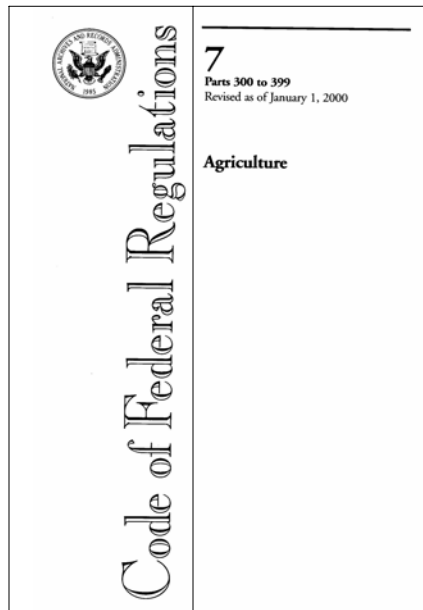


The CFR -- ORGANIZATION & CONTENTS



CFR

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	303.1	One provision of program/function rules
Paragraph	303.1(a)	Detailed, specific requirements

Paragraph Levels

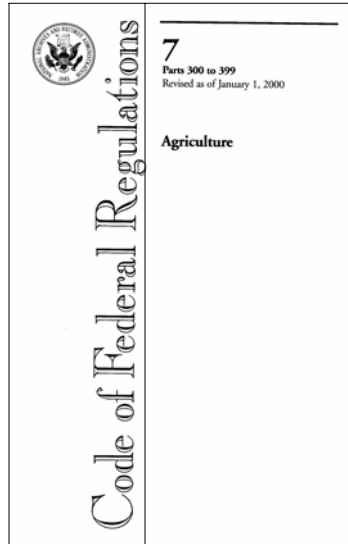
Sections may contain up to 6 levels of paragraphs.

✧ 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)

How are rules codified in the CFR ?

The Rulemaking Process from Start to Finish

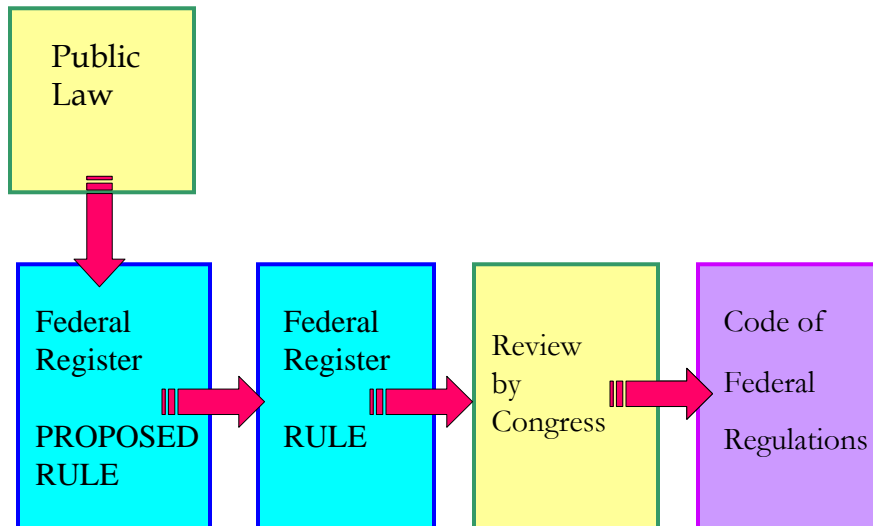


Rulemaking
Process

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**

The Regulatory Process



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 Process

Public Law Number → Public Law 104-250
104th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Animal Drug Availability Act of 1996".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

SEC. 2. EVIDENCE OF EFFECTIVENESS.

(a) ORIGINAL APPLICATIONS.—Paragraph (3) of section 512(d) (21 U.S.C. 360b(d)) is amended to read as follows:

"(3) As used in this section, the term 'substantial evidence' means evidence consisting of one or more adequate and well controlled investigations, such as—

"(A) a study in a target species;

"(B) a study in laboratory animals;

"(C) any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

"(D) a bioequivalence study; or

"(E) an in vitro study;

by experts qualified by scientific training and experience to evaluate

110 STAT. 3151 → Statutes at Large citation

Oct. 9, 1996 [H.R. 2508] → Date of enactment

Animal Drug Availability Act of 1996. 21 USC 301 note. → Popular name of law

Note the identifying information in headings and side notes

Rulemaking Process

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.

Rulemaking Process

110 STAT. 3154 PUBLIC LAW 104-250 – OCTOBER 9, 1996

United States Code citation in the side note

Regulations
Effective date
21 USC 360b note

Directive to HHS to issue regulations
Timeline for action

(e) IMPLEMENTATION.—
 (1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations implementing the amendments made by this Act as described in paragraph (2)(A) of this subsection, and not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments. Not later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the other amendments made by this Act as described in paragraphs (2)(B) and (2)(C) of this subsection, and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments.
 (2) CONTENTS.—In issuing regulations implementing the amendments made by this Act, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—
 (A) further define the term “adequate and well controlled”, as used in subsection (d)(3) of section 512 of such Act, 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;
 (B) further define the term “substantial evidence”, as defined in subsection (d)(3) of such section, in a manner that encourages the submission of applications and supplemental applications; and
 (C) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991.
 Until the regulations required by subparagraph (A) are

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

Federal Register/Vol. 62, No. 89/ Thursday, May 8, 1997/Proposed Rules 25153

NPRM
published
May 8, 1997

The public
has 75 days
to comment

**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: Notice of proposed rulemaking

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is publishing a proposed regulation to further define the term "adequate and well-controlled" to require that field investigations be designed and conducted in a scientifically sound manner. Elsewhere in this issue of the Federal Register, FDA is reopening docket number 96N-0411 to receive comments regarding a concept, "good study practices," that is related to the definition of adequate and well-controlled studies.

DATES: **Written comments by July 22, 1997.**

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.
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 6 months of its enactment, proposed regulations to further define the term "adequate and well-controlled" to require that field

Federal Register / Vol. 62, No. 89 / May 8, 1997/ Proposed Rules 25157

Proposed
Amendment
to the CFR

3. New Sec. 514.117 is added to subpart B to read as follows:

§ 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. 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)...

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

Final rule
published in FR
on March 5, 1998

Rule is effective
18 months from
enactment of
public law

References to
public law
and
proposed rule

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." 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

A. Section 514.117(a)

Point-by-point analysis and response to public comments



Discussion of variations between proposed rule and final rule



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.

Lists of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514--NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:
Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Section 514.111 is amended by revising paragraph (a)(5) to read as follows:
§ 514.111 Refusal to approve an application.

(a) * * *

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of one or more adequate and well-controlled studies by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * * *

3. New Sec. 514.117 is added to subpart B to read as follows:

§ 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.

Amendatory instructions



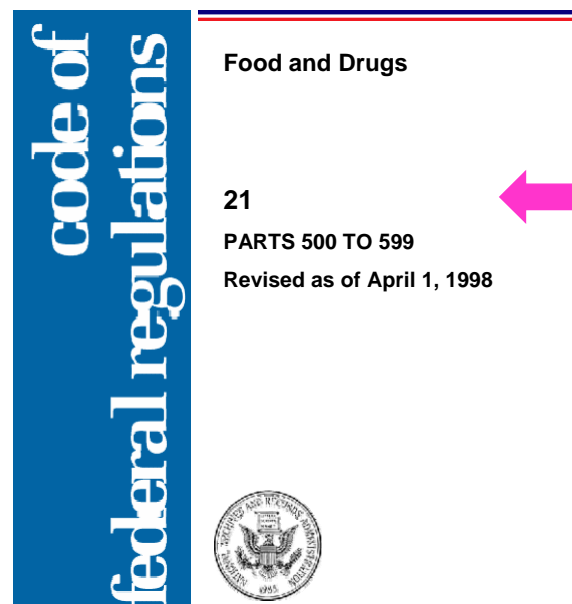
Text of new section 514.117 in part 514 of title 21



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

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.

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. ~~~~~

[63 FR 10770, Mar 5, 1998]

CFR Research Tools



Code of Federal Regulations

7

Parts 300 to 399
Revised as of January 1, 2000

Agriculture

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Chapters

Alphabetical List of Agencies
Appearing in the CFR

Redesignation Tables

List of CFR Sections Affected

CFR Research Tools

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 “Material Approved for Incorporation by Reference” (IBR) - *Moved to a sidebar on the e-CFR*
 - ✧ “Table of CFR Titles and Chapters”
 - ✧ “Alphabetical List of Agencies Appearing in the CFR”
 - ✧ Redesignation Tables
 - ✧ “List of CFR Sections Affected”

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1.100	Request for review of records for correction or amendment

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**

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

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