The Mechanics of Federal Rulemaking

A Look "Under the Hood"

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What 's Under the Hood? (Objectives)

- Legal Basis of the Federal Register system
- Historical background
- The Federal regulatory process and the role of the public
- Organization the *Federal Register* and CFR
- Relationships among Public Laws, the FR and CFR
- Helping Customers

Office of the Federal Register Publications

- *Federal Register*
- *Code of Federal Regulations*
- *Privacy Act Compilation*
- *U.S. Government Manual*
- *Compilation of Presidential Documents*
- *Public Papers of the Presidents*
- Public Laws
  - Slip Laws
  - *U.S. Statutes-at-Large*

Current Public Policy Debates

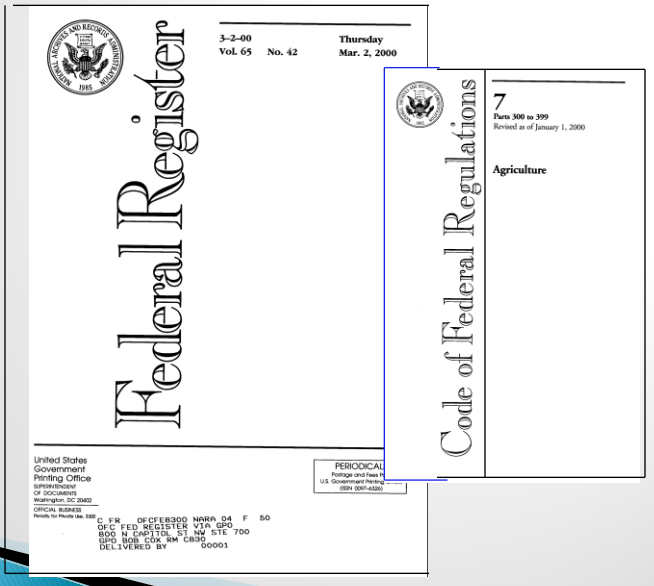
- *Keystone Oil Pipeline*
- *"Obamacare"*
- *NBA Ownership Rules*
- *Internet Neutrality*
- *Immigration Reform*
- *Same-sex Marriage*
- *Oklahoma Lethal Injection*

Legal Basis

- Constitution
- Public Laws
  - United States Statutes at Large (Stat)
  - United States Code (U.S.C.)
- Common Law
  - Litigation
- Regulations
  - Code of Federal Regulations
- Administrative Law
  - Adjudication

Where's the Federal Register ?

Historical Background



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

Federal Register Act

Enacted: July 26, 1935 Cite: 44 U.S.C. Chap. 15

- Established a central location
  - Office of the Federal Register
- Established a means of publicizing
  - The daily Federal Register
- Established a system of organization
  - The *Code of Federal Regulations*

Effect of Publishing in the *Federal Register*

- Official notice
- Legal authority of the agency
- Documents evidentiary status
- Shows how and when the CFR will be amended

Administrative Procedure Act

Enacted: June 11, 1946 Cite: 5 U.S.C. 551 et seq.

- Established a *Process*
  - Requires Proposed Rules
  - Delays Effective Date 30- to 60-days
  - "due process" – ensures fairness
- Established *Public Participation*
  - Requires Notice
  - Requires Taking Comments
  - "notice and comment" – ensures democratic values

Congressional Review Act

Part of the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121)

Additional procedural requirements to ensure:

Legislative *Oversight*

Major and significant regulatory actions

Separation of Powers

Constitutionally adequate veto of regulations

Other Parts of the Federal Regulatory Process

- Agency Dockets
- Administrative Requirements
- Regulatory Review (OIRA)

Agency Dockets

A central, publicly accessible location where:

- Agency official place relevant rulemaking materials;
- Members of the public place all comments and related materials that they want the agency to consider during the deliberative process

- A Single Rulemaking Activity
- All related materials
- Public Information
- Federal Docket Management System (FDMS)

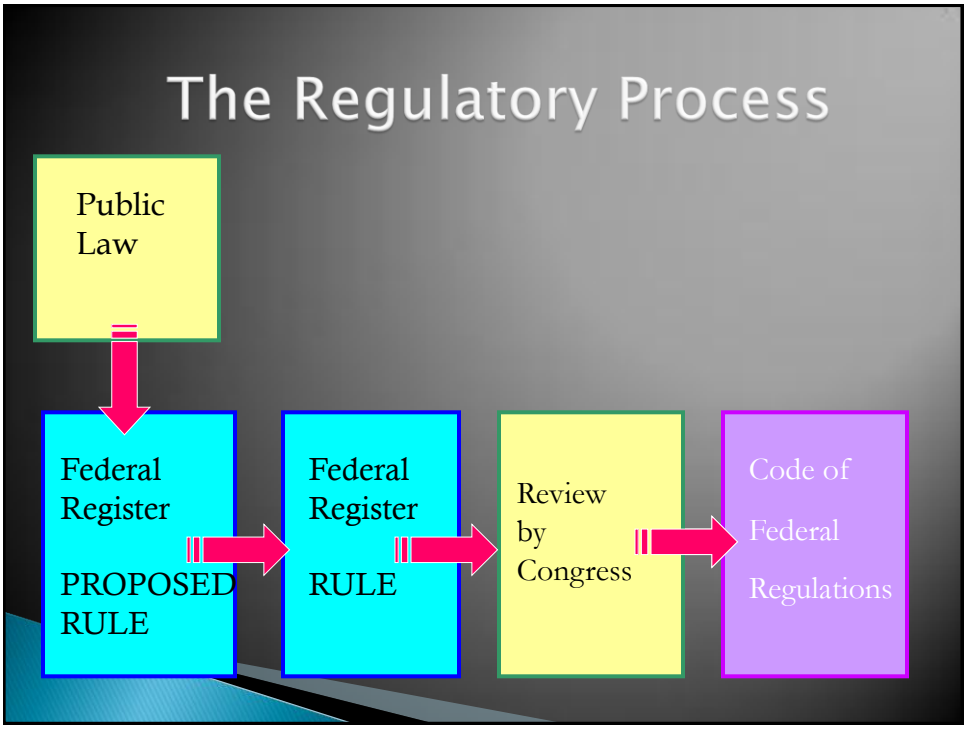
Administrative Requirements

- Regulatory Analyses
  - Legislative
  - Executive Order

Regulatory Review

Administration's policy input

- Office of Information and Regulatory Analysis (OIRA)
- Policy review
- Regulatory Agenda



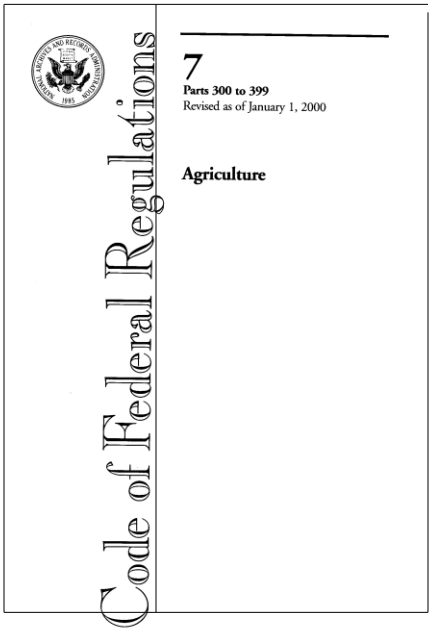
Summary – Why was the Federal Register System Established?

- Lack of Access – Office of the Federal Register
  - No centralized filing system
- Lack of Process – Federal Register publication
  - No centralized publication system
- Lack of Organization – Code of Federal Regulations
  - No organization to the system
- Constitutional Issues – Notice & Comment/ Congressional Review
  - Separation of Powers
  - Due Process
  - Fairness

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 by Congress
Courts review for constitutionality	Courts review for constitutionality & limits of delegated authority arbitrary and capricious actions Administrative Procedure Act reqs.
Representative Democracy: Congress acts collectively represent the will of the people	Participatory Democracy: Agencies must seek and consider to 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

The Code of Federal Regulations



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 200 volumes
  - Printed soft cover books
  - Microfiche
  - Online at: 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 rules	303.1	One provision of program/function
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.

Paragraph	Designations	Cite paragraph as
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)*

The Daily *FEDERAL REGISTER*

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

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:

What is the Rules and Regulations Section of the *Federal Register*?

- 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
- 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

What Notices are published in the Federal Register?

Non Rulemaking Documents

- Announcements
- Public Hearings
- Public Ations
- Availability of Material

Formating

- Standard FR Headings
- Paragraph Format

What Presidential Documents are published in the Federal Register ?

- 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

Public Inspection

- Required by Federal Register Act
- Establishes "Filing" Date and Time
- Documents must be scheduled for publication
- Regular and Special Filing
- Public Agency Action versus "Pre-decisional" Agency Action
- Electronic Public Inspection Desk
  - www.ofr.gov

Material Approved for Incorporation By Reference

- **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**
- **The incorporation by reference (IBR) table directs you to regulatory material not published in the FR & CFR**
  - **Located in the sidebar of the online e-CFR**

Federal Register 2.0

- Launched July 26, 2010 – 75th Anniversary of the Federal Register Act
- Currently an unofficial edition of the Federal Register and a beta website version
- Online newspaper look and feel
- www.federalregister.gov

Federal Register 2.0 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
- Calendar of Events
- Summary and Key Information
- Topics Index
- Social Networking and Web 2.0 Tools

Federal Register 2.0 Features

- Public Inspection Desk
- Currently Updated Federal Register Index
- Currently Updated Executive Order Disposition Tables
- Regulations.gov Docket Information and Ability to Submit Comments from Document Page on federalregister.gov
- Advanced Subscription Management
- Questions and Comments

Traditional 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)

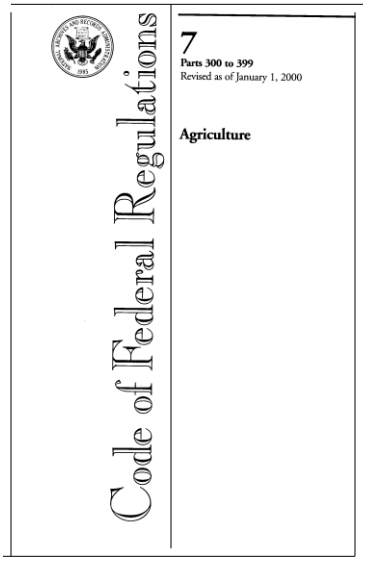
- Cumulative table
- Lists documents in numerical order by CFR title and part
- You can quickly determine:
  - The CFR titles and parts affected by documents published during the current month
  - Whether the documents affecting the CFR parts are rules or proposed rules
  - The number designation of Presidential documents published during the current month
  - The page numbers where the relevant documents begin

FR Pages and Dates (the current month)

- Cumulative table of page spans and dates
- Page spans are on the left side of the table with corresponding dates of publication on the right side
- Use the date table with entries from the *CFR Parts Affected During (the current month)* to find the date a document was published in FR

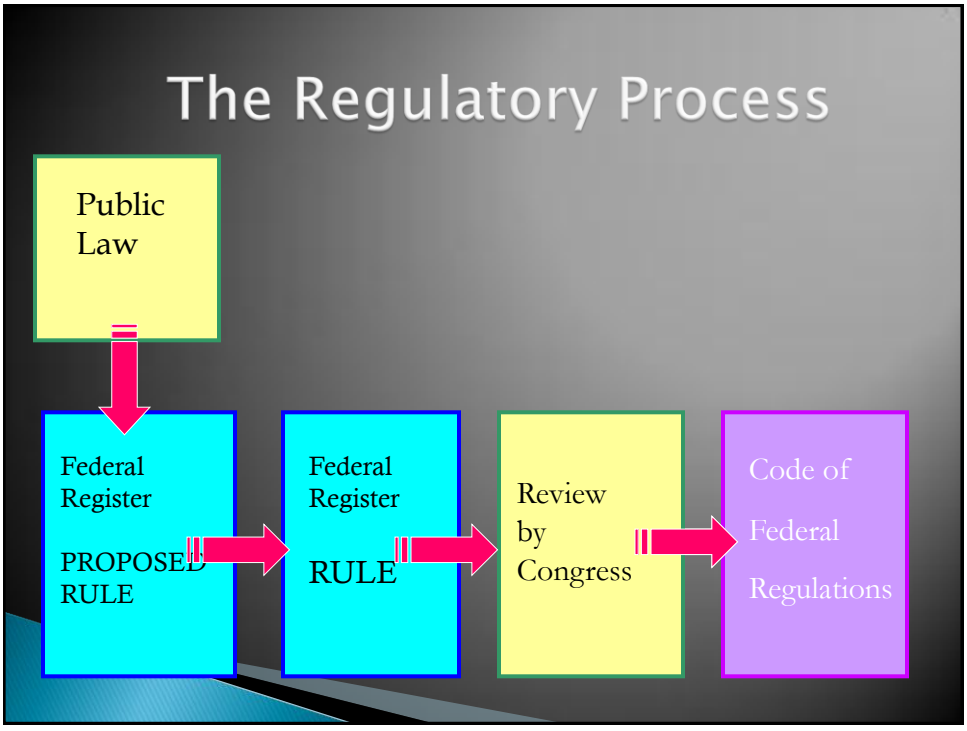
How are rules codified in the CFR ?

The Rulemaking Process from Start to Finish



What Triggers Rulemaking ?

- Legislation, Congressional hearings/reports
- Executive orders and OMB Circulars
- Court Orders
- Agencies act on own initiative to carry out mission
- Petitions for Rulemaking and informal requests from affected parties
- Federal Advisory Committee Recommendations
- Emergency situations, technological developments
- Political Factors

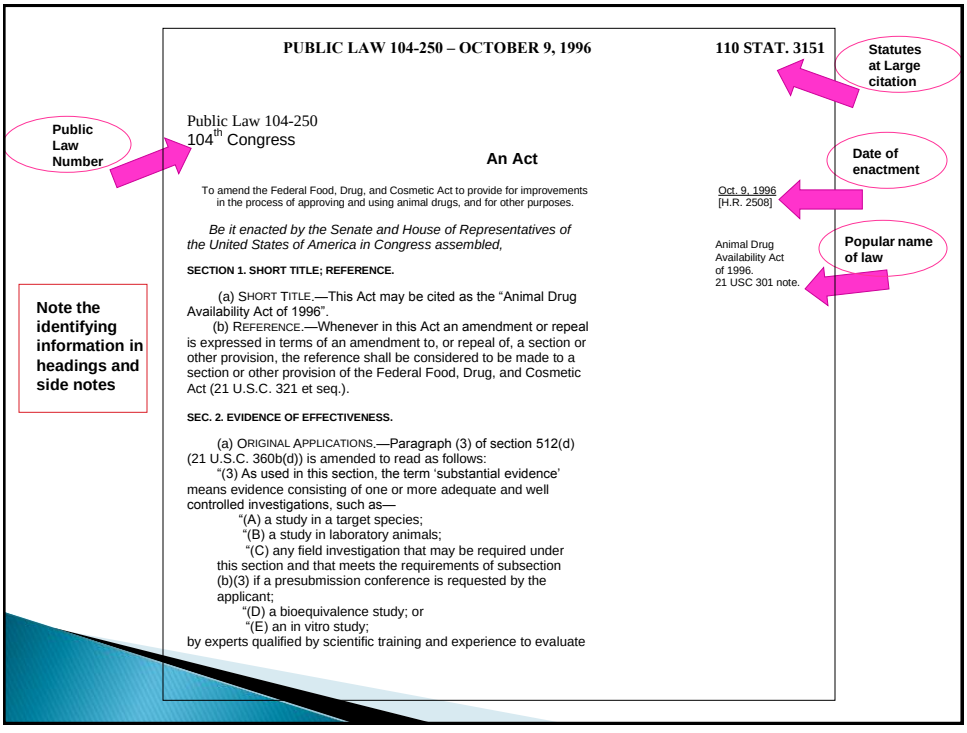


Authorization in Public Law

Rulemaking usually begins with Congressional action.

For Example:

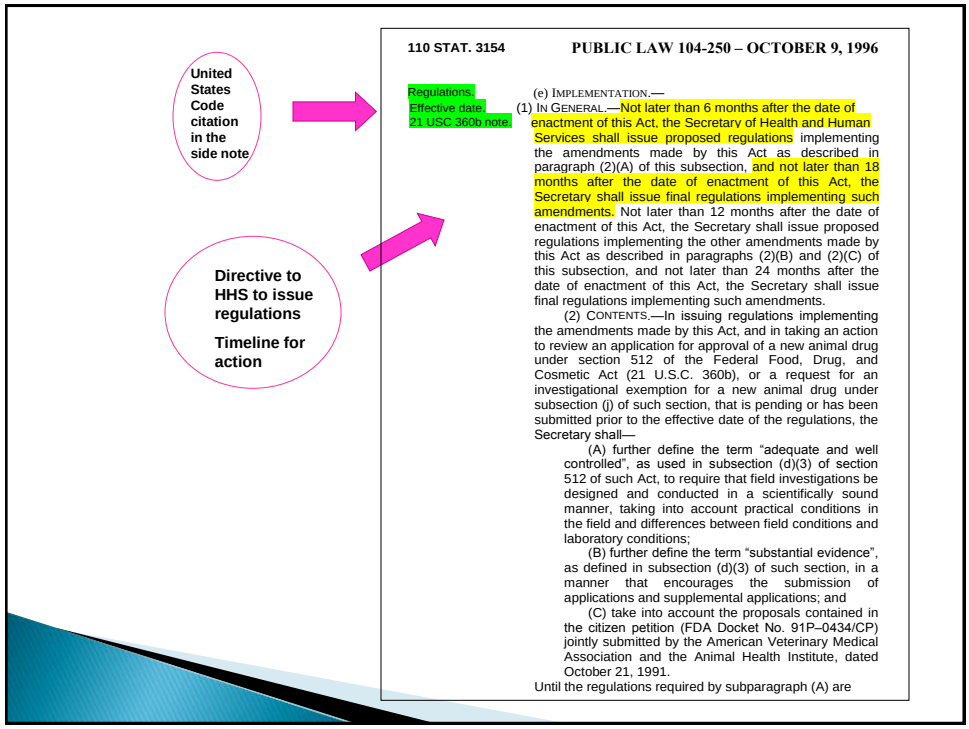
- The Animal Drug Availability Act of 1996 (ADAA) (Public Law 104- 250), enacted October 9, 1996, amended the Food, Drug and Cosmetic Act.
  - Signaled Congressional intent for Food and Drug Administration (FDA) to administer the regulations on behalf of the Secretary of Health and Human Services (HHS).



Rulemaking Instructions in the Law

FDA must issue regulations to implement the law.

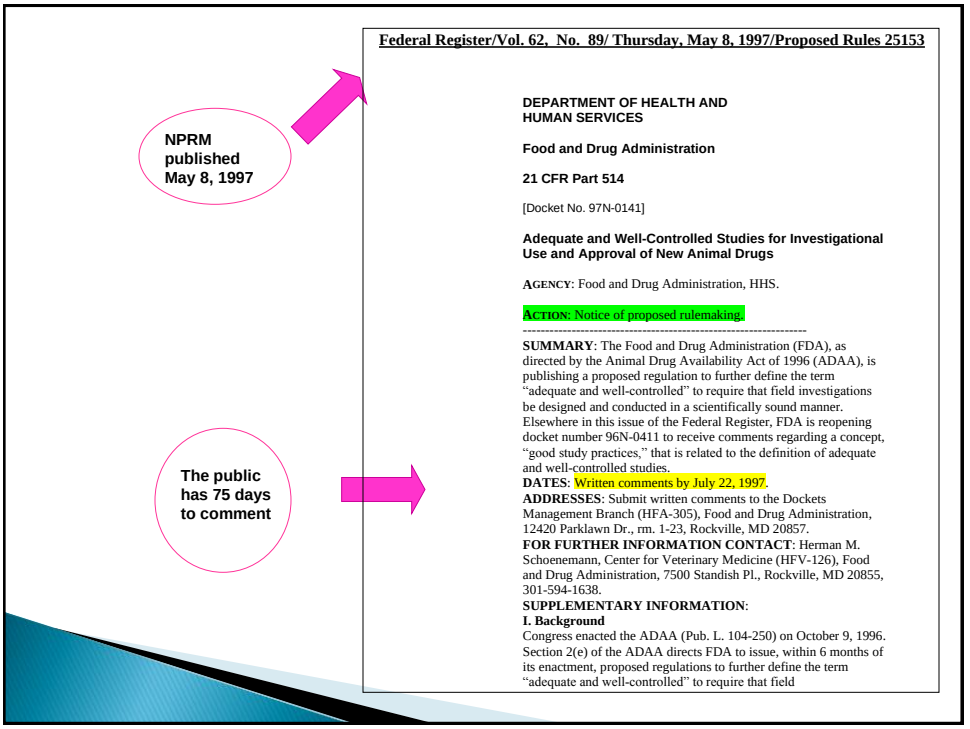
- Law sets a schedule for issuing proposed and final rules
- The agency must publish in *Federal Register* and follow APA notice and comment rulemaking process.

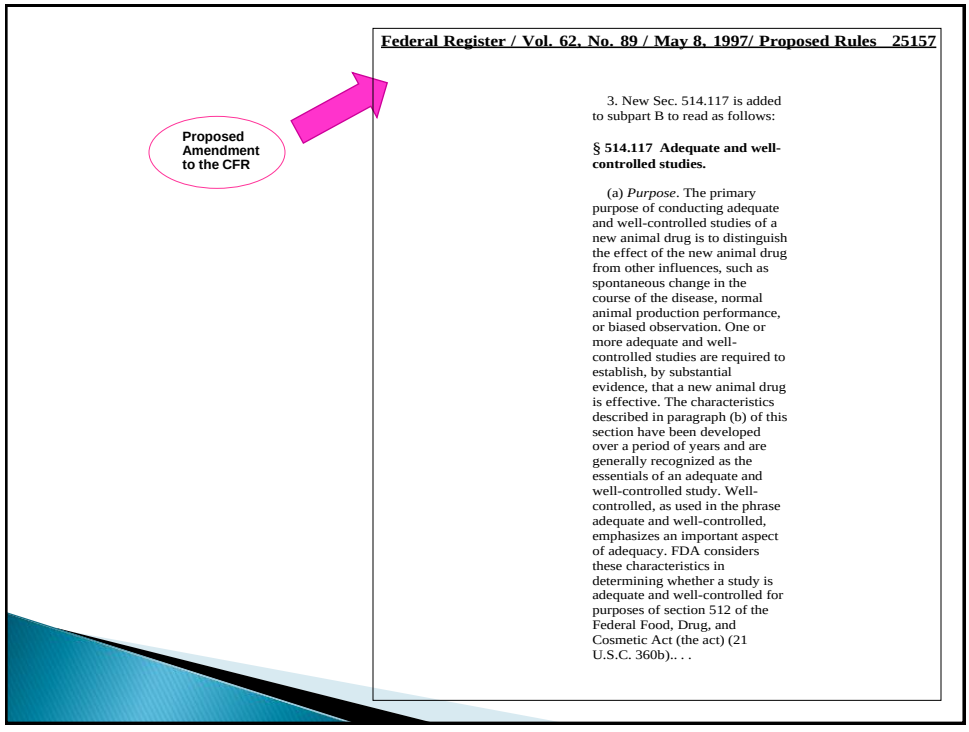


Proposed Rulemaking

ADAA Example

- Statute set a 6 month time limit for a Proposed Rule
- FDA published the proposed rule on May 8, 1997, about 7 months after the law was enacted, slightly past the deadline





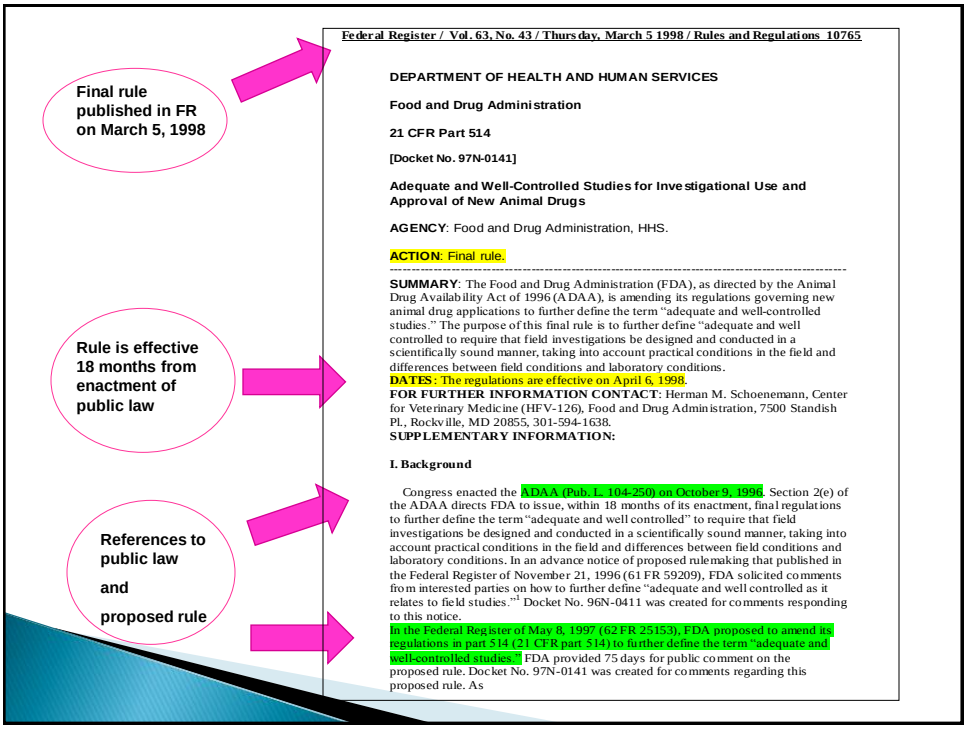
Final Rulemaking

ADAA

- FDA published the final rule on March 5, 1998, in time to meet the 18 month statutory deadline

The preamble of a final rule typically contains:

- Statement of the requirements in the law
- Cite to proposed rule and other rulemaking history
- Discussion and analysis of public comments received
- Justification for agency's final decisions



Federal Register / Vol. 63, No. 43 / Thursday, March 5 1998 / Rules and Regulations 10765

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N-0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is amending its regulations governing new animal drug applications to further define the term "adequate and well-controlled studies." The purpose of this final rule is to further define "adequate and well controlled to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions.

DATES: The regulations are effective on April 6, 1998.

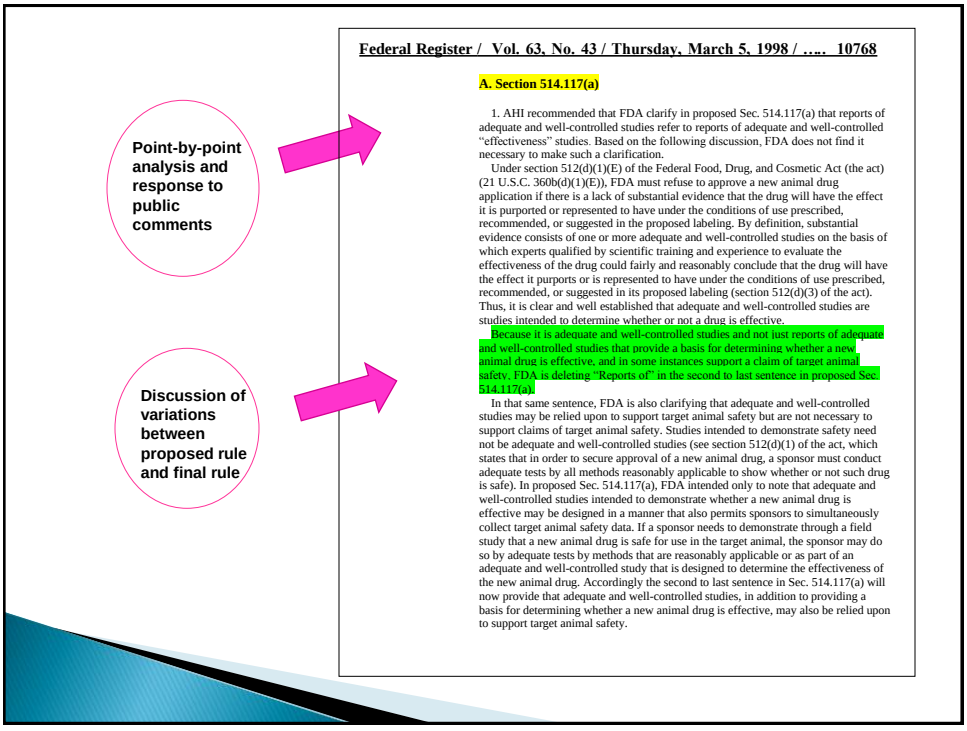
FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104-250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 18 months of its enactment, final regulations to further define the term "adequate and well controlled" to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. In an advance notice of proposed rulemaking that published in the Federal Register of November 21, 1996 (61 FR 59209), FDA solicited comments from interested parties on how to further define "adequate and well controlled as it relates to field studies."[1] Docket No. 96N-0411 was created for comments responding to this notice.

In the Federal Register of May 8, 1997 (62 FR 25153), FDA proposed to amend its regulations in part 514 (21 CFR part 514) to further define the term "adequate and well-controlled studies." FDA provided 75 days for public comment on the proposed rule. Docket No. 97N-0141 was created for comments regarding this proposed rule. As



Federal Register / Vol. 63, No. 43 / Thursday, March 5, 1998 / 10768

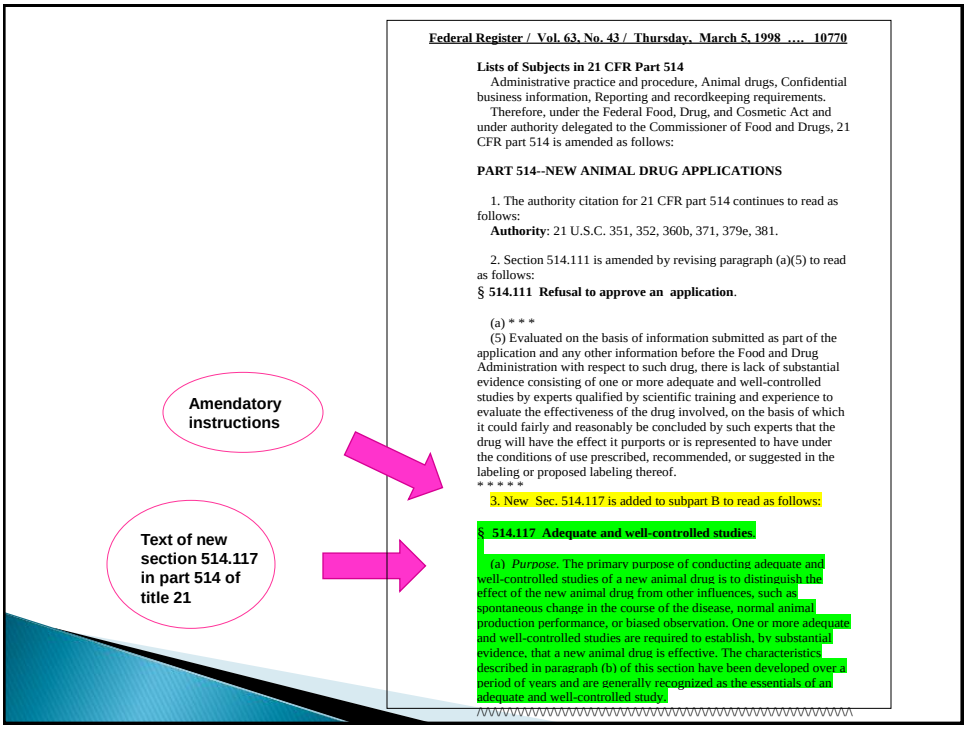
A. Section 514.117(a)

1. AHI recommended that FDA clarify in proposed Sec. 514.117(a) that reports of adequate and well-controlled studies refer to reports of adequate and well-controlled "effectiveness" studies. Based on the following discussion, FDA does not find it necessary to make such a clarification.

Under section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)(E)), FDA must refuse to approve a new animal drug application if there is a lack of substantial evidence that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling. By definition, substantial evidence consists of one or more adequate and well-controlled studies on the basis of which experts qualified by scientific training and experience to evaluate the effectiveness of the drug could fairly and reasonably conclude that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling (section 512(d)(3) of the act). Thus, it is clear and well established that adequate and well-controlled studies are studies intended to determine whether or not a drug is effective.

Because it is adequate and well-controlled studies and not just reports of adequate and well-controlled studies that provide a basis for determining whether a new animal drug is effective, and in some instances support a claim of target animal safety, FDA is deleting "Reports of" in the second to last sentence in proposed Sec. 514.117(a).

In that same sentence, FDA is also clarifying that adequate and well-controlled studies may be relied upon to support target animal safety but are not necessary to support claims of target animal safety. Studies intended to demonstrate safety need not be adequate and well-controlled studies (see section 512(d)(1) of the act, which states that in order to secure approval of a new animal drug, a sponsor must conduct adequate tests by all methods reasonably applicable to show whether or not such drug is safe). In proposed Sec. 514.117(a), FDA intended only to note that adequate and well-controlled studies intended to demonstrate whether a new animal drug is effective may be designed in a manner that also permits sponsors to simultaneously collect target animal safety data. If a sponsor needs to demonstrate through a field study that a new animal drug is safe for use in the target animal, the sponsor may do so by adequate tests by methods that are reasonably applicable or as part of an adequate and well-controlled study that is designed to determine the effectiveness of the new animal drug. Accordingly the second to last sentence in Sec. 514.117(a) will now provide that 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.



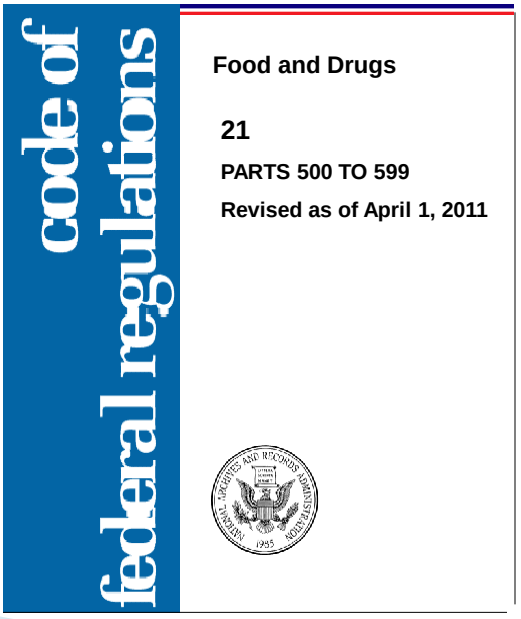
CFR Codification

ADAA

- FDA published the new animal drugs rule on March 5, 1998
- The rule was integrated into the April 1, 1998 revision of title 21 -- “Food and Drugs”

Title 21, like most CFR titles, has multiple volumes.

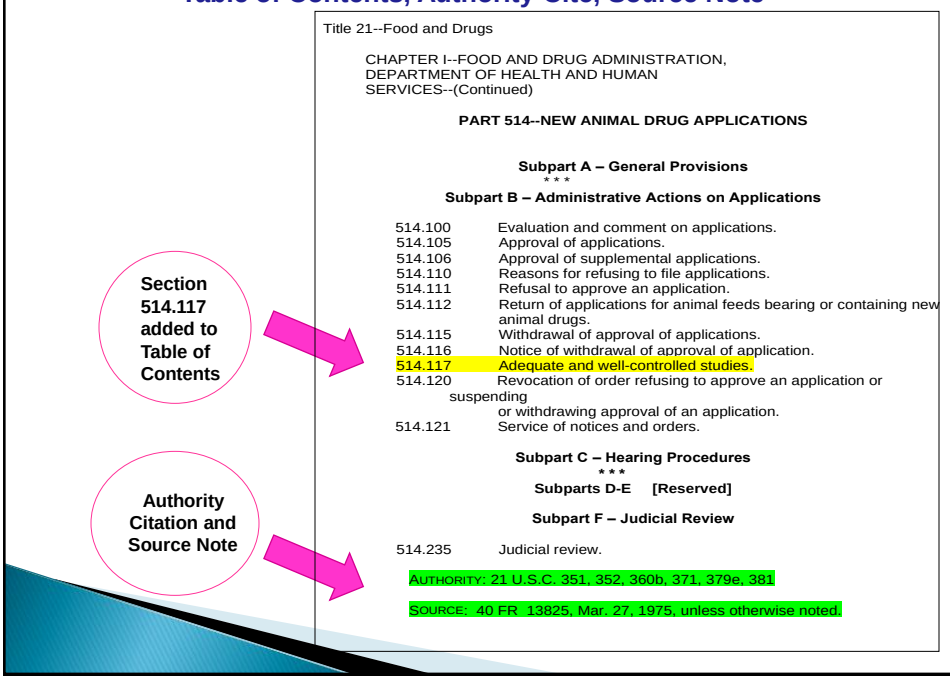
The new rule was codified in the volume containing parts 500-599 of title 21.



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



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.

[63 FR 10770, Mar.5, 1998]

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 since 1986 by year and FR page number
- Lists the type of amendment and the text affected down to the paragraph level
- For years before 2000, use the eleven separate volumes of the *List of CFR Sections Affected*
- A cumulative, monthly LSA is also published separately

Contacts and Resources

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- Official Federal Register Publications
  - www.fdsys.gov
    Online versions of the publications (FR, CFR, etc.)
- Unofficial Federal Register
  - www.federalregister.gov
    "Federal Register 2.0"
- Unofficial Code of Federal Regulations
  - www.ecfr.gov
    Electronic Code of Federal Regulations "e-CFR"

On-line Resources (cont.)

- Federal Register Information
  - www.ofr.gov
    Information about the publications
    Information about the Federal regulatory process
    Public Inspection Desk
- Other Resources:
  - **Federal Register Table of Contents ListServ**
  - https://listerv.access.gpo.gov
  - **National Archives FR Home Page**
  - www.archives.gov/federal-register
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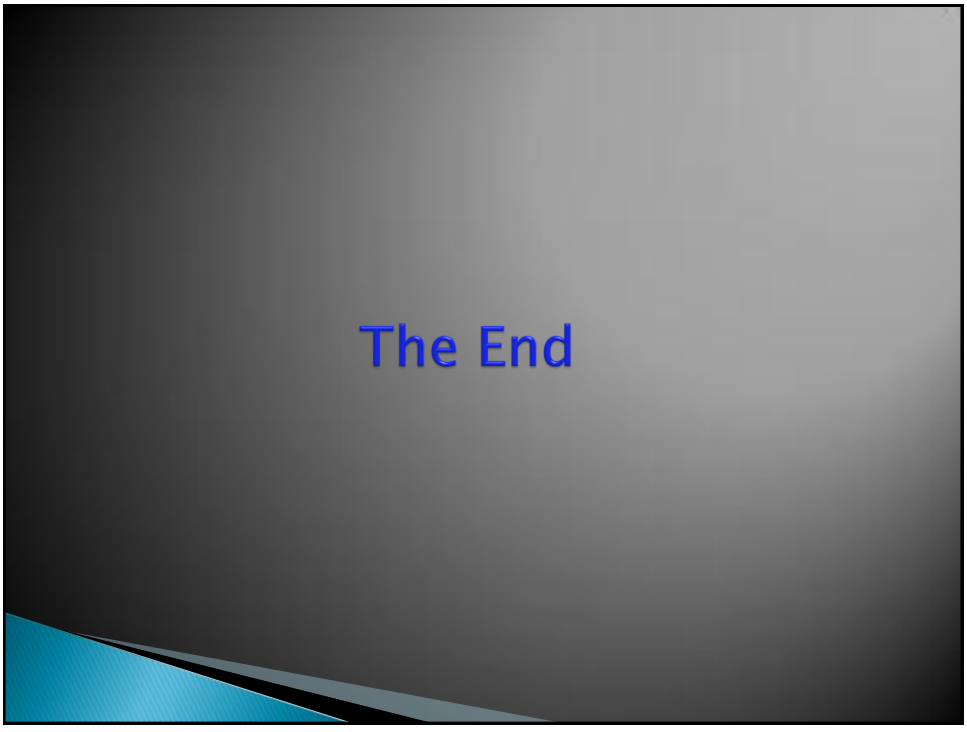
The End