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PLR Implementation, CDER Staff for Labeling Review, and Labeling Resources

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Disclaimer

- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.
- Reference to any marketed products is for illustrative purposes only and does not constitute endorsement by the FDA.

Overview

- Physician Labeling Rule (PLR) vs. non-PLR format
- CDER staff involved in prescribing information (PI) review
- Labeling resources

PLR vs. Non-PLR ("old") Format

PLR Format**

HIGHLIGHTS OF PRESCRIBING INFORMATION

- Product Names, Other Required Information
- Boxed Warning
- Recent Major Changes
- Indications and Usage
- Dosage and Administration
- Dosage Forms and Strengths
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Use in Specific Populations

FULL PRESCRIBING INFORMATION: CONTENTS

FULL PRESCRIBING INFORMATION

- Boxed Warning
- 1 Indications and Usage
- 2 Dosage and Administration
- 3 Dosage Forms and Strengths
- 4 Contraindications
- 5 Warnings and Precautions
- 6 Adverse Reactions
- 7 Drug Interactions
- 8 Use in Specific Populations
- 9 Drug Abuse and Dependence
- 10 Overdosage
- 11 Description
- 12 Clinical Pharmacology
- 13 Nonclinical Toxicology
- 14 Clinical Studies
- 15 References
- 16 How Supplied/Storage and Handling
- 17 Patient Counseling Information

Old Format*

- Description
- Clinical Pharmacology
- Indications and Usage
- Contraindications
- Warnings
- Precautions
- Adverse Reactions
- Drug Abuse and Dependence
- Overdosage
- Dosage and Administration
- How Supplied

Optional sections:

- Animal Pharmacology and/or Animal Toxicology
- Clinical Studies
- References

CDER Prescription Drug and Biological Product Labeling in PLR Format

(NDAs/BLAs only)[1]

Month/Year	Proportion of CDER Prescription Drug and Biological Product Labeling in PLR Format (NDAs/BLAs only)
January 2014	~ 45%
January 2016	~ 56%
January 2017	~ 61%
September 2017	**~ 64%**

CDER labeling in PLR format:

- BLAs (93%), NDAs (62%), ANDAs (38%)

NDAs = New Drug Applications; BLAs = Biologics License Applications

[1] September 2017 analysis based on Structured Product Labeling (SPL) files generally only includes marketed products and excludes repackers, relabelers, and redistributor labeling

Labeling in PLR Format (Required and Voluntary)[1]

FDA appreciates industry's hard work on the PLR conversions!

	NDAs, BLAs, and ESs	Applications with Labeling in PLR Format (September 2017)
Required	NDAs, BLAs, ES submitted and approved on or after 6/30/2006	100%
PLR Rule Effective Start Date (6/30/2006) ----------		
Required	NDAs, BLAs, ES approved 6/30/2001 to 6/30/2006 or pending on 6/30/2006	96%
Voluntary	NDAs/BLAs approved from 1938 to 6/29/2001 (without an ES approved on or after 6/30/2001)	~15%

In 2013 ~71% in PLR format

In 2012 ~1% in PLR format

[1] Data in table as of September 2017; 21 CFR 201.56(b) and (c); ESs = efficacy supplements

Submitted PLR Conversions Labeling Supplements to Date[1]

Required and voluntary PLR conversions are part of efforts to update labeling

	Submitted PLR Conversions to Date	
	Voluntary (n=218)	Required (n=214)
Number Approved	186	185
Number Pending (under review in CDER)	32	29

[1] Based on number of PLR conversion labeling supplements submitted (NDAs/BLAs); excludes efficacy supplements and original NDAs/BLAs

CDER Staff Involved in Labeling Review

CDER Staff Who May be Involved in PI Review[1]

CDER Staff that Typically Review PI	Additional CDER staff that Review PI
Division Management	Deputy Director for Safety
Clinical (medical officers)	Clinical Microbiology (antimicrobial products)
Regulatory Project Managers	Office Management
Pharmacology/Toxicology	Labeling Development Team[2]
Associate Directors for Labeling[2]	Office of New Drugs
Division of Pediatric and Maternal Health	
Office of Clinical Pharmacology (includes Labeling and Health Communications staff[2])	Office of Biostatistics — Office of Translational Sciences
Office of Pharmaceutical Quality — Office of Pharmaceutical Quality	Office of Biotechnology Products Labeling Reviewer[2] (for biological products)
Division of Medication Error Prevention and Analysis	Division of Risk Management; Division of Pharmacovigilance — Office of Surveillance and Epidemiology
Office of Prescription Drug Promotion	Controlled Substance Staff (controlled substances) — Office of Center Director (CDER)
Division of Medical Policy Programs (patient labeling) — Office of Medical Policy	

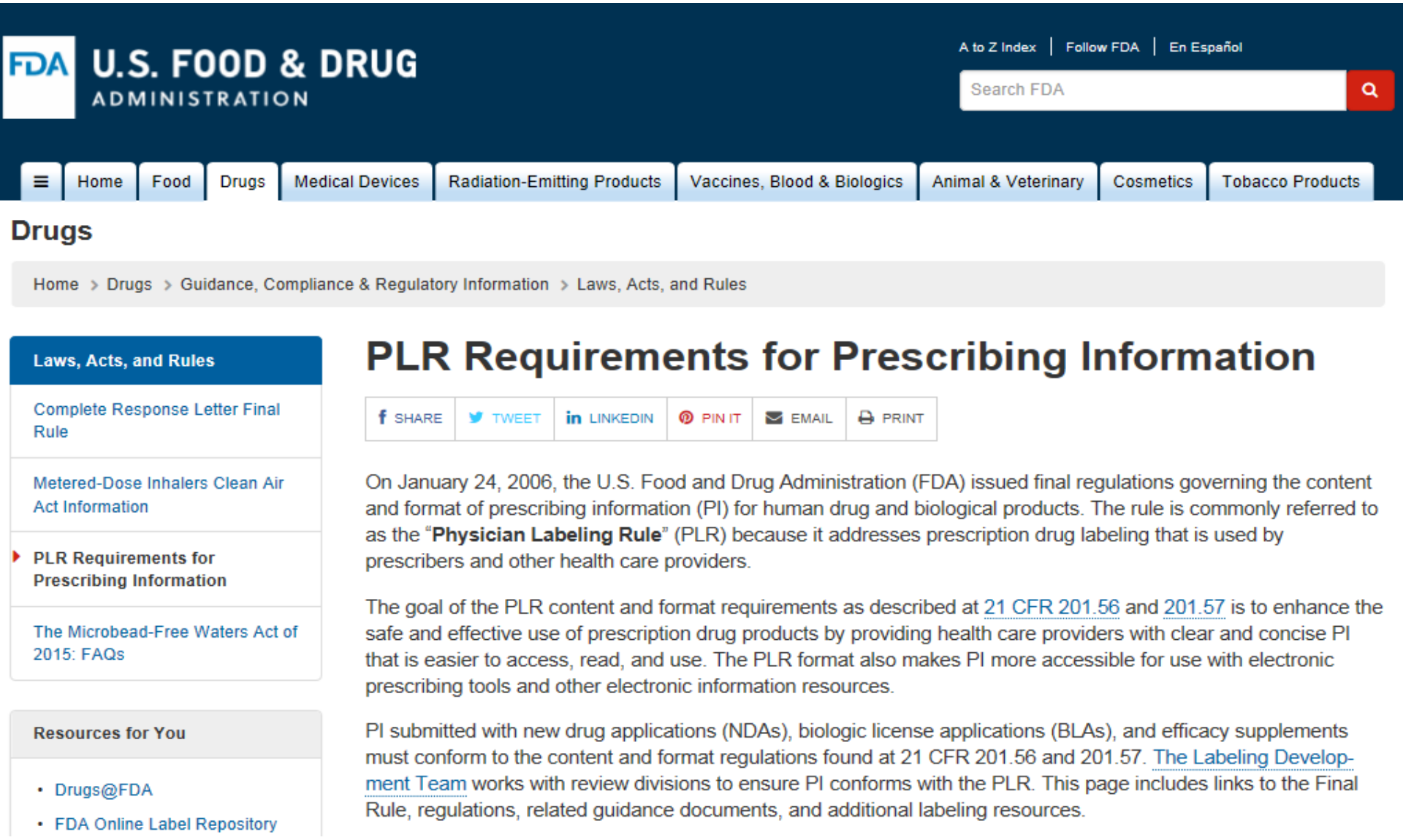
[1] Involvement depends on labeling type and review division
[2] Labeling specialists (each color represents a different CDER office)

Associate Directors for Labeling: Roles and Responsibilities

- ADL positions created in summer of 2015
- One ADL in each prescription drug review division (16 total ADLs)
- Serves as principal senior labeling advisor for division
- Ensures that division labeling:
  - Meets regulations and is appropriately consistent with labeling guidances and FDA policies
  - Is appropriately consistent within and across drug classes and indications
  - Is clear and concise for healthcare providers

Labeling Review Resources

PLR Requirements for Prescribing Information Website[1]



[1] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm

PLR Requirements for Prescribing Information Website[1]

- PLR Final Rule and Labeling Requirements
- Labeling Guidances
- Labeling Presentations – Labeling Content
- Articles with Labeling Content
- Labeling Presentations – Labeling Review Process and Resources
- Sample Templates and Format Labeling Tools
- Product Quality-Related Resources for Prescribing Information
- ANDA Labeling
- Established Pharmacologic Class Resources
- Additional Labeling Resources

[1] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm

CDER Novel Drug Approvals Website[1]

No.	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date
34.	Verzenio	abemaciclib	9/28/2017	To treat certain advanced or metastatic breast cancers Press Release
33.	Solosec	secnidazole	9/15/2017	To treat bacterial vaginosis
32.	Aliqopa	copanlisib	9/14/2017	To treat adults with relapsed follicular lymphoma Press Release Drug Trials Snapshot
31.	benznidazole	benznidazole	8/29/2017	To treat children ages 2 to 12 years old with Chagas disease Press Release Drug Trials Snapshot
30.	Vabomere	meropenem and vaborbactam	8/29/2017	To treat adults with complicated urinary tract infections Press Release Drug Trials Snapshot
29.	Besponsa	inotuzumab ozogamicin	8/17/2017	To treat adults with relapsed or refractory acute lymphoblastic leukemia Press Release Drug Trials Snapshot
28.	Mavyret	glecaprevir and pibrentasvir	8/3/2017	To treat adults with chronic hepatitis C virus Press Release Drug Trials Snapshot

[1] https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm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