What is the CFR?

Office of the Federal Register
National Archives and Records Administration

2018
What topics will this workshop cover?

- Historical background and legal basis of the CFR
- Relationships among Public Laws, the Federal Register and CFR
- Organization of the CFR
- Research tools and Finding Aids
- Where to find it online
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

Public Law

Federal Register

PROPOSED RULE

Federal Register

RULE

Review by Congress

Code of Federal Regulations (CFR)
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 over 240 volumes
  ◦ *Printed soft cover books*
  ◦ *Microfiche*
  ◦ *Online at: govinfo.gov*
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
<table>
<thead>
<tr>
<th>CFR Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
</tr>
<tr>
<td>Chapter</td>
</tr>
<tr>
<td>Part</td>
</tr>
<tr>
<td>Section</td>
</tr>
<tr>
<td>Paragraph</td>
</tr>
</tbody>
</table>
Sections may contain up to 6 levels of paragraphs.  
- *We strongly recommend no more than 3 levels.*

<table>
<thead>
<tr>
<th>Paragraph Level</th>
<th>Designations</th>
<th>Cite Paragraph as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>(a), (b), (c), etc.</td>
<td>§ 303.1(a)</td>
</tr>
<tr>
<td>Level 2</td>
<td>(1), (2), (3), etc.</td>
<td>§ 303.1(a)(1)</td>
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<tr>
<td>Level 3</td>
<td>(i), (ii), (iii), etc.</td>
<td>§ 303.1(a)(1)(i)</td>
</tr>
<tr>
<td>Level 4</td>
<td>(A), (B), (C), etc.</td>
<td>§ 303.1(a)(1)(i)(A)</td>
</tr>
<tr>
<td>Level 5</td>
<td>(1), (2), (3), etc.</td>
<td>§ 303.1(a)(1)(i)(A)(1)</td>
</tr>
<tr>
<td>Level 6</td>
<td>(i), (ii), (iii), etc.</td>
<td>§ 303.1(a)(1)(i)(A)(1)(i)</td>
</tr>
</tbody>
</table>
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.
PART 514--NEW ANIMAL DRUG APPLICATIONS

Subpart A – General Provisions

Subpart B – Administrative Actions on Applications

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

Subpart C – Hearing Procedures

Subparts D-E [Reserved]

Subpart F – Judicial Review

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>514.235</td>
<td>Judicial review.</td>
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</tbody>
</table>

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

SOURCE: 40 FR 13825, Mar. 27, 1975, unless otherwise noted.
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
§ 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 \textit{Federal Register}.

§ 514.117 Adequate and well-controlled studies.

(a) \textit{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.\footnote{[63 FR 10770, Mar. 5, 1998]}
Each year is given its own cover color to distinguish it from other years on the shelf.

<table>
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<tr>
<th>Year</th>
<th>Cover Color</th>
<th>Pantone Code</th>
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</thead>
<tbody>
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<td>“Update Slate”</td>
<td>433U</td>
</tr>
<tr>
<td>2013</td>
<td>“Regulatory Red”</td>
<td>186U</td>
</tr>
<tr>
<td>2014</td>
<td>Charley Barth purple</td>
<td>266U</td>
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<tr>
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<td>Hyrum Green (selected by new Managing Editor)</td>
<td>355U</td>
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<tr>
<td>2016</td>
<td>Royal Blue</td>
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<tr>
<td>2017</td>
<td>Orange</td>
<td>1655U</td>
</tr>
<tr>
<td>2018</td>
<td>Flint</td>
<td>5497U</td>
</tr>
</tbody>
</table>
Title 3

- Title 3 – The President
- This title is not codified, it is compilation of the Presidential Documents Published in the Federal Register during that year
- Because it is an annual compilation the paper volume should be retained as a permanent reference source
- Its cover color is reversed from the other books in the CFR
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 shows page numbers for the beginning of each part.

### Table of Contents to a Subtitle

**Subtitle A—Office of the Secretary of Agriculture**

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<td>95</td>
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<tr>
<td>1b</td>
<td>National Environmental Policy Act</td>
<td>96</td>
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<tr>
<td>1c</td>
<td>Protection of human subjects</td>
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<td>Delegations of authority by the Secretary of Agriculture and general officers of the Department</td>
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<td>5</td>
<td>Determination of parity prices</td>
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<td>12</td>
<td>Highly erodable land and wetland conservation</td>
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<td>13</td>
<td>[Reserved]</td>
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<td>Determining the primary purpose of certain payments for Federal tax purposes</td>
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<td>15a</td>
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<td>Education programs or activities receiving or benefiting from Federal financial assistance</td>
<td></td>
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<tr>
<td>15c</td>
<td>Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance</td>
<td></td>
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<tr>
<td>15e</td>
<td>Enforcement of nondiscrimination on the basis of handicap in programs or activities conducted by the United States Department of Agriculture</td>
<td>404</td>
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<tr>
<td>15f</td>
<td>Adjudications under section 741</td>
<td>410</td>
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<tr>
<td>16</td>
<td>[Reserved]</td>
<td></td>
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</tbody>
</table>
Table of Contents lists the sections in the part and subparts
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
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.
CFR Books Online

- PDF version of paper CFR books online at www.govinfo.gov
- Updated once a year – staggered by the 4 groups
- From 1996 through present
Electronic Code of Federal Regulations (e-CFR)

- 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
- 2-3 day lag
- “Point-in-Time” view back to January 1, 2015
- Fully Searchable
- Searchable by specific category of information (CFR element)
New eCFR Website in Development

- https://ecfr.criticaljuncture.org
- Based on XML version of daily eCFR
- Recent changes
- Compare feature
- Once the website is live, users can create a personal account for notification – related to MyFR account
Federal Register Online Resources

- CFR Volumes Online
  - www.govinfo.gov
- Electronic Code of Federal Regulations (e-CFR)
  - www.ecfr.gov
- New ECFR in development
  - ecfrcriticaljuncture.org
- Federal Register
  - www.federalregister.gov
- National Archives OFR Home Page
  - www.archives.gov/federal-register
- Public Participation in Rulemaking
  - www.regulations.gov
Thank you!

John Hyrum Martinez

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