogliptin) [4/2016 version]
- Neurontin (gabapentin) [9/2015 version]

- **Need for PDF and XML version of Medication Guides**
- **Process that fits into pharmacy and clinician workflow**
- **Linking to NDCs**

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DailyMed Hosted by the NLM

https://dailymed.nlm.nih.gov/

DAILYMED

ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS

MORE WAYS TO SEARCH: ADVANCED SEARCH | BROWSE DRUG CLASSES | LABEL ARCHIVES | TABLET/CAPSULE ID TOOL

This website contains 97708 drug listings as submitted to the Food and Drug Administration (FDA).
At the present time, this Web site does not contain a complete listing of labels for approved prescription drugs.

NEWS

DailyMed Announcements

Posted: October 06, 2017

Drug Listing Certification is Coming

Slides and recordings from the FDA's October 5, 2017 meeting titled Electronic Drug Registration & Listing Using CDER Direct are now available.

http://nbiaevents.com/edrls-2017/

MORE INFO

Get RSS News & Updates

The DailyMed RSS feed provides updates and information about new drug labels approved by the FDA and published on NLM's DailyMed Web site.

ABOUT DAILYMED

DailyMed provides trustworthy information about marketed drugs in the United States. DailyMed is the official provider of FDA label information (package inserts). This Web site provides a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling found in medication package inserts.

The National Library of Medicine (NLM) provides this as a public service and does not accept advertisements. The drug labeling

FDA GUIDANCES & INFORMATION

Drug Guidance, Compliance & Regulatory Information

View FDA Structured Product Labeling Resources
View FDA Drug Labeling Guidances
View All FDA Drug Guidances

NLM SPL RESOURCES

The following Structured Product Labeling (SPL) resources have been created to assist industry professionals.

Download Data

All Drug Labels
All Indexing & REMS Files
All Mapping Files

SPL Image Guidelines

Guidelines for SPL image files of oral solid dosage forms that are submitted to the FDA with SPL documents.

Presentations & Articles

Stay informed through recent SPL related articles, online workshops, presentations and more.

APPLICATION DEVELOPMENT SUPPORT

Resources to Get the Most Out of DailyMed

Web Services

NLM SPL RESOURCES

The following Structured Product Labeling (SPL) resources have been created to assist industry professionals.

Download Data

All Drug Labels
All Indexing & REMS Files
All Mapping Files

- Allows PDF and XML version of Medication Guides
- Allows for process that fits into clinician workflow
- Allows extraction and linking to NDC codes

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Background

- **Utilize basic programming languages and technology to mine Structured Product Labeling (SPL) data from DailyMed**
- **Incorporation of extracted SPL data into database tables**
- **Mine the extracted SPL data for updating internal databases**
- **Computer "looks" for coded SPL sections**
  - Correct codification is VERY IMPORTANT (LOINC Section Codes)
- **Generation of Medication Guide documents mapped to NDCs extracted from SPL**

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Medication Guides Sourced from SPL by the Numbers

- **Weekly provision of SPL Medication Guides since 2010 to a client**

Year	Medication Guides	Mapped NDCs
2010	> 900 documents	> 5,300
2017	> 6800 documents	> 28,000

- **SPL Medication Guide code *Missing/Miscoded* or content needs to be included within the SPL**
  - Majority are Repackagers and Relabelers

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Objectives

- Learn about Medication Guides sourced from FDA Structured Product Labeling (SPL)
- **Discuss issues regarding incorrect SPL Section LOINC codification or missing Medication Guides**
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LOINC Codes

- Logical Observation Identifiers Names and Codes (LOINC)
- Universal code to identify medical terminology
- Section heading LOINC codes provide automation in matching section title with content

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

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LOINC Codes for Sections/Subsections that Only Appear in Non-PLR Format

Part of Labeling	LONIC Code
WARNINGS SECTION	34071-1
PRECAUTIONS SECTION	42232-9
GENERAL PRECAUTIONS SECTION	34072-9
INFORMATION FOR PATIENTS SECTION	34076-0
LABORATORY TESTS SECTION	34075-2
DRUG & OR LABORATORY TEST INTERACTIONS SECTION	34074-5
HOW SUPPLIED SECTION	34069-5

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

No LOINC Codes for Several Popular Subsections/Sections (PLR format)

Section/ Subsection	Part of Labeling	LONIC Code
PRESCRIBING INFORMATION (PLR format)		
6	ADVERSE REACTIONS section	34084-4
6.1	Clinical Trials Experience subsection	No LONIC Code
6.2	Immunogenicity subsection	No LONIC Code
6.2 or 6.3	Postmarketing Experience subsection	No LONIC Code
8	USE IN SPECIFIC POPULATIONS section	43684-0
8.6, 8.7 or 8.8	Renal Impairment subsection	No LONIC Code
8.6, 8.7 or 8.8	Hepatic Impairment subsection	No LONIC Code
16	HOW SUPPLIED/STORAGE AND HANDLING section	No LONIC Code
17	PATIENT COUNSELING INFORMATION section	No LONIC Code
LABELING PART NOT CLASSIFIED		
N/A	SPL UNCLASSIFIED SECTION	42229-5

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

What LOINC Code Do You Use for Patient Counseling Information Section?

Part of Labeling	LONIC Code
PATIENT LABELING	
INSTRUCTIONS FOR USE SECTION	59845-8
SPL MEDGUIDE SECTION	42231-1
SPL PATIENT PACKAGE INSERT SECTION	42230-3
PATIENT MEDICATION INFORMATION SECTION	68498-5
PRESCRIBING INFORMATION	
Patient Counseling Information	No LONIC Code
LABELING PART NOT CLASSIFIED	
SPL UNCLASSIFIED SECTION	42229-5

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

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LOINC Codes Options for Patient Labeling

Choose "SPL MEDGUIDE" LOINC Code for Medication Guides (do not choose "SPL UNCLASSIFIED SECTION")

Part of Labeling	LONIC Code
PATIENT LABELING	
INSTRUCTIONS FOR USE SECTION	59845-8
SPL MEDGUIDE SECTION	42231-1
SPL PATIENT PACKAGE INSERT SECTION	42230-3
PATIENT MEDICATION INFORMATION SECTION	68498-5
PRESCRIBING INFORMATION	
Patient Counseling Information	No LONIC Code
LABELING PART NOT CLASSIFIED	
SPL UNCLASSIFIED SECTION	42229-5

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

Section Heading LOINC Codes

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

42231-1	**SPL MEDGUIDE SECTION**	**(MEDICATION GUIDE)**

Has been coded as:

42229-5	SPL UNCLASSIFIED SECTION
68498-5	PATIENT MEDICATION INFORMATION SECTION
34076-0	INFORMATION FOR PATIENTS SECTION
34069-5	HOW SUPPLIED SECTION
59845-8	INSTRUCTIONS FOR USE SECTION
42230-3	SPL PATIENT PACKAGE INSERT SECTION
34067-9	INDICATIONS & USAGE SECTION
34068-7	DOSAGE & ADMINISTRATION SECTION
34073-7	DRUG INTERACTIONS SECTION
34082-8	GERIATRIC USE SECTION

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Medication Guide coded as 42231-1 Generates DailyMed Hyperlink…

DRUG LABEL INFORMATION

Updated August 31, 2017

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

MEDICATION GUIDE: HTML

OFFICIAL LABEL (PRINTER FRIENDLY)

VIEW ALL SECTIONS

DailyMed - CHLORDIAZEPO × | Chlordiazepoxide Hydrochlo × | +

https://dailymed.nlm.nih.gov/dailymed/

CHLORDIAZEPOXIDE HYDROCHLORIDE- chlordiazepoxide hydrochloride capsule, gelatin coated

---

This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 8/2016

Revised: 8/2017

Medication Guide content is MISSING

(non-PLR format)

Coded as having a Medication Guide

CLOSE

MEDICATION GUIDE

Contains LOINC code = 42231-1

But… Medication Guide content is MISSING

This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 8/2016

CLOSE

PRINCIPAL DISPLAY PANEL - 10 MG

R x only

Chlordiazepoxide Hydrochloride USP CIV

10 mg 30 Capsules

Each capsule contains 10 mg of chlordiazepoxide hydrochloride USP.

See enclosed package insert for dosage information.

Keep this and all drugs out of reach of children.

Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F)

Dispense in a tight, light-resistant container, with a child resistant closure, as defined in USP/NF.

(non-PLR format)

Coded as having a Medication Guide (…but Content is Missing)

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the U.S. Food and Drug Administration Issued: 8/2016</paragraph>
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RECENTLY updated

(non-PLR format)

Not Coded for Required Medication Guide and Content Missing

LABEL: risedronate sodium tablet, film coated

LABEL RSS SHARE

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: None
Marketing Status: New Drug Application

DRUG LABEL INFORMATION

Updated March 24, 2010

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML OFFICIAL LABEL (PRINTER FRIENDLY)

SAFETY

Report Adverse Events

FDA Safety Recalls

No Hyperlink to indicate Medication Guide

***DOES NOT* Contain LOINC code = 42231-1**

Medication Guide content is MISSING

(PLR format)

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Not Coded for Required Medication Guide and Content is Missing

14 CLINICAL STUDIES

14.1 Treatment of Osteoporosis in Postmenopausal Women - The fracture efficacy mg daily in the treatment of postmenopausal osteoporosis was demonstrated ...

16 HOW SUPPLIED/STORAGE AND HANDLING

is available as follows: mg film-coated, mg on the other.

17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling (17.1)] The patient should be informed to pay particular attention to the dosing instructions as clinical benefits may be compromised by failure to ...

PATIENT PACKAGE INSERT

Patient Information - (risedronate sodium) tablets mg, (risedronate sodium) tablets risedronate sodium) tablets ...

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - 5 MG LABEL

(PLR format)

FDA Medication Guide is Required

https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

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*biologic or drug/biologic combination

(risedronate sodium) [2015 version]

- Accutane (isotretinoin) [2010 version]
- Actemra (tocilizumab) [8/2017 version]
- Actiq (fentanyl citrate) [2015 version]
- Actonel (risedronate sodium) [2015 version]
- Actonel with Calcium (risedronate sodium and calcium carbonate) [2015 version]
- Actoplus Met (metformin hydrochloride and pioglitazone hydrochloride) [2014 version]
- Actoplus Met XR (metformin hydrochloride and pioglitazone hydrochloride) [2016 version]
- Actos (pioglitazone hydrchloride) [2016 version]
- Adasuve (loxapine) [2016 version]
- Adderall (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine
- Nesina (alogliptin) [4/2016 version]
- Neurontin (gabapentin) [9/2015 version]
- Nexium (esomeprazole magnesium) [3/2014 version]
- Nizoral (ketoconazole) [2014 version]
- Nocdiva (desmopressin acetate) [3/2017 version]
- Nolvadex (tamoxifen) [2006 version]
- Noroxin (norfloxacin) [2016 version]
- Norpramin (desipramine hydrochloride) [2014 version]
- Novantrone (mitoXantrone) [2012 version]
- Nplate* (romiplostim) [4/2016 version]
- NSAID (Nonsteroidal Anti-inflammatory Drugs) [3/2017version]
- Nucynta (tapentadol hydrochloride) [11/2016 version]

Medication Guide Included, but coded as 42229-5 - "SPL UNCLASSIFIED SECTION"

: OXYCODONE HYDROCHLORIDE- oxycodone hydrochloride tablet

LABEL RSS SHARE

CKAGE PHOTOS

/ MORE

Warnings

: Adverse Events

ıfety Recalls

ce in Breast Milk

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CII
Marketing Status: Abbreviated New Drug Application

DRUG LABEL INFORMATION

Updated July 13, 2017

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

VIEW ALL SECTIONS

BOXED WARNING (WHAT IS THIS?)

No Hyperlink to indicate Medication Guide

Because it contains LOINC code = 42229-5 *(SPL Unclassified Section)*, instead of code = *42231-1 (Medication Guide)*

(non-PLR format)

ashp

Medication Guide Included, but coded as 42229-5 - "SPL UNCLASSIFIED SECTION"

SPL UNCLASSIFIED SECTION

Medication Guide

Oxycodone Hydrochloride Tablets USP, CII

(ox" i koe' done hye" droe klor' ide)

Oxycodone hydrochloride tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

(non-PLR format)

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Medication Guide Included, but coded as 42229-5 - “SPL UNCLASSIFIED SECTION”

Should be 42231-1

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Hydrochloride Tablets USP, CII<br/>(ox" i koe' done hye" droe klor' ide)<br/>
                  </content>
                </td>
              </tr>..........
</section >
```

Should be <title>Medication Guide</title>

(non-PLR format)

Coded as 68498-5 - "PATIENT MEDICATION INFORMATION SECTION"

LABEL: OXYCODONE AND ACETAMINOPHEN- oxycodone and acetaminophen tablet

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

NDC Code
Packager:

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CII
Marketing Status: Abbreviated New Drug Application

VIEW MORE

DRUG LABEL INFORMATION

Updated January 17, 2012

If you are a consumer or patient please visit this version.

SAFETY
Boxed Warnings
Report Adverse Events

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

No Hyperlink to indicate Medication Guide

Because it contains LOINC code = 68498-5 *(Patient Medication Information)*, instead of code = *42231-1 (Medication Guide)*

(non-PLR format)

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Coded as 68498-5 - "PATIENT MEDICATION INFORMATION SECTION"

CLOSE

PATIENT MEDICATION INFORMATION

Medication Guide

Oxycodone Hydrochloride (ox" i koe' done hye" droe klor' ide) and Acetaminophen (a seet" a min' oh fen)

Tablets, CII

Oxycodone Hydrochloride and Acetaminophen Tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain, severe enough to require an opioid analgesic and for which alternative treatments are inadequate and when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about Oxycodone Hydrochloride and Acetaminophen Tablets:

(non-PLR format)

Coded as 68498-5 - “PATIENT MEDICATION INFORMATION SECTION”

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              <content styleCode="bold">Medication Guide <br/>
                  <content styleCode="bold">Oxycodone Hydrochloride (ox" i koe'
done hye" droe klor' ide) and Acetaminophen (a seet" a min' oh fen)</content>
                  <br/>Tablets, CII </content>
            </paragraph>
 </section >
</component>
```

(non-PLR format)

Medication Guide Coded as 34076-0 – "INFORMATION FOR PATIENTS"

LABEL: LEVETIRACETAM- levetiracetam solution

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: None
Marketing Status: Abbreviated New Drug Application

SAFETY
- Report Adverse Events
- FDA Safety Recalls
- Presence in Breast Milk

DRUG LABEL INFORMATION

Updated July 29, 2016

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

VIEW ALL SECTIONS

No Hyperlink to indicate Medication Guide

Because it contains LOINC code = *34076-0 (Information for Patients)*, instead of code = *42231-1 (Medication Guide)*

(PLR format)

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Coded as 34076-0 - "INFORMATION FOR PATIENTS" Buried within this Section of SPL

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Suicidal Behavior and Ideation

Counsel patients, their caregivers, and/or families that antiepileptic drugs (AEDs), including levetiracetam, may increase the risk of suicidal thoughts and behavior and advise patients to be alert for the emergence or worsening of symptoms of depression; unusual changes in mood or behavior; or suicidal thoughts, behavior, or thoughts about self-harm. Advise patients, their caregivers, and/or families to immediately report behaviors of concern to a healthcare provider.

Psychiatric Reactions and Changes in Behavior

Advise patients that levetiracetam may cause changes in behavior (e.g. aggression, agitation, anger, anxiety, apathy, depression, hostility, and irritability) and psychotic symptoms.

Effects on Driving or Operating Machinery

Inform patients that levetiracetam may cause dizziness and somnolence. Inform patients not to drive or operate machinery until they have gained sufficient experience on levetiracetam to gauge whether it adversely affects their ability to drive or operate machinery.

Dermatological Adverse Reactions

Advise patients that serious dermatological adverse reactions have occurred in patients treated with levetiracetam and instruct them to call their physician immediately if a rash develops.

Pregnancy

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during levetiracetam therapy. Encourage patients to enroll in the North American Antiepileptic Drug (NAAED) pregnancy registry if they become pregnant. This registry is collecting

MEDICATION GUIDE

Levetiracetam Oral Solution

(lee" va tye ra'se tam)

Read this Medication Guide before you start taking levetiracetam oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about levetiracetam oral solution?

Like other antiepileptic drugs, levetiracetam oral solution may cause suicidal thoughts or actions

(PLR format)

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Coded as 34076-0 – "INFORMATION FOR PATIENTS" Buried within this Section of SPL

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        <component>
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            <paragraph>Advise the patient to read the FDA-approved patient labeling
(Medication Guide).</paragraph>
……..
 <paragraph>
              <content styleCode="bold">MEDICATION GUIDE</content>
            </paragraph>
            <paragraph>
              <content styleCode="bold">Levetiracetam Oral Solution</content>
            </paragraph>
```

(PLR format)

Coded as 34069-5 – "HOW SUPPLIED SECTION" Buried within this Section of SPL

LABEL: METHYLPHENIDATE HYDROCHLORIDE - methylphenidate hydrochloride tablet

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

NDC Code(s)
Packager:

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CII
Marketing Status: Abbreviated New Drug Application

Report Adverse Events
FDA Safety Recalls
Presence in Breast Milk

DRUG LABEL INFORMATION

Updated February 1, 2010

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

No Hyperlink to indicate Medication Guide

Because it contains LOINC code = *34069-5 (How Supplied Section)*, instead of code = *42231-1 (Medication Guide)*

(non-PLR format)

Coded as 34069-5 – "HOW SUPPLIED SECTION" Buried within this Section of SPL

HOW SUPPLIED

Methylphenidate Hydrochloride 10 mg Tablets USP are available as follows:

Protect from light.

Dispense in a tight, light-resistant container, as defined in the USP, with a child-resistant closure.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature.

Protect from moisture.

Do not store above 30°C (86°F).

Manufactured By:

Distributed By:

MEDICATION GUIDE

CII

(methylphenidate HCl tablets USP)

methylphenidate HCl extended-release tablets USP)

Read the Medication Guide that comes with and : before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with and

(non-PLR format)

Coded as 34069-5 – “HOW SUPPLIED SECTION” Buried within this Section of SPL


```
<section>
        <id root=“XXXX-XXXXXXX-XXXXX-XXXXX"/>
        <code code="34069-5" codeSystem="2.16.840.1.113883.6.1" displayName="HOW SUPPLIED SECTION"/>
        <title>HOW SUPPLIED</title>
        <text>
          <paragraph>Methylphenidate Hydrochloride 10 mg Tablets USP are available as follows:</paragraph>
……..
<br/>
          <br/>
          <br/>MEDICATION GUIDE<paragraph>
            <content styleCode="bold">CII</content>
          </paragraph>
          <paragraph>
            <content styleCode="bold">-----------------</content>
            <sup>--------------/sup>
            <content styleCode="bold">
(methylphenidate HCl tablets USP)</content>
          </paragraph>
          <paragraph>
            <content styleCode="bold">-------------</content>
            <sup>™</sup>
            <content styleCode="bold"> ----
(methylphenidate HCl extended-release tablets USP)</content>
          </paragraph>
          <paragraph>Read the Medication Guide that comes with ----------
```

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Medication Guide Coded as 34069-5 – "HOW SUPPLIED SECTION"

HOW SUPPLIED

Indomethacin capsules are supplied containing 25 mg or 50 mg of indomethacin, USP.

The 25mg capsule is a hard-shell gelatin capsule with ar
debossed with on both the body and cap. They are supplied in bottles of 15 and 30 as follows:

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Protect from light.

Rx Only

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

PHARMACIST: Dispense a Medication Guide with each prescription.

Manufactured for:

Manufactured by:

Repackaged by:

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines called non-steroidal anti-inflammatory drugs (NSAIDs)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases:

(non-PLR format)

ashp

Objectives

- Learn about Medication Guides sourced from FDA Structured Product Labeling (SPL)
- Discuss issues regarding incorrect SPL Section LOINC codification or missing Medication Guides
- **Review issues with bulleted lists and formatting of content**
- Review feedback to the FDA
- Discuss the benefits of SPL and the importance of careful coding and content review

ashp

Extra Style Tagging (Elements) Makes it Difficult to Mine the Data – Place All Title Content within One <title> Element

```
<section ID="">
        <id root=""/>
        <code code="42229-5" codeSystem="2.16.840.1.113883.6.1" displayName="SPL UNCLASSIFIED SECTION"/>
        <title>
          <content styleCode="bold">7.</content>
          <content styleCode="bold">1</content>

            <content styleCode="bold">Cytochrome P450-</content>
          <content styleCode="bold">Based </content>
          <content styleCode="bold">Interaction</content>
          <content styleCode="bold">s</content>
        </title>
        <text>
          <paragraph>---------- is primarily metabolized by CYP3A4.  Concomitant use of CYP3A4 inhibitors increases ---------- plasma
concentrations, and use of CYP3A4 inducers decreases them.  Increased plasma concentrations may exacerbate bradycardia and conduction
disturbances.</paragraph>
          <paragraph>The concomitant use of strong CYP3A4 inhibitors is contraindicated <content styleCode="italics">[</content>
            <content styleCode="italics">s</content>
            <content styleCode="italics">ee </content>
            <content styleCode="italics">
```

Correctly coded <title>:

<title>7.1 Cytochrome P450-Based Interactions</title>

Forced Bulleted Lists

```
<content styleCode="bold">Gabapentin can cause serious side effects including: </content>
        </paragraph>
        <paragraph>
          <content styleCode="bold"> </content>
        </paragraph>
        <paragraph>
          <content styleCode="bold">1. Suicidal Thoughts. Like other antiepileptic drugs,
gabapentin may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.
</content>
        </paragraph>
        <paragraph>
          <content styleCode="bold">Call a healthcare provider right away if you have any of these
symptoms, especially if they are new, worse, or worry you: </content>
        </paragraph>
        <paragraph> ·  thoughts about suicide or dying </paragraph>
        <paragraph>·  attempts to commit suicide </paragraph>
        <paragraph>·  new or worse depression </paragraph>
        <paragraph>·  new or worse anxiety </paragraph>
        <paragraph>·  feeling agitated or restless </paragraph>
        <paragraph>·  panic attacks </paragraph>
```

Correctly Coded Bulleted List

```
<content styleCode="bold">Gabapentin can cause serious side effects including: </content>
        </paragraph>
        <paragraph>
          <content styleCode="bold"> </content>
        </paragraph>
        <paragraph>
          <content styleCode="bold">1. Suicidal Thoughts. Like other antiepileptic drugs, gabapentin may cause
suicidal thoughts or actions in a very small number of people, about 1 in 500. </content>
        </paragraph>
        <paragraph>
          <content styleCode="bold">Call a healthcare provider right away if you have any of these symptoms,
especially if they are new, worse, or worry you: </content>
        </paragraph>
          <list listType="unordered“>
        <item>thoughts about suicide or dying </item>
        <item>attempts to commit suicide </item>
        <item>new or worse depression </item>
        <item>new or worse anxiety </item>
        <item>feeling agitated or restless </item>
        <item>panic attacks </item>
          ……..
          </list>
```

Poorly Formatted Table and Bulleted Lists

- if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**
- if you are breastfeeding. **Talk to your doctor.**

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effects include:		Other side effects include:	
•	heart attack	•	stomach pain
•	stroke	•	constipation
•	high blood pressure	•	diarrhea
•	heart failure from body swelling (fluid retention)	•	gas
•	kidney problems including kidney failure	•	heartburn
•	bleeding and ulcers in the stomach and intestine	•	nausea
•	low red blood cells (anemia)	•	vomiting
•	life-threatening skin reactions	•	dizziness
•	life-threatening allergic reactions		
•	liver problems including liver failure		
•	asthma attacks in people who have asthma		

Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing

ashp

Poorly Reviewed Blank Space in Content

MEDICATION GUIDE

Aripiprazole Tablets

(air-eh-PIP-rah-zole)

Read this Medication Guide before you start taking aripiprazole tablets and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about aripiprazole tablets?

(For other side effects, also see "What are the possible side effects of aripiprazole tablets?").

Serious side effects may happen when you take aripiprazole tablets, including:

- **Increased risk of death in elderly patients with dementia-related psychosis:**

- **Extra line breaks <br/> in content**
- **Causes printing issues**
- **Difficult to comprehend the content**

ashp

Poorly Reviewed Extra Line Breaks <br/> within Content

```
<component>
    <section ID="Unclassified_Section_30">
      <id root=                                        '"/>
      <code code="42229-5" codeSystem="2.16.840.1.113883.6.1" displayName="SPL UNCLASSIFIED SECTION"/>
      <title>MEDICATION GUIDE</title>
      <text>
        <br/>
        <paragraph>Aripiprazole Tablets</paragraph>
        <br/>
        <br/>
        <br/>
        <br/>
        <br/>
        <paragraph> (air-eh-PIP-rah-zole)<br/>Read this Medication Guide before you start taking aripiprazole tablets and each time you get a refill. There may be
new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. </paragraph>
        <br/>
        <br/>
        <br/>
        <br/>
        <paragraph>
          <content styleCode="bold">What is the most important information I should know about aripiprazole tablets?</content>
        </paragraph>
        <br/>
        <br/>
        <br/>
        <br/>
        <paragraph> (For other side effects, also see "What are the possible side effects of aripiprazole tablets?").</paragraph>
        <br/>
        <br/>
        <br/>
        <br/>
```

Poorly Reviewed Extra Line Breaks <br/> within Content

SPL MEDICATION GUIDE

Medication Guide

Fluoxetine Capsules, USP

(floo-ox-e-teen)

Read the Medication Guide that comes with fluoxetine capsules before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about fluoxetine capsules?

Fluoxetine capsules and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

• **Fluoxetine capsules and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months oftreatment or when the dose is changed.**

Poorly Reviewed Extra Line Breaks <br/> within Content

```
<section ID="Unclassified_Section_63">
        <id root="d8625e26-6529-4612-820e-5480cd715df7"/>
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        <title>SPL MEDICATION GUIDE</title>
        <text>
          <br/>
          <paragraph>
            <content styleCode="bold">Medication Guide</content>
          </paragraph>
          <br/>
          <br/>
          <br/>
          <br/>
          <paragraph> Fluoxetine Capsules, USP </paragraph>
          <br/>
          <br/>
          <br/>
          <br/>
          <paragraph> (floo-ox-e-teen)</paragraph>
          <paragraph>Read the Medication Guide that comes with fluoxetine capsules before you start taking it and each time you get a refill.
There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.
Talk with your healthcare provider if there is something you do not understand or want to learn more about. <br/>
```

Text Overlay Display Issue and Confusing Bullets

Medication Guide
Oxycodone Hydrochloride (ox" i koe' done hye" droe klor' ide) Tablets USP, CII

Oxycodone hydrochloride tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to requir
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribe

Important information about oxycodone hydrochloride tablets:

- **Get emergency help right away if you take too much oxycodone hydrochloride tablets (overdose).** When you first st lead to death may occur.
- Taking oxycodone hydrochloride tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous s
- Never give anyone else your oxycodone hydrochloride tablets. They could die from taking it. Store oxycodone hydrochlo

Do not take oxycodone hydrochloride tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- allergy to oxycodone.

Before taking oxycodone hydrochloride tablets, tell your healthcare provider if you have a history of:

- head injury, seizures • liver, kidney, thyroid problems
- problems urinating • pancreas or gallbladder problems
- **tell your healthcare provider if you** alcohol addiction, or mental health problems
- **pregnant or planning to become pregnant**. Prolonged use of oxycodone hydrochloride tablets during pregnancy can ca
- **breastfeeding**. Oxycodone hydrochloride tablets pass into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxycodone hydrochloride tabl

When taking oxycodone hydrochloride tablets:

- Do not change your dose. Take oxycodone hydrochloride tablets exactly as prescribed by your healthcare provider. Use th
- Take your prescribed dose every 4 to 6 hours. Do not take more than your prescribed dose. If you miss a dose, take your n
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking oxycodone hydrochloride tablets regularly, do not stop taking oxycodone hydrochloride tablets w

Coding as a Caption and List Item

```
<td styleCode="Rrule Lrule Botrule " valign="top">
   <paragraph>
      <content styleCode="bold">Before taking oxycodone hydrochloride tablets, tell your healthcare provider if you have a history of:</conte
   </paragraph>
   <list listType="unordered">
      <item>
         <caption>â€¢</caption>head injury, seizures                    â€¢  liver, kidney, thyroid problems</item>
      <item>
         <caption>â€¢</caption>problems urinating                       â€¢  pancreas or gallbladder problems</item>
      <item>
         <caption>â€¢</caption>abuse of street or prescription drugs, alcohol addiction, or mental health problems.</item>
      <item>
         <caption/>
         <content styleCode="bold">Tell your healthcare provider if you are:</content>
      </item>
      <item>
         <caption>â€¢</caption>
         <content styleCode="bold">pregnant or planning to become pregnant</content>. Prolonged use of oxycodone hydrochloride tablets durin
      <item>
         <caption>â€¢</caption>
         <content styleCode="bold">breastfeeding</content>. Oxycodone hydrochloride tablets pass into breast milk and may harm your baby. </i
      <item>
         <caption>â€¢</caption>taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxycodone hydrochlo
   </list>
</td>
```

Use Specific SPL LOINC Section Codes Whenever Available Instead of 42229-5 - “SPL UNCLASSIFIED SECTION”

```
<section ID="                                                    ">
        <id root="                                              />
        <code code="42229-5" codeSystem="2.16.840.1.113883.6.1" displayName="SPL
UNCLASSIFIED SECTION"/>
        <title/>
        <text>
          <table width="653px">
            <col/>
            <tbody>
              <tr>
                <td styleCode="    Botrule        Toprule        Lrule        Rrule    ">
                  <content styleCode="bold">Medication Guide<br/>Oxycodone
Hydrochloride Tablets USP, CII<br/>(ox" i koe' done hye" droe klor' ide)<br/>
                  </content>
                </td>
              </tr>..........
</section >
```

Section Heading LOINC Codes

https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm

42231-1	**SPL MEDGUIDE SECTION**	**(MEDICATION GUIDE)**
34069-5	HOW SUPPLIED SECTION	
34076-0	INFORMATION FOR PATIENTS SECTION	
59845-8	INSTRUCTIONS FOR USE SECTION	
42229-5	SPL UNCLASSIFIED SECTION	
42230-3	SPL PATIENT PACKAGE INSERT SECTION	
34067-9	INDICATIONS & USAGE SECTION	
34068-7	DOSAGE & ADMINISTRATION SECTION	
34073-7	DRUG INTERACTIONS SECTION	
34082-8	GERIATRIC USE SECTION	

ashp

Drug Interactions Listed Under Precautions

PRECAUTIONS

General

The possibility of suicide is inherent in any severely depressed patient and persists until a significant remission occurs. When a patient with a serious suicidal potential is not hospitalized, the prescription should be for the smallest amount feasible.

In schizophrenic patients activation of the psychosis may occur and require reduction of dosage or the addition of a major tranquilizer to the therapeutic regimen.

Manic or hypomanic episodes may occur in some patients, in particular those with cyclic-type disorders. In some cases therapy with must be discontinued until the episode is relieved, after which therapy may be reinstituted at lower dosages if still required.

Concurrent administration of . and electroshock therapy may increase the hazards of therapy. Such treatment should be limited to those patients for whom it is essential. When possible, discontinue the drug for several days prior to elective surgery.

should be used with caution in patients with impaired liver function.

Chronic animal studies showed occasional occurrence of hepatic congestion, fatty infiltration, or increased serum liver enzymes at the highest dose of 60 mg/kg/day.

Both elevation and lowering of blood sugar have been reported with tricyclic antidepressants.

(non-PLR format)

Uncoded Drug Interactions subsection under Precautions

Drug Interactions

Cimetidine

There is evidence that cimetidine inhibits the elimination of tricyclic antidepressants. Downward adjustment of dosage may be required if cimetidine therapy is initiated; upward adjustment if cimetidine therapy is discontinued.

Alcohol

Patients should be warned that the concomitant use of alcoholic beverages may be associated with exaggerated effects.

Catecholamines/Anticholinergics

It has been reported that tricyclic antidepressants can potentiate the effects of catecholamines. Similarly, atropine-like effects may be more pronounced in patients receiving anticholinergic therapy. Therefore, particular care should be exercised when it is necessary to administer tricyclic antidepressants with sympathomimetic amines, local decongestants, local anesthetics containing epinephrine, atropine or drugs with an anticholinergic effect. In resistant cases of depression in adults, a dose of 2.5 mg/kg/day may have to be exceeded. If a higher dose is needed, ECG monitoring should be maintained during the initiation of therapy and at appropriate intervals during stabilization of dose.

Drugs Metabolized by P450 2D6

(non-PLR format)

Drug Interactions Coded as 42229-5 - “SPL Unclassified Section”

```
<component>
   <section ID="  _                                        '>
      <id root="
      <code code="42229-5" codeSystem="2.16.840.1.113883.6.1" displayName="SPL UNCLASSIFIED SECTION"/>
      <title>Drug Interactions</title>
      <text>
         <paragraph>
            <content styleCode="italics">Cimetidine</content>
         </paragraph>
         <paragraph>There is evidence that cimetidine inhibits the elimination of tricyclic antidepressa
         <paragraph>
            <content styleCode="italics">Alcohol</content>
         </paragraph>
         <paragraph>Patients should be warned that the concomitant use of alcoholic beverages may be ass
         <paragraph>
            <content styleCode="italics">Catecholamines/Anticholinergics</content>
         </paragraph>
         <paragraph>It has been reported that tricyclic antidepressants can potentiate the effects of ca
         <paragraph>
            <content styleCode="italics">Drugs Metabolized by P450 2D6</content>
         </paragraph>
         <paragraph>The biochemical activity of the drug metabolizing isozyme cytochrome P450 2D6 (debri
         <paragraph>In addition, certain drugs inhibit the activity of the isozyme and make normal metab
         <paragraph>Concomitant use of tricyclic antidepressants with drugs that can inhibit cytochrome
         <paragraph>
            <content styleCode="italics">Monoamine Oxidase Inhibitors (MAOIs)</content>
         </paragraph>
         <paragraph>(See <content styleCode="bold">
               <linkHtml href='                                        '>CONTRAINDICATIONS</linkHtml>
```

(non-PLR format)

Geriatric Use Coded as 34082-8 - "Geriatric Use Section" (same SPL)

Geriatric Use

Clinical studies of were not adequate to determine whether subjects aged 65 and over respond differently from younger subjects.

The pharmacokinetics of were not substantially altered in the elderly (see CLINICAL PHARMACOLOGY).

is known to be substantially excreted by the kidney. Clinical circumstances, some of which may be more common in the elderly, such as hepatic or renal impairment, should be considered

(non-PLR format)

Geriatric Use Coded as 34082-8 - "Geriatric Use Section" (same SPL)

```
<component>
   <section ID="                                                    ">
      <id root="
      <code code="34082-8" codeSystem="2.16.840.1.113883.6.1" displayName="GERIATRIC USE SECTION"/>
      <title>Geriatric Use</title>
      <text>
         <paragraph>Clinical studies of                                    were not adequate to determine whether subjects aged 65
         <paragraph>The pharmacokinetics of                 were not substantially altered in the elderly (see <content styleCode="
               <linkHtml href="                                        ">CLINICAL PHARMACOLOGY</linkHtml>
            </content>).</paragraph>
         <paragraph>                  known to be substantially excreted by the kidney.  Clinical circumstances, some of which may be
               <linkHtml href="                                        ">PRECAUTIONS</linkHtml> - <linkHtml
            </content>).</paragraph>
         <paragraph>Greater sensitivity (e.g., confusional states, sedation) of some older individuals cannot be ruled out (see<
               <linkHtml href="                                        ">ADVERSE REACTIONS</linkHtml>
            </content>).  In general, dose selection for an elderly patient should be cautious, usually starting at a lower dose
               <linkHtml href="                                        ">DOSAGE AND ADMINISTRATION</linkHtml>
            </content>).</paragraph>
      </text>
      <effectiveTime value="20150209"/>
   </section>
</component>
```

(non-PLR format)

Drug Interactions Coded as 34073-7 – "Drug Interactions Section" (different SPL)

7 DRUG INTERACTIONS

7.1 Central Nervous System Depressants

The concomitant use of fentanyl transdermal system with other CNS depressants, including sedatives, hypnotics, tranquilizers, general anesthetics, phenothiazines, other opioids, and alcohol, can increase the risk of respiratory depression, profound sedation, coma and death. Monitor patients receiving CNS depressants and fentanyl transdermal system for signs of respiratory depression, sedation and hypotension.

When combined therapy with any of the above medications is considered, the dose of one or both agents should be reduced *[see Dosage and Administration (2.2)* and *Warnings and Precautions (5.5)]*.

7.2 Drugs Affecting Cytochrome P450 3A4 Isoenzymes

Inhibitors of CYP3A4

Because the CYP3A4 isoenzyme plays a major role in the metabolism of fentanyl, drugs that inhibit CYP3A4 activity may cause decreased clearance of fentanyl which could lead to an increase in fentanyl

(PLR format)

ashp

Drug Interactions Coded as 34073-7 – "Drug Interactions Section" (different SPL)

```
<component>
   <section ID=                                        ">
      <id root=
      <code code="34073-7" codeSystem="2.16.840.1.113883.6.1" displayName="DRUG INTERACTIONS SECTION"/>
      <title>7 DRUG INTERACTIONS</title>
      <effectiveTime value="20170914"/>
      <excerpt>
         <highlight>
            <text>
               <list listType="unordered" styleCode="Disk">
                  <item>
                     <paragraph>Mixed agonist/antagonist and partial agonist opioid analgesics: Avoid use with fentanyl tra
                  </item>
                  <item>
                     <paragraph>Monoamine oxidase inhibitors (MAOIs): Avoid fentanyl transdermal system in patients taking
                  </item>
               </list>
            </text>
         </highlight>
      </excerpt>
      <component>
```

(PLR format)

Kit Products with Incomplete SPLs

LABEL

diclofenac sodium, capsaicin

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

NDC Code
Packager:

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: None
Marketing Status: Abbreviated New Drug Application

SAFETY
- Report Adverse Events
- FDA Safety Recalls
- Presence in Breast Milk

RELATED RESOURCES
- Medline Plus
- Clinical Trials
- + PubMed
- Biochemical Data Summary

MORE INFO FOR THIS DRUG
- View Label Archives
- RxNorm
- Get Label RSS Feed

DRUG LABEL INFORMATION

Updated August 3, 2016

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

VIEW ALL SECTIONS

PATIENT PACKAGE INSERT

DICLOFENAC SODIUM- diclofenac sodium solution
HIGHLIGHTS OF PRESCRIBING INFORMATION - These highlights do not include all the information ...

STORAGE AND HANDLING

Keep away from heat and flame. Store at 20C to 25C (68 to 77F). (See USP - Controlled Room Temperature)

WARNINGS

Keep this and all medication out of reach of children.

QUESTIONS

INGREDIENTS AND APPEARANCE

diclofenac sodium, capsaicin kit

(non-PLR format)

ashp

Reuse of ANDA Packaged with Another Product

(non-PLR format)

Reuse of ANDA Packaged with Another Product

Drugs@FDA https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code
DICLOFENAC SODIUM	DICLOFENAC SODIUM	1.5%	SOLUTION;TOPICAL	Prescription	AT

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for

Therapeutic Equivalents for ANDA

DICLOFENAC SODIUM

SOLUTION;TOPICAL; 1.5%
TE Code = AT

CSV Excel Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application
DICLOFENAC SODIUM	DICLOFENAC SODIUM	1.5%	SOLUTION;TOPICAL	Prescription	No	AT	
DICLOFENAC SODIUM	DICLOFENAC SODIUM	1.5%	SOLUTION;TOPICAL	Prescription	No	AT	
DICLOFENAC SODIUM	DICLOFENAC SODIUM	1.5%	SOLUTION;TOPICAL	Prescription	No	AT	2
DICLOFENAC SODIUM	DICLOFENAC SODIUM	1.5%	SOLUTION;TOPICAL	Prescription	No	AT	

ashp

Virtually Empty SPLs

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CII
Marketing Status: unapproved drug other

DISCLAIMER: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DRUG LABEL INFORMATION

Updated April 9, 2014

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML

OFFICIAL LABEL (PRINTER FRIENDLY)

CLOSE ALL SECTIONS

LABEL

fentaNYL Citrate 10 mcg/mL

in 0.9% Sodium Chloride 60 mL* Bag

10 mcg/mL Total Dose: (0.6 mg/60 mL)

BUD: Lot: xxxxx Rx Only

Store at Room Temperature. Eq. to Base.
Preservative Free. Protect from Light.
Single-Dose Bag. For Slow IV or Epidural Use.

*Prefilled
50 mL Bag
with 60 mL
Total Volume
60 mL*

C-II

1

CLOSE

INGREDIENTS AND APPEARANCE

FENTANYL CITRATE
fentanyl citrate injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	

(non-PLR format)

Question #1: Which additional LOINC Names (and Codes) for PLR format subsections should be added? (can select one or more)

1) Hepatic Impairment subsection
2) Renal Impairment subsection
3) Postmarketing Experience subsection
4) Immunogenicity subsection
5) Clinical Trials Experience subsection
6) All
7) None

ashp

LOINC Codes for Sections/Subsections that are Common to PLR and non-PLR Format

Would it be helpful to distinguish between PLR sections/subsections from non-PLR subsections/sections (e.g., PLR DRUG INTERACTIONS section vs. non-PLR Drug Interactions subsection in PRECAUTIONS section)?

Part of Labeling	LONIC Code
BOXED WARNING SECTION	34066-1
DESCRIPTION SECTION	34089-3
CLINICAL PHARMACOLOGY SECTION	34090-1
INDICATIONS & USAGE SECTION	34067-9
CONTRAINDICATIONS SECTION	34070-3
DRUG INTERACTIONS SECTION	34073-7
CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY SECTION	34083-6
PREGNANCY SECTION	42228-7
LABOR & DELIVERY SECTION	34079-4
NURSING MOTHERS SECTION	34080-2
PEDIATRIC USE SECTION	34081-0
GERIATRIC USE SECTION	34082-8
ADVERSE REACTIONS SECTION	34084-4
DRUG ABUSE AND DEPENDENCE SECTION	42227-9
OVERDOSAGE SECTION	34088-5
DOSAGE & ADMINISTRATION SECTION	34068-7

Question #2: Would it be helpful for the LOINC Names to state whether or not the section/subsection is in PLR and/or non-PLR format?

For example:

"PLR format/Non-PLR format: Drug Interactions"

"Non-PLR format: How Supplied section"

"PLR format: Warnings and Precautions section"

1) Yes
2) No

ashp

Objectives

- Learn about Medication Guides sourced from FDA Structured Product Labeling (SPL)
- Discuss issues regarding incorrect SPL Section LOINC codification or missing Medication Guides
- Review issues with bulleted lists and formatting of content
- **Review feedback to the FDA**
- Discuss the benefits of SPL and the importance of careful coding and content review

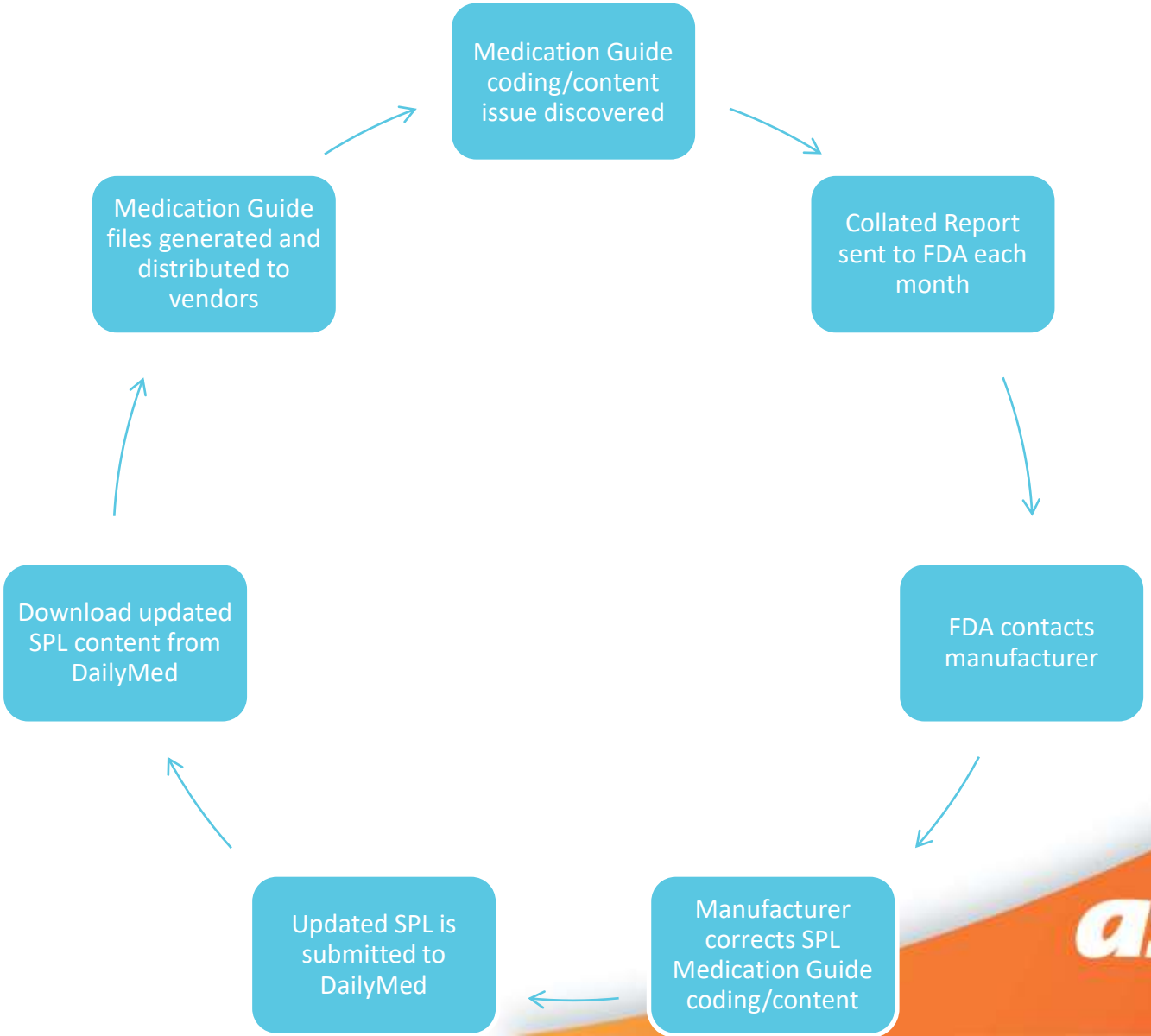
ashp

Feedback to FDA and Progress

- **Reporting SPL issues to the FDA since 2010**
- **Over 600 Medication Guides have been updated or corrected as manufacturers update content**
- **Over the past year we have been reporting SPL issues bimonthly to the FDA**
- **Progress has been made, but continue to find issues with data integrity and incorrect coding**
  - Most often Repackagers and Relabelers

ashp

Feedback Process to FDA



Good News! Delisting of Outdated SPLs

New! 21 CFR 207 published August 2016 and implemented November 2016.

> ***21 CFR 207.57 (b)(2)*** ***For each listed drug, certify that no changes*** *subject to reporting under paragraph (b)(1)(iv) of this section have occurred* ***if no such changes have occurred since the last review and update****. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single "no changes" certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.*

Beginning in 2017, there is now an annual requirement to update listing or certify that no changes have occurred.

This could help with valid SPL data.

ashp

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Benefits of Carefully Codified SPL Sections

- **Correctly codified SPLs:**
  - Increases SPL reliability
  - Increases confidence in SPL
  - Drives more users to adopt SPL
  - Provides more feedback (crowd review) and usage of SPL with regard to clinical content
  - Allows for richer data mining and dissemination of clinical information

ashp

Benefits of Carefully Codified SPL Sections

- **REMS SPL will be a driving force for future SPL usage**
- **Goal of all clinically important content to safely prescribe, dispense, and administer a medication in one easily discoverable location**
  - SPL MedWatch
    - Recalls
    - Alerts
    - Drug Shortage Information
  - SPL Warning Letters
  - SPL Indexing of Content

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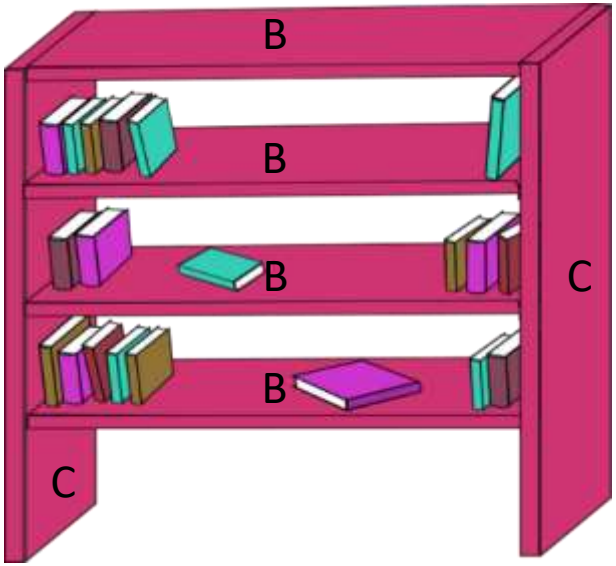
Summary

- Missing or incorrect coding is mainly an issue with Repackagers and Relabelers
- Codification of SPL is JUST as important as the content of labeling
- In some instances, codification is more useful than the PDF of labeling for data mining purposes
- Review all SPL content as carefully as PDFs and documents available at Drugs@FDA

ashp

Summary

- **Ensure all sections are coded as specifically as allowed by the SPL Guidance documents**
  - Refer to SPL Section Headings (LOINC)
  - https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162057.htm
- **Ensure a clinician is reviewing the SPL for errors**
- **Ensure a technical person who understands SPL and eXtensible Markup Language (XML) reviews**
- **Review your SPLs at DailyMed: https://dailymed.nlm.nih.gov**
- **Update, Update, Update**
  - No less frequently that submission to the Drugs@FDA website and corporate website

ashp

Thank you!
Questions?