



# The Federal Register Publication System:

## WHAT IT IS AND HOW TO USE IT

Office of the Federal Register  
National Archives and Records Administration

2016

# Federal Register Workshop

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Office of the Federal Register (OFR),

- [www.federalregister.gov](http://www.federalregister.gov)
- [www.ofr.gov](http://www.ofr.gov)

National Archives and Records Administration (NARA)

- [www.archives.gov/](http://www.archives.gov/)

Federal Register publications are produced by:

OFR and the Government Printing Office (GPO)

- GPO: [www.fdsys.gov](http://www.fdsys.gov)

# What topics will this workshop cover?

Historical background and legal basis

The regulatory process and the role of the public

Organization the *Federal Register* and CFR

Relationships among Public Laws, the FR and CFR

Research tools and Finding Aids

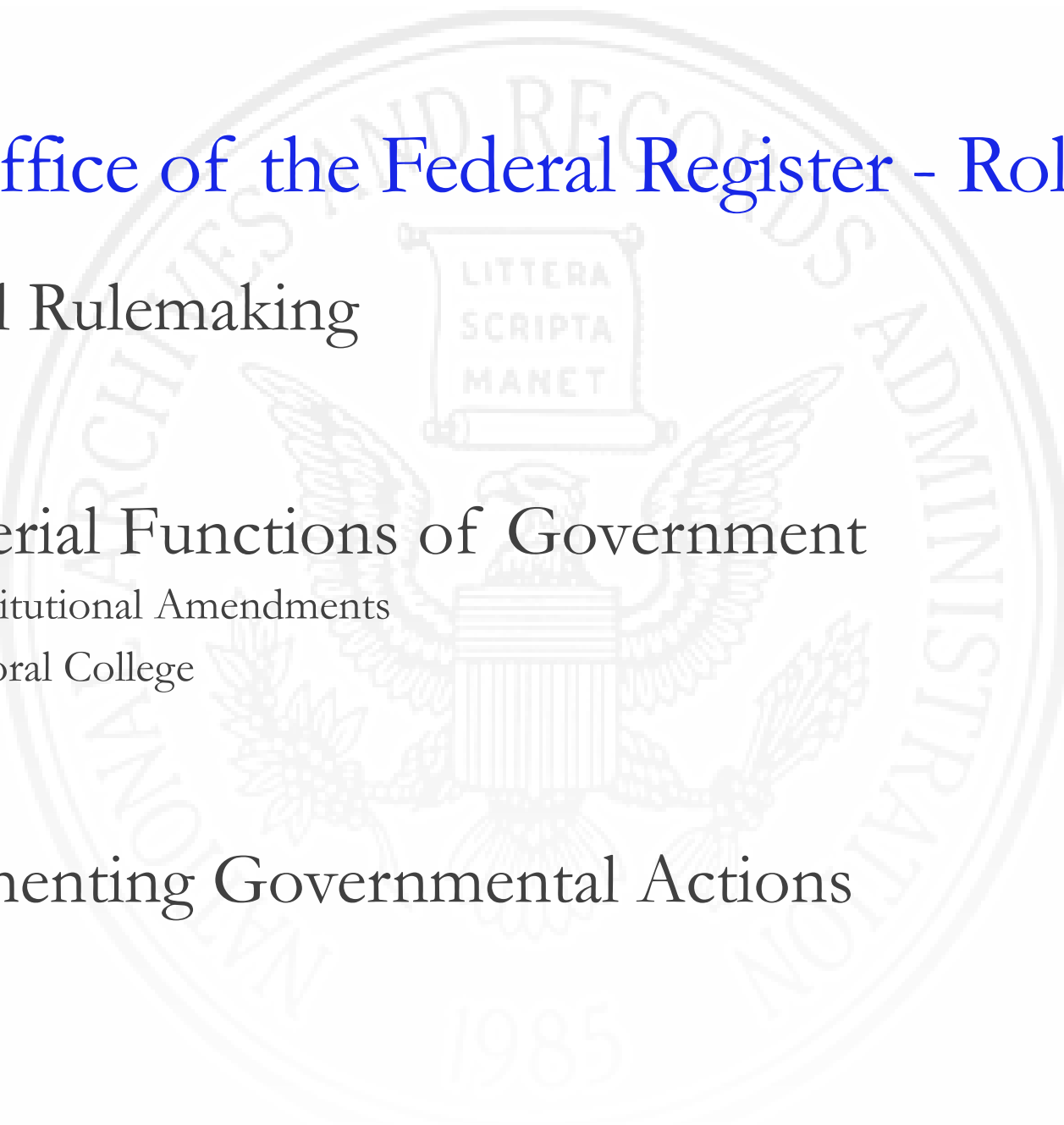
# Office of the Federal Register - Roles

Federal Rulemaking

Ministerial Functions of Government

- Constitutional Amendments
- Electoral College

Documenting Governmental Actions



# Office of the Federal Register - Publications

## Ministerial Functions of Government

- Public Laws/Slip Laws
- *U.S. Statutes-at-Large*

## Documenting Governmental Actions

- *Daily Compilation of Presidential Documents*
- *Public Papers of the Presidents*
- *United States Government Manual*
- Privacy Act Issuances

## Federal Rulemaking

- *Federal Register*
- *Code of Federal Regulations*

# Federal Rulemaking - *The Rule of Law*

Law – principles and regulations established, administered, and enforced for a community by some authority

## Separation of Powers

- Legislative
- Executive
- Judicial

# The Rule of Law



## Legislative Law

Public

- (Permanent, Temporary, Standby, Organic, Positive)

Private

## Judicial Law

- Case Law – Common Law

## Executive Law

- Rules/Regulations
- Administrative Law

# Laws vs. Rules

## Is there a difference?

Have the force and effect of Law (enforceable)

Have general applicability to the public

Note: Each branch of government also has *internal rules* of operations

- Legislative - Senate Rules
- Judicial – Rules of Evidence
- Executive - OMB Directives, Executive Orders





# Publishing Laws

Signed Enrolled Bills

Public Laws  
(OFR publication)

*U.S. Statutes-at-Large*  
(OFR publication)

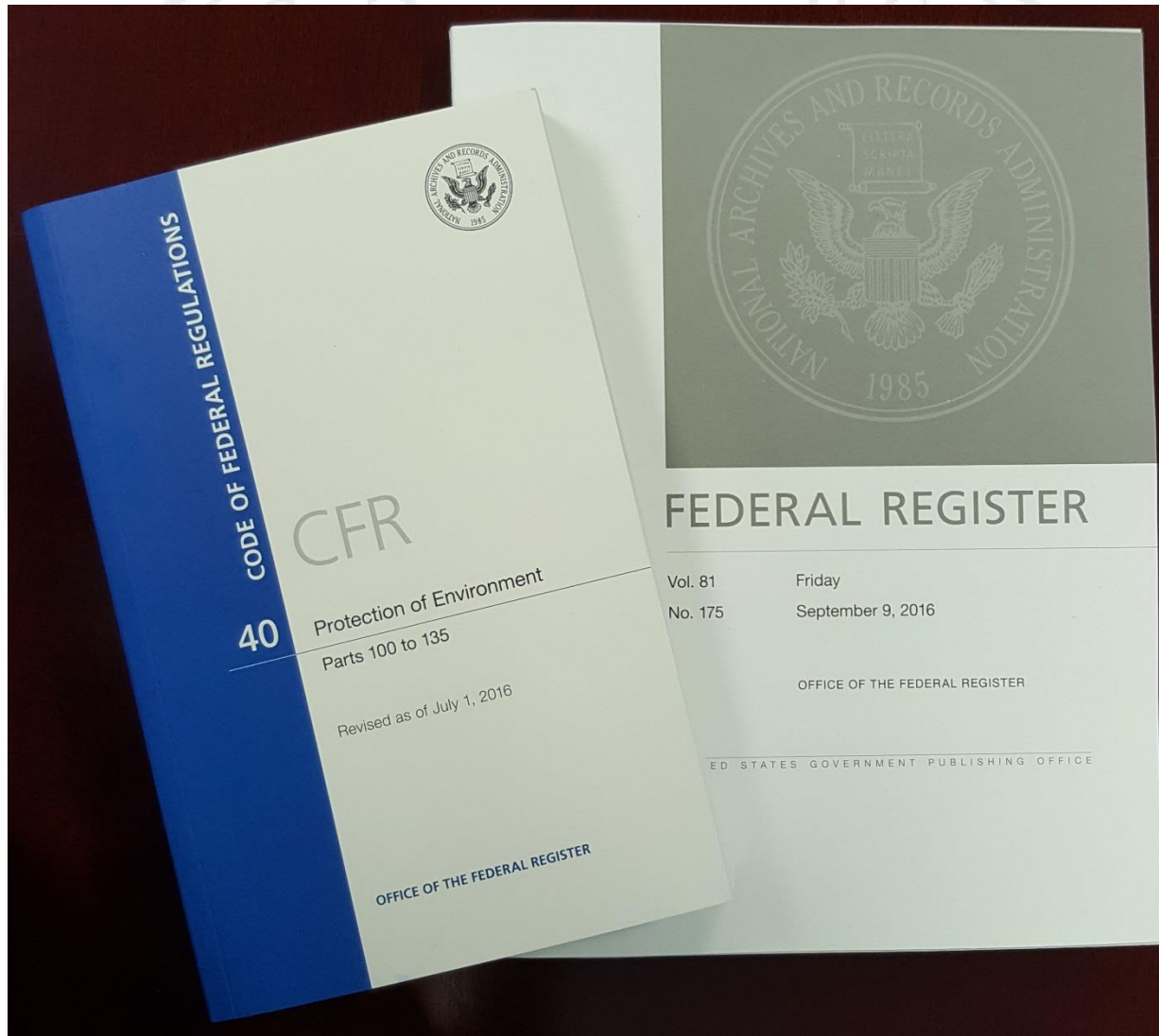
*United States Code – U.S.C.*

(Codified by the Law Revision Counsel of the U.S. House of Representatives)

# Comparison of Laws and Rules

Congress Passes Laws	Executive Agencies Issue Rules
Publish Slip Law / Statutes at Large Codified in U.S. Code	Publish in Federal Register Codified in CFR
Power comes from Constitution	Power delegated from Congress
Courts Review for constitutionality	Courts review for: Constitutionality; Limits of delegated authority; Arbitrary and capricious actions; Administrative Procedure Act
Representative Democracy: Congress acts collectively to represent the will of the people	Participatory Democracy: Agencies must seek and consider public comment on benefits of rules v. burdens and costs
Set broad social and economic goals and legal requirements	Prescribe specific legal requirements to meet goals

# Historical Background & Legal Basis



# Why was the Federal Register System Established ?

## New Deal Legislation

- A growing government
- New agencies regulating new areas

## Lack of Process

- No centralized publication system

## Lack of Access

- No centralized filing system

## Lack of Organization

- No organization to the system

## Constitutional Issues

- Separation of Powers
- Due Process
- Fairness

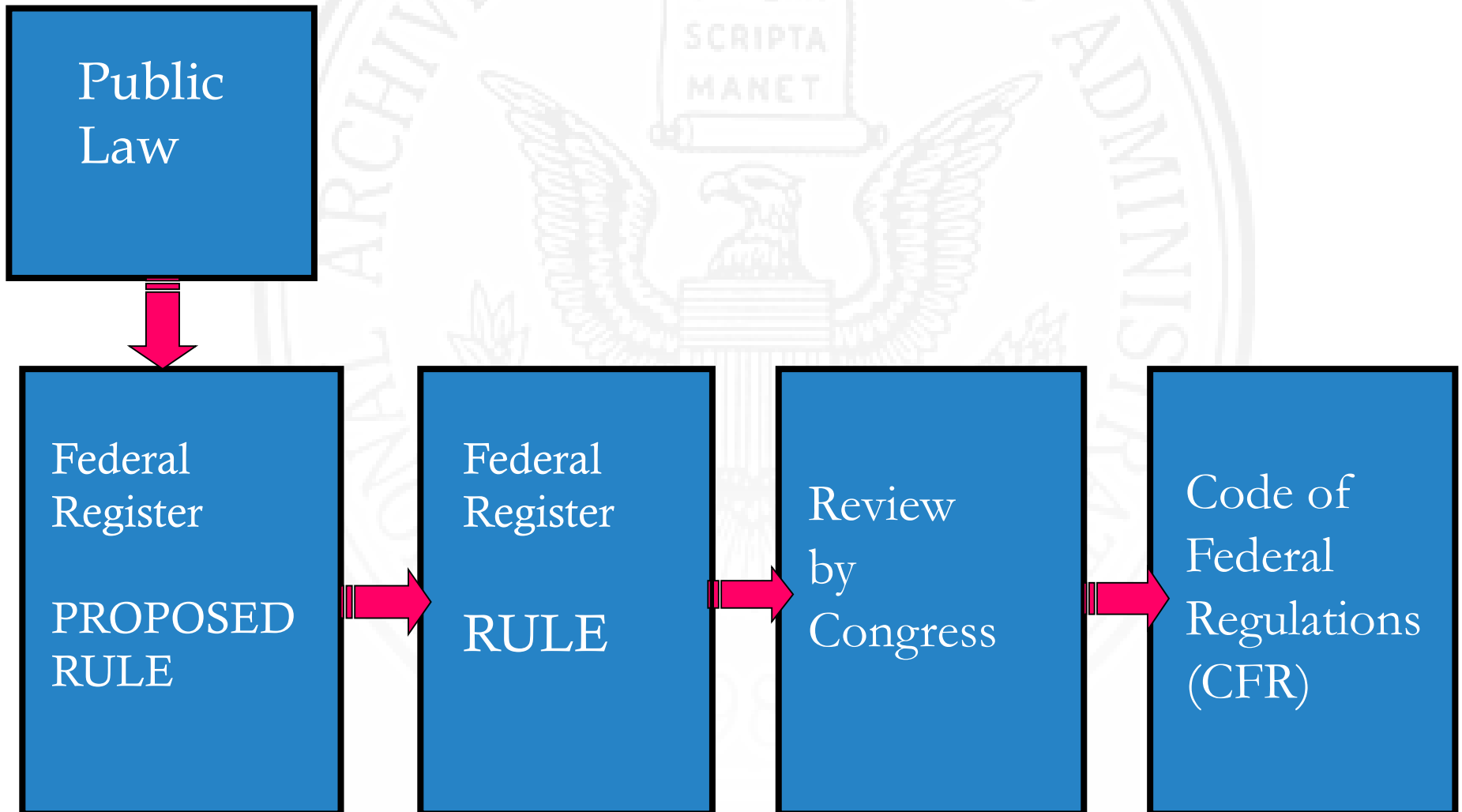
# Federal Regulatory Process – the Congressional Response

## Legal structure:

- The Federal Register Act
- The Administrative Procedure Act (APA)
- Congressional Review Act
- Other individual laws

Designed to allow Federal agencies to issue  
and enforce legally effective regulations

# The Regulatory Process



# Other Parts of the Federal Regulatory Process

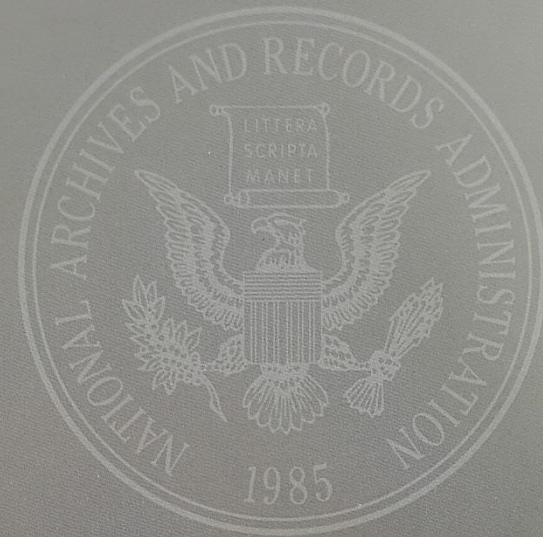


Agency Dockets

Administrative Requirements

Regulatory Review (OIRA)

**The Daily**  
***FEDERAL***  
***REGISTER***



**FEDERAL REGISTER**

Vol. 81

Friday

No. 175

September 9, 2016

OFFICE OF THE FEDERAL REGISTER

UNITED STATES GOVERNMENT PUBLISHING OFFICE



# The *Federal Register*

An official daily legal publication

Informs citizens of:

- rights and obligations
- opportunities for funding and Federal benefits
- actions of Federal agencies for accountability to public

Citation: 64 FR 34567 (June 5, 1999)

# *Federal Register* Documents

## Document categories:

1. Presidential Documents
2. Rules and Regulations
3. Proposed Rules
4. Notices

## Additional sections:

Separate Parts

Reader Aids

# 1. Proposed Rule

Announces possible changes to the CFR

Sets out proposed regulatory text or describes proposal

Solicits public comment on proposal

Initiates the “notice and comment rulemaking” process under the APA (5 U.S.C. 553)

# What Types of documents are in the Proposed Rules section ?

## Proposed Rules

- AKA: “Notice of Proposed Rulemaking” (NPRM)

## Preliminary Rulemaking Documents

## Miscellaneous proposals and updates

# Standard Preamble Headings and Captions

Headings: Agency name, CFR title and part(s), docket info, subject matter

## Captions

AGENCY:

ACTION:

SUMMARY:

DATES:

ADDRESSES:

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:



# Advance Notices and Preliminary Rulemaking Documents

Advance Notice of Proposed Rulemaking

Petition for Rulemaking

Negotiated Rulemaking (“RegNeg”) document

# Miscellaneous Proposed Rule Documents

- Extension of time to submit comments on proposed rule
- Further notice of proposed rulemaking to make changes in response to comments or events
- Withdrawal of proposed rule
- Annual review of regulations -- opportunity to comment

## 2. Rules and Regulations

Documents with:

- Final legal effect
- General applicability to the public

Most, rules amend and are codified in the CFR



# Final Rule

Generally issued to amend the CFR

Finalizes a proposed rule

Takes final action without a prior proposed rule

## Effective Dates:

- At least 30 days from date of publication
- At least 60 days from date of publication for major rules
- On date of publication
  - emergency
  - good cause

# What Types of Documents are in the Rules & Regulations Section ?

- Final Rules
- Interim Final Rules
- Direct Final Rules
- Documents that relate to previous rules & regulations

# Standard Preamble Headings and Captions

Headings: Agency name, CFR title and part(s), docket info, subject matter

## Captions

AGENCY:

ACTION:

SUMMARY:

DATES:

ADDRESSES:

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

# Final Rule Amendments and Regulatory Text

Follow the “Supplementary Information” section  
of the Preamble

Preceded by the “List of Subjects”

Numbered amendatory instructions specifically  
state how the CFR will be amended

# Interim Final Rule

## Issued:

- To react to an emergency situation
- To relieve unnecessary restrictions on the public
- To take public comments on interim action

## Effective:

- On date of publication; or
- Less than 30 days from date of publication

## Comment Period:

- Yes

# Direct Final Rule

Issued:

Non-controversial actions

Effective:

30, 60 to 90 days from date of publication, if it is not withdrawn due to adverse comments

Is there a comment period?

Yes

Withdrawn:

Monitor the *Federal Register* for a withdrawal document

# Documents that Relate to Previous Rules & Regulations

## Examples:

Interpretive Rule; Policy Statement on Enforcement; Clarification

Temporary Rule; Deviation; Waiver

Establishment, Delay, Suspension of Effective Date

Reconsideration of recently issued Final Rule

Withdrawal or Confirmation of Direct Final Rule

# 3. Notice Documents

Describe official actions and functions that:

- May affect the public or provide important information BUT Do not amend the CFR.

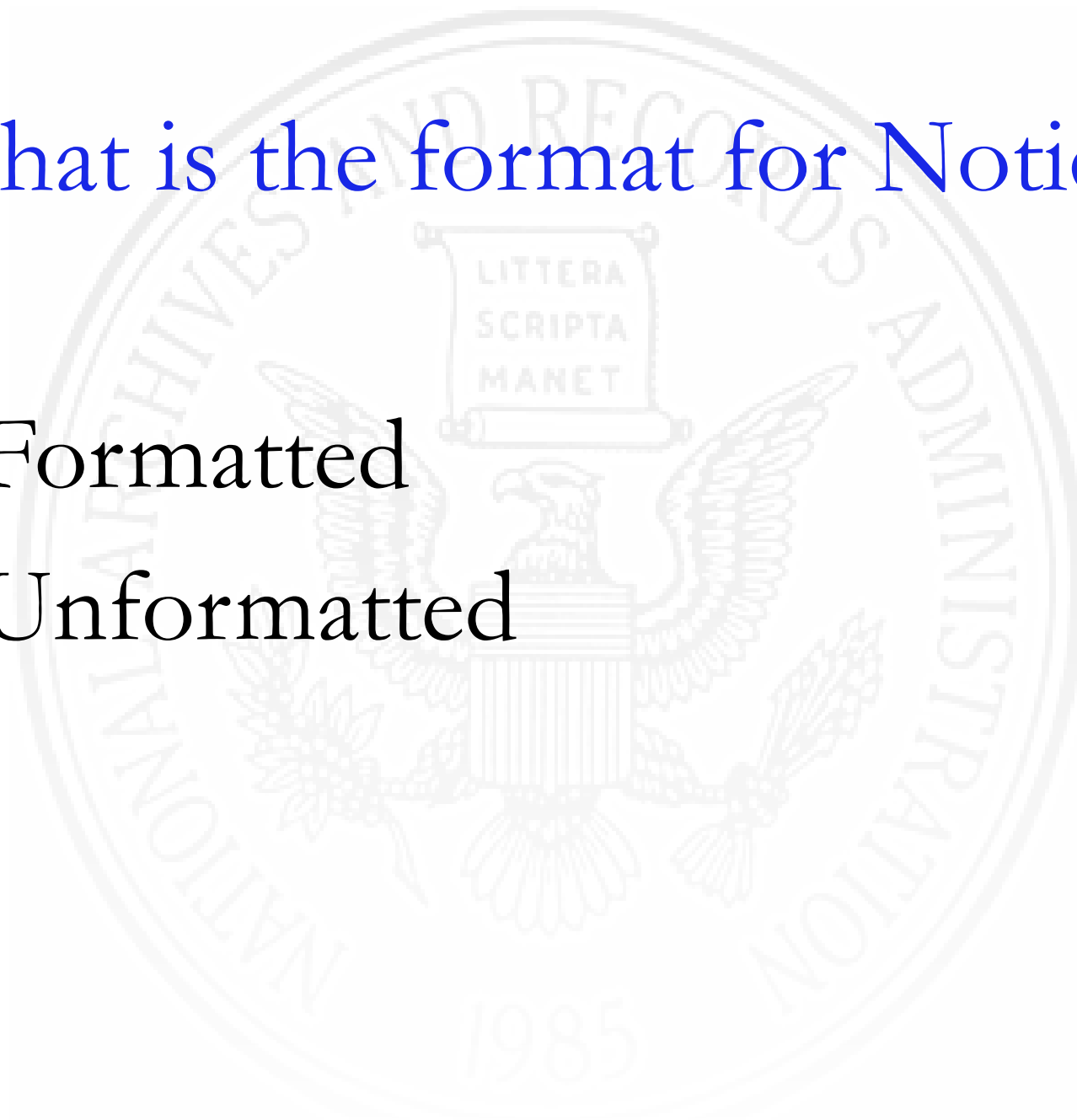
Examples:

- Sunshine Act and Federal Advisory Committee Act meeting notices
- Grant announcements and funding availability
- Environmental impact statements



# What is the format for Notices ?

- Formatted
- Unformatted

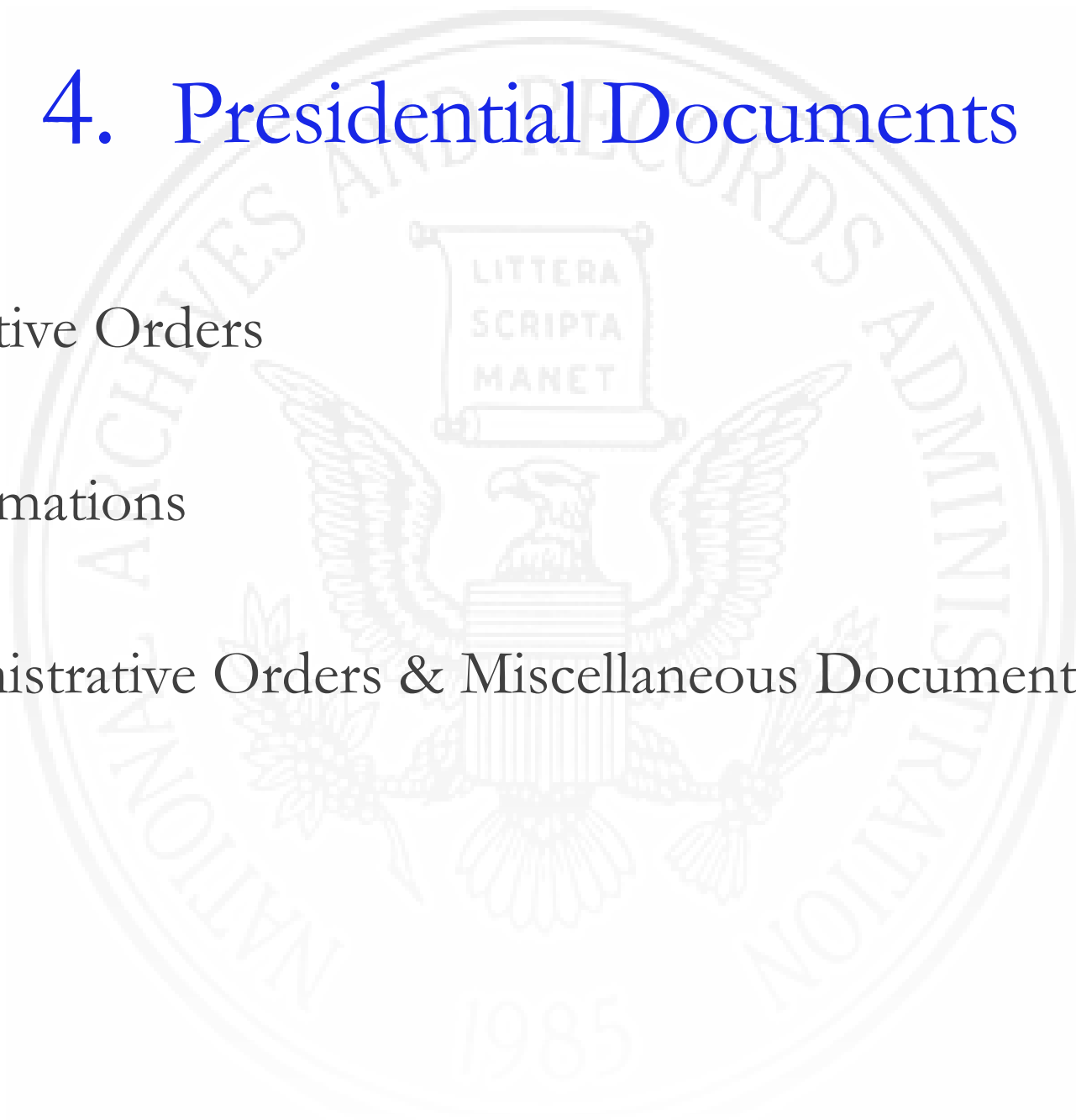


# 4. Presidential Documents

Executive Orders

Proclamations

Administrative Orders & Miscellaneous Documents



# Executive Orders

Directed at Executive agencies to manage operations

President has constitutional authority to issue E.O.s as Chief Executive and as Commander-in-Chief

Numbered consecutively as received by OFR

Reprinted annually in 3 CFR, not codified

# Proclamations

## TYPES

- Ceremonial
- Substantive

Numbered consecutively as received by OFR

No legal distinction between E.O.s & Proclamations

Reprinted annually in 3 CFR, not codified

# Administrative Orders and Miscellaneous Documents

Determinations

Memoranda

Reorganization Plans

Notices of Continuation of National Emergencies

Comprehensive record of Presidential statements and directives:

*Compilation of Presidential Documents*

*Public Papers of the Presidents* series

# Separate Parts

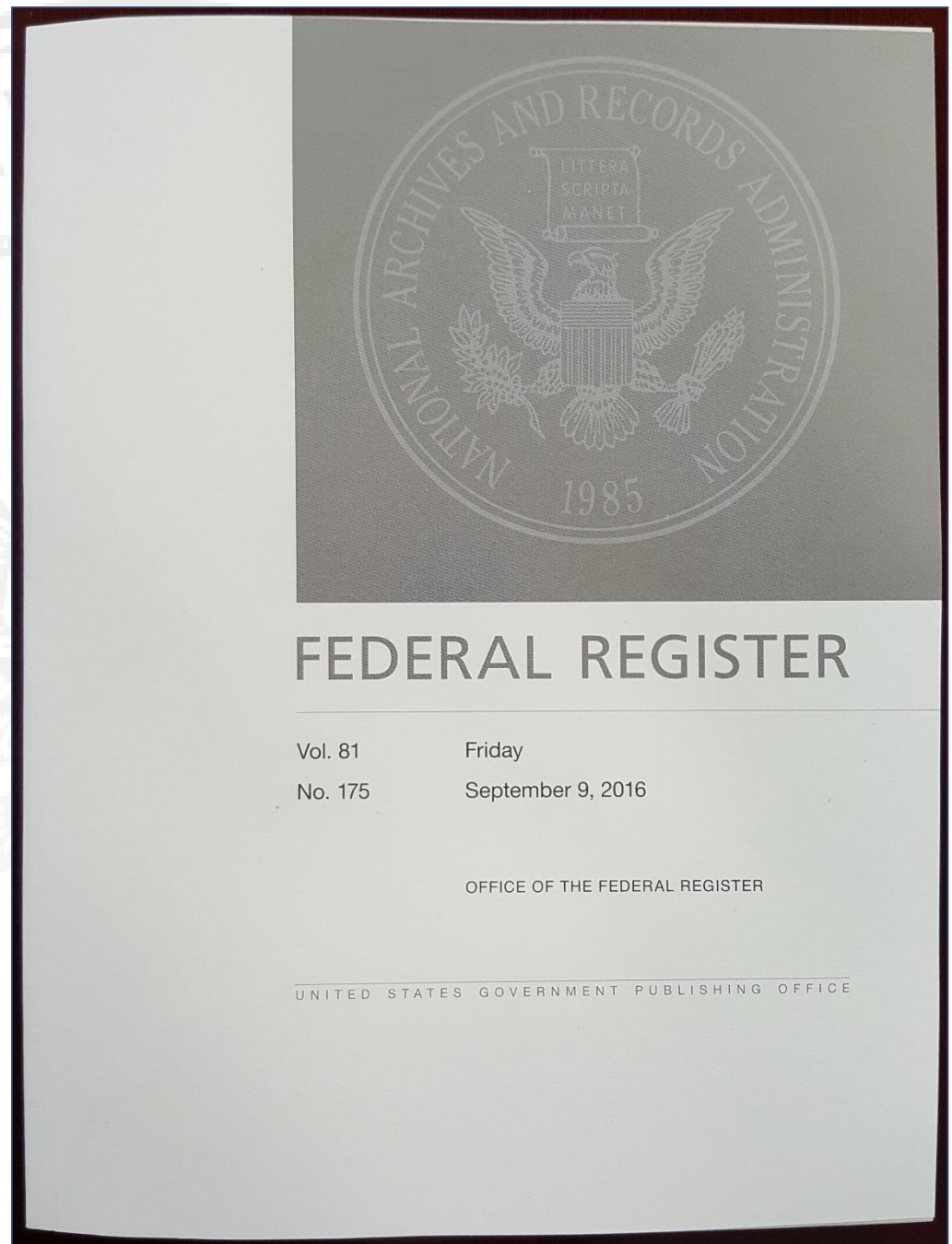
Appear at the end of the daily *Federal Register* issue

Agencies request

- For high profile documents.
- To group related Final Rules, Proposed Rules and Notices together

OFR places late arriving documents in separate parts for production purposes

*Daily Federal  
Register*  
Finding Aids  
and Research  
Tools in Print  
and On-line





# Daily *Federal Register* Research Tools and Finding Aids

Table of Contents

CFR Parts Affected in this Issue

Reader Aids





# *Federal Register*

## Table of Contents

Arranged by agency name in alphabetical order

Cross-references

Each agency document is arranged by category

Presidential Documents are arranged as follows:

- Executive Orders
- Proclamations
- Determinations/Memoranda

# “CFR Parts Affected” in this Issue

Located after the Table of Contents

Lists CFR titles and parts affected in an issue

Indicates whether the documents affecting CFR parts are rules or proposed rules

Lists the number designations of all Presidential documents in the issue

Cites the page numbers where relevant documents begin

# CFR Parts Affected During (the current month)

Cumulative table

Lists documents in numerical order by CFR title and part

You can quickly determine:

- The CFR titles and parts affected by documents published during the current month
- Whether the documents affecting the CFR parts are rules or proposed rules
- The number designation of Presidential documents published during the current month
- The page numbers where the relevant documents begin

# On-line: FederalRegister.gov

Launched July 26, 2010 – 75th Anniversary of the Federal Register Act

Currently an unofficial, web-based edition of the Federal Register

Online newspaper look and feel

[www.federalregister.gov](http://www.federalregister.gov)

# FederalRegister.gov Features

Persistence of documents (“articles”)

“News” sections – topical organization

Agency pages with list of recently published documents and documents with comment periods that are opening or closing soon

Summary and Key Information

Regulations.gov Docket Information and Ability to Submit Comments from Document Page on federalregister.gov

# FederalRegister.gov Additional Features



Topics Index

Social Networking Tools

Public Inspection Desk

Currently Updated Federal Register Index

Currently Updated Executive Order Disposition Tables

“My FR”

Advanced Subscription Management

# Recent FederalRegister.gov Upgrades

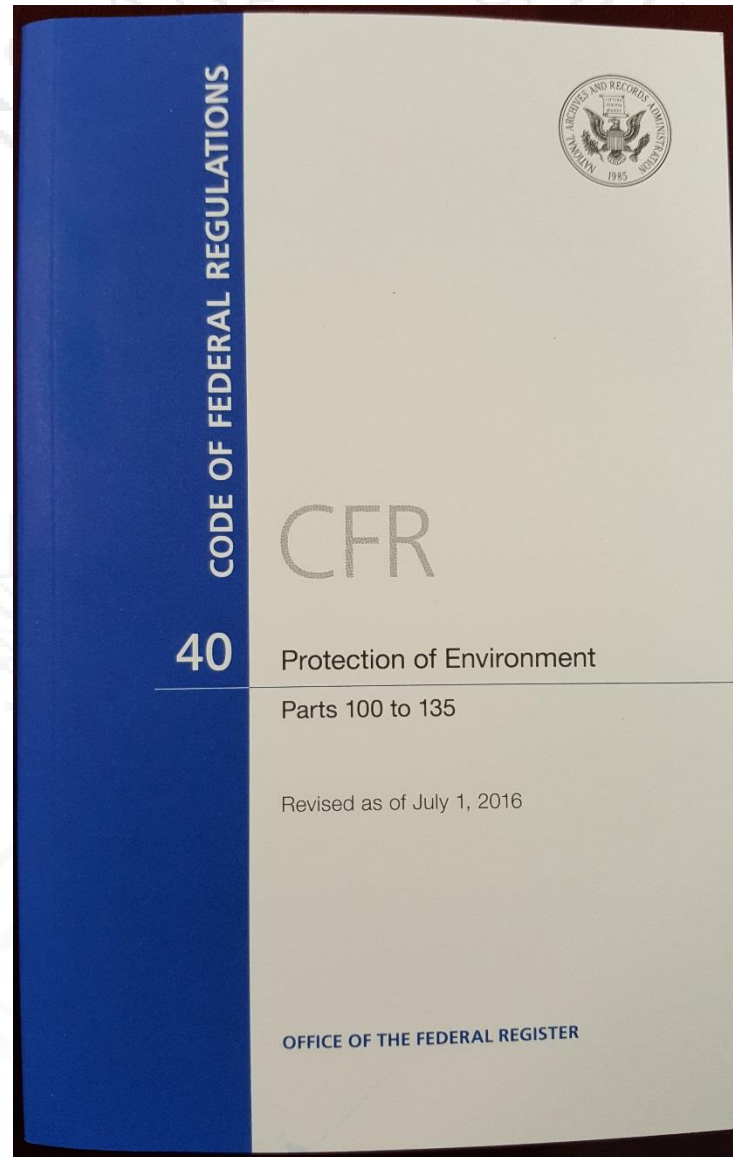
In September 2016 major upgrades were made to the website

Content Box

Improved Document View

Application Programming Interface (API)

# The CFR – Organization and Contents





# What is the Code of Federal Regulations ?

The CFR contains Federal rules that have:

- General applicability to the public
- Current and future effect as of the date specified

Always published first in the FR as amendments to the CFR

The CFR is published in a set of about 230 volumes

- Printed soft cover books
- Microfiche
- Online at: [www.access.gpo.gov/nara](http://www.access.gpo.gov/nara)

# How is the CFR organized ?

Federal regulations are organized into:

- 50 titles
- Broad subject matter categories
  - Environment, Defense, Public Health, Transportation

Each title is completely revised and reissued once each year on a staggered schedule.

- Titles 1 -- 16 updated as of January 1
- Titles 17 -- 27 updated as of April 1
- Titles 28 -- 41 updated as of July 1
- Titles 42 -- 50 updated as of October 1

# What is the CFR numbering system ?

The CFR has a uniform numbering system

- Titles 3, 41, and 48 have significant variations

The section is the basic unit of the CFR

Cite the CFR by title and section: 12 CFR 303.1

Text is divided into descending levels of units

# CFR Structure

Title	12	Broad subject area of regulations
Chapter	III	Rules of individual agency
Part	303	Rules on a single program or function
Section	303.1	One provision of program/function rules
Paragraph	303.1(a)	Detailed, specific requirements

# Paragraph Levels

Sections may contain up to 6 levels of paragraphs.

- We strongly recommend no more than 3 levels.

<u>Paragraph</u>	<u>Designations</u>	<u>Cite paragraph as</u>
Level 1	(a), (b), (c), etc.	§ 303.1(a)
Level 2	(1), (2), (3), etc.	§ 303.1(a)(1)
Level 3	(i), (ii), (iii), etc.	§ 303.1(a)(1)(i)
Level 4	(A), (B), (C), etc.	§ 303.1(a)(1)(i)(A)
Level 5	(1), (2), (3), etc.	§ 303.1(a)(1)(i)(A)(1)
Level 6	(i), (ii), (iii), etc.	§ 303.1(a)(1)(i)(A)(1)(i)



# Material Approved for Incorporation By Reference (IBR)

(5 U.S.C. 552(a) and 1 CFR Part 51)

IBR material has the force of law as though it were published in full text the FR & CFR

Congress authorized IBR to enforce voluntary standards already used in science & industry

Under the FOIA, the Director of the Federal Register must approve IBR to give it force and effect of law

# Part Level Table of Contents, Authority Citations, and Source Notes

A new entry in the table of contents at the part level to reflect the newly added section of regulatory text

The authority citation below the table of contents

The source note below the authority cite

# Table of Contents, Authority Cite, Source Note

Title 21--Food and Drugs

CHAPTER I--FOOD AND DRUG ADMINISTRATION,  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES--(Continued)

## PART 514--NEW ANIMAL DRUG APPLICATIONS

### Subpart A – General Provisions

\* \* \*

### Subpart B – Administrative Actions on Applications

514.100	Evaluation and comment on applications.
514.105	Approval of applications.
514.106	Approval of supplemental applications.
514.110	Reasons for refusing to file applications.
514.111	Refusal to approve an application.
514.112	Return of applications for animal feeds bearing or containing new animal drugs.
514.115	Withdrawal of approval of applications.
514.116	Notice of withdrawal of approval of application.
514.117	Adequate and well-controlled studies.
514.120	Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.
514.121	Service of notices and orders.

### Subpart C – Hearing Procedures

\* \* \*

### Subparts D-E [Reserved]

### Subpart F – Judicial Review

514.235	Judicial review.
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**AUTHORITY:** 21 U.S.C. 351, 352, 360b, 371, 379e, 381

**SOURCE:** 40 FR 13825, Mar. 27, 1975, unless otherwise noted.

**Section  
514.117  
added to  
Table of  
Contents**

**Authority  
Citation and  
Source Note**





# CFR Text, Section Level Source Notes, and Authority Citations


The text of new section 514.117 inserted into CFR Title 21, Chapter I, Part 514,  
Subpart B

A source note

No separate authority citation for this section

# CFR Text & Section Source Note

Text of  
§ 514.117  
added to  
CFR



Updated  
Source  
Note cites  
to the final  
rule



## TITLE 21--FOOD AND DRUGS

### CHAPTER I--FOOD AND DRUG ADMINISTRATION, DE AND HUMAN SERVICES--(Continued)

#### PART 514--NEW ANIMAL DRUG APPLICATIONS--Table

##### Subpart B--Administrative Actions on Applications

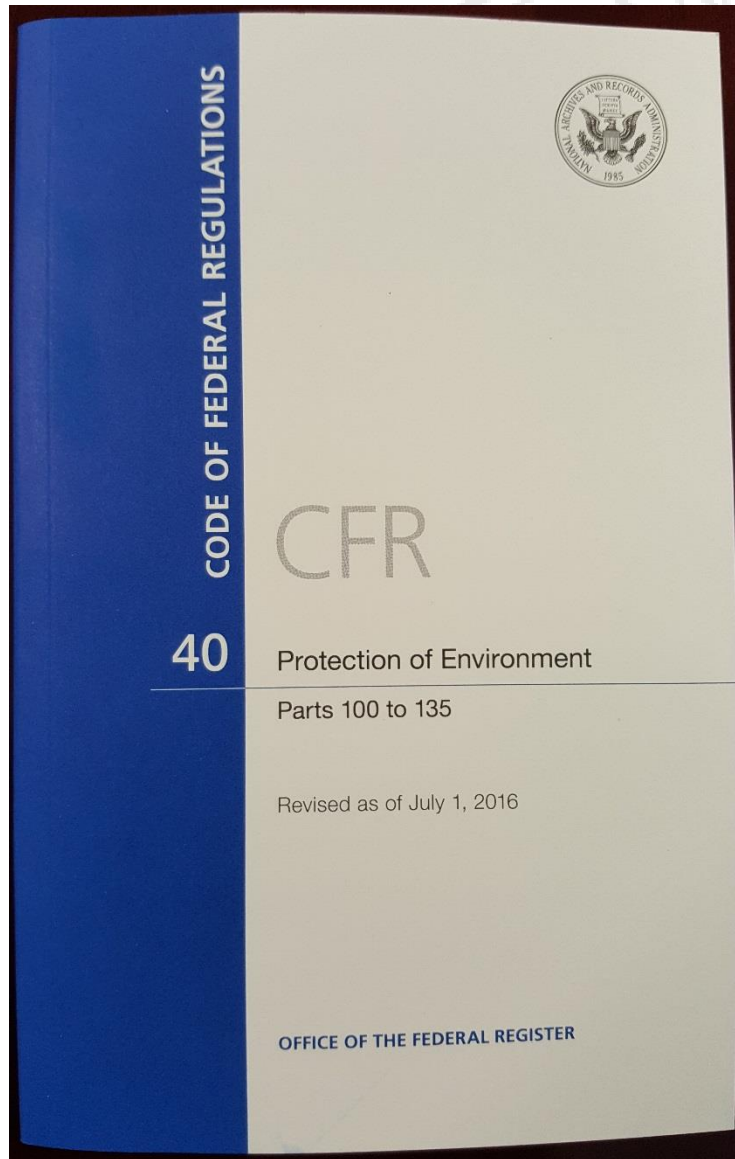
#### § 514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

#### § 514.117 Adequate and well-controlled studies.

- (a) *Purpose.* The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well controlled, as used in the phrase adequate and well controlled, emphasizes an important aspect of adequacy. The Food and Drug Administration (FDA) considers these characteristics in determining whether a study is adequate and well controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Adequate and well-controlled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be relied upon to support target animal safety. ~~~~~

# CFR Research Tools in Print and On-line



**Tables of Contents**

**Incorporation by Reference  
Tables**

**Table of CFR Titles and Chapters**

**Alphabetical List of Agencies  
Appearing in the CFR**

**Redesignation Tables**

**List of CFR Sections Affected**

**e-CFR**

# What research tools are in each printed volume of the CFR ?

At the front of each CFR volume, look for:

- Tables of contents to all material within the book
- Tables of contents to the title, subtitle(s), chapter(s), and subchapter(s) within the book

At the back of each CFR volume, look for:

- “Table of CFR Titles and Chapters”
- “Alphabetical List of Agencies Appearing in the CFR”
- Redesignation Tables
- “List of CFR Sections Affected”

# Table of Contents to a Subtitle

Table of Contents shows page numbers for the beginning of each part

## Subtitle A—Office of the Secretary of Agriculture

<i>Part</i>		<i>Page</i>
1	Administrative regulations .....	5
1a	Law enforcement authorities .....	95
1b	National Environmental Policy Act .....	96
1c	Protection of human subjects .....	98
2	Delegations of authority by the Secretary of Agriculture and general officers of the Department ...	108
3	Debt management .....	238
4	[Reserved]	
5	Determination of parity prices .....	258
6	Import quotas and fees .....	263
7	Selection and functions of Agricultural Stabilization and Conservation State, county and community committees .....	282
8	4-H Club name and emblem .....	295
9-10	[Reserved]	
11	National Appeals Division rules of procedure .....	298
12	Highly erodible land and wetland conservation .....	309
13	[Reserved]	
14	Determining the primary purpose of certain payments for Federal tax purposes .....	331
15	Nondiscrimination .....	334
15a	Education programs or activities receiving or benefiting from Federal financial assistance .....	366
15b	Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance .....	382
15e	Enforcement of nondiscrimination on the basis of handicap in programs or activities conducted by the United States Department of Agriculture .....	404
15f	Adjudications under section 741 .....	410
16	[Reserved]	

# Part Level Table of Contents

Table of Contents lists the sections in the part and subparts

## **PART 1—ADMINISTRATIVE REGULATIONS**

### **Subpart A—Official Records**

- Sec.
- 1.1 Purpose and scope.
  - 1.2 Policy.
  - 1.3 Agency implementing regulations.
  - 1.4 Implementing regulations for the Office of the Secretary.
  - 1.5 Public access to certain materials.
  - 1.6 Requests for records.
  - 1.7 Aggregating requests.
  - 1.8 Agency response to requests for records.
  - 1.9 Search services.
  - 1.10 Review services.
  - 1.11 Handling information from a private business.
  - 1.12 Date of receipt of requests or appeals.
  - 1.13 Appeals.
  - 1.14 Extension of administrative deadlines.
  - 1.15 Failure to meet administrative deadlines.
  - 1.16 Fee schedule.
  - 1.17 Exemptions and discretionary release.
  - 1.18 Annual report.
  - 1.19 Compilation of new records.
  - 1.20 Authentication.
  - 1.21 Records in formal adjudication proceedings.
  - 1.22 Preservation of records.

### **APPENDIX A TO SUBPART A—FEE SCHEDULE**

### **Subpart B—Departmental Proceedings**

- 1.26 Representation before the Department of Agriculture.
- 1.27 Rulemaking and other notice proceedings.
- 1.28 Petitions.
- 1.29 Subpoenas relating to investigations under statutes administered by the Secretary of Agriculture.

### **Subpart C—Judicial Proceedings**

- 1.41 Service of process.

### **Subpart D—Claims**

- 1.51 Claims based on negligence, wrongful act or omission.

### **Subpart E—Cooperative Production of Television Films**

- 1.71 Purpose.
- 1.72 Policy.
- 1.73 Responsibility.
- 1.74 Basis for special working relationships.
- 1.75 General stipulations.
- 1.76 Department cooperation.
- 1.77 Assignment of priorities.
- 1.78 Development of special working relationships.
- 1.79 Credits.

### **Subpart G—Privacy Act Regulations**

- 1.110 Purpose and scope.
- 1.111 Definitions.
- 1.112 Procedures for requests pertaining to individual records in a record system.
- 1.113 Times, places, and requirements for identification of individuals making requests.
- 1.114 Disclosure of requested information to individuals.
- 1.115 Special procedures: medical records.
- 1.116 Request for correction or amendment to record.
- 1.117 Agency review of request for correction or amendment of record.
- 1.118 Appeal of initial adverse agency determination on correction or amendment.
- 1.119 Disclosure of record to person other than the individual to whom it pertains.
- 1.120 Fees.
- 1.121 Penalties.
- 1.122 General exemptions.
- 1.123 Specific exemptions.

### **APPENDIX A TO SUBPART G—INTERNAL DIRECTIVES**

### **Subpart H—Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes**

- 1.130 Meaning of words.
- 1.131 Scope and applicability of this subpart.
- 1.132 Definitions.
- 1.133 Institution of proceedings.
- 1.134 Docket number.
- 1.135 Contents of complaint or petition for review.
- 1.136 Answer.
- 1.137 Amendment of complaint, petition for review, or answer; joinder of related matters.
- 1.138 Consent decision.
- 1.139 Procedure upon failure to file an answer or admission of facts.
- 1.140 Conferences and procedure.
- 1.141 Procedure for hearing.
- 1.142 Post-hearing procedure.
- 1.143 Motions and requests.
- 1.144 Judges.
- 1.145 Appeal to Judicial Officer.
- 1.146 Petitions for reopening hearing; for rehearing or reargument of proceeding; or for reconsideration of the decision of the Judicial Officer.
- 1.147 Filing; service; extensions of time; and computation of time.
- 1.148 Depositions.
- 1.149 Subpoenas.
- 1.150 Fees of witnesses.
- 1.151 Ex parte communications.

# Table of CFR Titles and Chapters

A list of all CFR titles, subtitles, chapters, and part spans in numerical order -- titles 1 to 50

Includes the names of agencies assigned to CFR chapters

A more detailed list is located in the *CFR Index and Finding Aids*, a separate publication

# Alphabetical List of Agencies Appearing in the CFR

A list of all agencies that publish in the CFR

References to sub-agencies under main agencies

Location of the regulations of each agency and sub-agency appear in the CFR by title, subtitle and chapter



# Redesignation Tables

A Redesignation Table helps you find the new location of parts and sections of regulations

An agency publishes this table when it has done extensive reorganization and renumbering

The table appears in the preamble of the rule document and is then included as a research tool in the back of the CFR

# List of CFR Sections Affected (in a specific CFR volume)

This list helps you track amendments in each CFR volume for the previous five years with FR page numbers

Lists the type of amendment and the text affected down to the paragraph level

For earlier years, use the *List of CFR Sections Affected* (LSA)

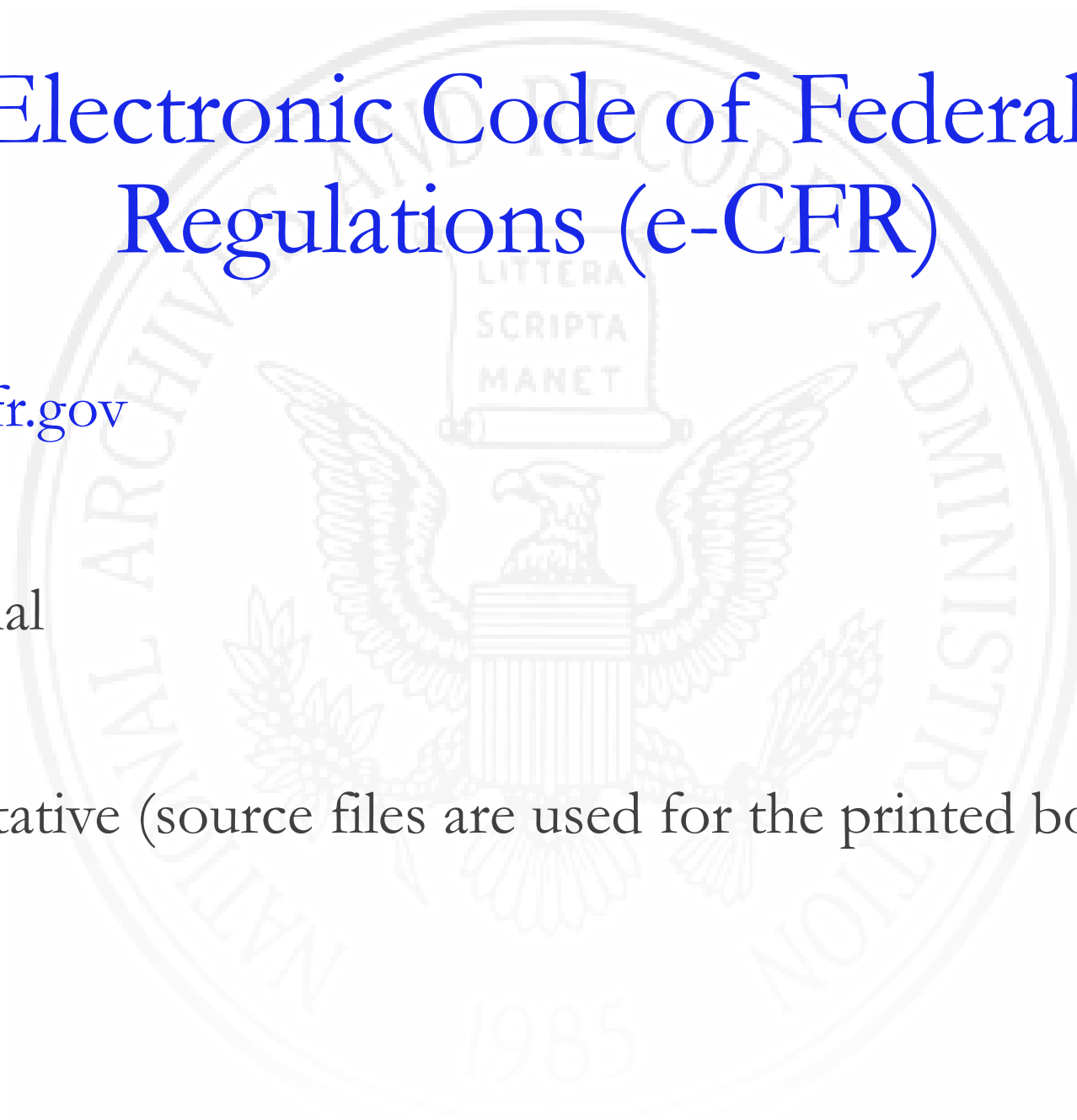
A cumulative, monthly LSA is also published separately

# Electronic Code of Federal Regulations (e-CFR)

[www.ecfr.gov](http://www.ecfr.gov)

Unofficial

Authoritative (source files are used for the printed books)



# e-CFR Features

Updated daily to incorporate all changes

Includes links to published amendments that will be effective at a future date

1-2 day lag

“Point-in-Time” view back to January 1, 2015

Fully Searchable

Searchable by specific category of information (CFR element)

# Federal Register On-line Resources

## Official Federal Register Publications

- [www.fdsys.gov](http://www.fdsys.gov)  
Online versions of the publications
- [www.federalregister.gov](http://www.federalregister.gov)  
Federal Register 2.0  
Public Inspection Desk

## Federal Register Information

- [www.ofr.gov](http://www.ofr.gov)  
Information about the publications  
Information about the Federal regulatory process

# Federal Register On-line Resources (cont.)

## Electronic Code of Federal Regulations (e-CFR)

- [www.ecfr.gov](http://www.ecfr.gov)

## National Archives FR Home Page

- [www.archives.gov/federal-register](http://www.archives.gov/federal-register)

## Public Participation in Rulemaking

- [www.regulations.gov](http://www.regulations.gov)

Thank you!

