

# **NCLA's Help! I'm an Accidental Government Information Librarian presents...**

## **Regulate This! Federal Regulations**

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Colorado School of Mines

April 16, 2014



<http://www.jklossner.com/computerworld/regulation.html>

# Poll: How Familiar are you with Federal regulatory sources?

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- ▶ A. Expert— regularly use FR and CFR through many platforms, comfortable showing others how to use them, and plan on contacting the Office of the Federal Register to offer my services!
  - ▶ B. Knowledgeable – have used both the Federal Register and the Code of Federal Regulations, are aware of how they work together, and will attempt to show others how to use them.
  - ▶ C. Somewhat familiar – know of the existence of the Federal Register and/or the Code of Federal Regulations, have found regulations in the past, but am kind of scared of showing anybody how to use them.
  - ▶ D. Novice – know that regulations probably come from laws, but don't really know to use them how to access them appropriately.
  - ▶ E. Regulatory Naiveté – there are regulations in the United States that could affect me or others?
- 



# What we will cover during this session

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- ▶ Cover a brief history of U.S. or Federal regulations
- ▶ Describe the organization and content of the Federal Register, the Code of Federal Regulations, and related regulatory sources as well as forming citations for these sources
- ▶ Describe some of the electronic tools used for searching the Federal regulatory content (both free and for fee/subscription)



# Regulations Problems in U.S?

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- ▶ 1930's – New Deal Legislation
- ▶ Citizens needed to access to regulations
- ▶ Regulations and their effects needed to be known in advance by citizens
- ▶ U.S. courts began to see “secret law” as a violation and against the U.S. Constitution



# U.S. Regulation History

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## **Federal Register Act (1935)**

- ▶ Legal structure for regulatory system
- ▶ Single publication – Federal Register – allowed for central filing/public inspection
- ▶ Includes Proposed/Final Rules, Notices, Presidential Documents
- ▶ Code of Federal Regulations-codification of the Federal Register – added in 1937

## **Administrative Procedure Act (1946)**

- ▶ Added due process – public participation
  - ▶ Agencies must give notice of proposed rules in the FR
  - ▶ Agencies must receive and take action on public comments
  - ▶ Rules need to state the legal basis and purpose
  - ▶ Rules effective only after 30 days – sometimes longer
- 



# Sources: Tangible and Electronic



**FEDERAL REGISTER**  
The Daily Journal of the United States Government



# What Triggers Rulemaking?



Executive Branch



Congressional Branch



<http://forgottenmanblog.blogspot.com/>

UNIFIED AGENDA and REGULATORY PLAN



Other Petitions for Rulemaking



Judicial Branch



# Some Federal Register & CFR Contributors



Transportation  
Security  
Administration



# Organization in the FR & CFR

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## ▶ Federal Register (FR)

- ▶ Initial publishing of the information in chronological order
- ▶ Each issue is first organized alphabetically by agency
- ▶ Within each agency, the organization is: Rules (Final), Proposed Rules, and then Notices
- ▶ CFR Parts Affected
  - ▶ End of Table of Contents – list of CFR parts affected for FR issue
  - ▶ Readers Aid (at end of issue) – list of CFR parts affected for current month

## ▶ Code of Federal Regulations (CFR)

- ▶ Republishing of regulations in codified form by subject
  - ▶ 50 Titles representing the subjects (over 200 volumes)
  - ▶ Each title is completely revised and reissued yearly –  $\frac{1}{4}$  of the volumes are reprinted quarterly
    - ▶ Title 1 - Title 16 – as of January 1
    - ▶ Title 17 – 27 – as of April 1
    - ▶ Title 28 - Title 41 – as of July 1
    - ▶ Title 42 - Title 50 – as of October 1
- 



# Federal Register Content

## Proposed Rules

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- ▶ Preliminary Rulemaking – advanced notices, petitions, and negotiated rulemaking
  - ▶ Proposed Rules – also known as NPRM (Notice of Proposed Rulemaking)
    - ▶ Announces changes to CFR
    - ▶ Gives proposed regulatory text, often gives detailed description of proposal
    - ▶ Solicits public comments on proposed rule – must consider comments and justify decisions to finalize, change, or withdraw proposed rules
  - ▶ Misc. Proposals and Updates – extend time for comments, withdraw/change proposed rules, waivers, exemptions, and interpretations of enforcement policy
- 





# FEDERAL REGISTER

Vol. 79                      Wednesday,  
No. 10                      January 15, 2014

Pages 2581–2760

OFFICE OF THE FEDERAL REGISTER

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ORV that you want to use for recreational purposes on designated ORV trails. The operator of the ORV must have the permit in his or her possession when the ORV is in use.

(5) Violating any term or condition of a permit is prohibited.

(6) The recreational use of ORVs without a permit is prohibited.

(d) *May I operate an ORV for subsistence uses in the FEIS Wilderness Area?* (1) In the FEIS Wilderness Area, local rural residents may operate ORVs for subsistence uses on the following trails and trail corridors:

(i) Black Mountain Trails and trail corridors.

(ii) Tanada Lake Trail and trail corridors.

(2) ORVs may be operated in the trail corridors outside of the established trails only for purposes of game retrieval.

(3) Local rural residents may not operate an ORV for subsistence uses in the FEIS Wilderness Area outside of the trails and trail corridors identified in paragraph (d)(1) of this section.

(4) Trails and trail corridors in the FEIS Wilderness Area, and the boundaries of the FEIS Wilderness Area, will be shown on the Upper Copper/Jacksina Wilderness map available at

BILLING CODE 4312-EJ-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 98

[EPA-HQ-OAR-2009-0927; FRL-9905-48-OAR]

RIN 2060-AR78

### Greenhouse Gas Reporting Program: Amendments and Confidentiality Determinations for Fluorinated Gas Production

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule: Extension of public comment period.

**SUMMARY:** The EPA is announcing an extension of the public comment period for the proposed rule titled "Greenhouse Gas Reporting Program: Amendments and Confidentiality Determinations for Fluorinated Gas Production."

**DATES:** The public comment period started on November 19, 2013 (78 FR 69337). This document announces the extension of the deadline for public comment from January 21, 2014 to

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www.regulations.gov your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA

Also Included in Rule (but not shown here) are:

- Addresses
- For further information contact
- Supplementary Information

# Federal Register Content

## Final Rules

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- ▶ Final Rules – final legal effect, general applicability to public
    - ▶ Amends the CFR, finalizes a proposed rule (or takes action without a prior proposed rule for GOOD CAUSE)
    - ▶ Effective at least 30 days from date of publication in most cases (60 days for major rules and on date of publication for emergencies)
    - ▶ Also Interim Final Rules, Direct Final Rules, other documents relating to previous rules
    - ▶ Generally includes less supplementary information as compared to the Proposed Rule
- 



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**ENVIRONMENTAL PROTECTION  
AGENCY****40 CFR Parts 1039, 1042, and 1068****[EPA-HQ-OAR-2012-0102; FRL-9905-35-  
OAR]****RIN 2060-AR48; 2127-AL31****Nonroad Technical Amendments****AGENCY:** Environmental Protection  
Agency (EPA).**ACTION:** Final rule.

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**SUMMARY:** EPA is adopting amendments to the technical hardship provisions under the Transition Program for Equipment Manufacturers related to the Tier 4 standards for nonroad diesel engines, and to the replacement engine exemption generally applicable to new nonroad engines. These provisions may have minor impacts on the costs and emission reductions of the underlying regulatory programs amended in this action, though in most cases these are simple technical amendments. For those provisions that may have a minor impact on the costs or benefits of the amended regulatory program, any potential impacts would be small and we have not attempted to quantify the potential changes.**DATES:** This final rule is effective on March 10, 2014, except for § 1039.625(m) which will be effective on February 6, 2014.**FOR FURTHER INFORMATION CONTACT:**  
Alan Stout, Environmental Protection  
Agency, Office of Transportation and  
Air Quality, Assessment and Standards  
Division, 2000 Traverwood Drive, Ann  
Arbor, Michigan 48105; telephone  
number: (734) 214-4805; email address:  
[stout.alan@epa.gov](mailto:stout.alan@epa.gov).

\*The technical hardship provision at § 1039.625(m) allows EPA to make a judgment that an equipment manufacturer that buys engines from another company, through no fault of its own, needs additional allowances to manage the transition to Tier 4 products.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2014-N-0108]

New Animal Drug Applications;  
Confidentiality of Data and Information  
in a New Animal Drug Application File

AGENCY: Food and Drug Administration,  
HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulation regarding the confidentiality of data and information in and about new animal drug application files to change when certain approval-related information will be disclosed by the Agency. This change will ensure that the Agency is able to update its list of approved new animal drug products within the statutory timeframe. It will also permit more timely public disclosure of approval-related information, increasing the transparency of FDA decision making in the approval of new animal drugs.

**DATES:** This rule is effective July 30, 2014. Submit either electronic or

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA-2014-N-0108 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Scott Fontana, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0656.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 512(i) (21 U.S.C. 360b(i)) was added to the Federal Food, Drug, and

Agency shall publish a list of approved new animal drug products and revise that list every 30 days to include each new animal drug that has been approved during that 30-day period. This list, as well as related patent information and marketing exclusivity periods, is contained in a document generally known as the “Green Book,” available at the Agency’s public Web site at <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts>.

The editorial and clearance processes for publishing the **Federal Register** notice announcing the approval of an NADA varies from 1 to 2 months after the approval letter is issued to the applicant. Consequently, the addition of newly approved product information to the “Green Book” and public disclosure of certain other approval-related information at the Agency’s public Web site is delayed until after that **Federal Register** notice is published. Such other approval-related information may include the summary of information forming the basis for approval (known also as the Freedom of Information Summary) and documentation of environmental review. Trade and proprietary information in the application file remains confidential and is not disclosed.

Example of Direct Final Rule – no proposed rule – FDA is trying to increase its own transparency



# List of CFR Sections Affected (LSA)

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- ▶ Additional monthly publication to track changes to the CFR
- ▶ Official publication to ensure that the most current changes are available for CFR sections
- ▶ Print CFR is published yearly – print volumes are often NOT be up to date
- ▶ eCFR (<http://www.ecfr.gov>) provides for electronic updating of the Code of Federal Regulations
  - ▶ Currency note – e-CFR Data is current as of April 10, 2014
  - ▶ User note – not considered an official, legal edition – but much easier to use!



# Unified Regulatory Agenda

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- ▶ Since 1983 the Agenda issued twice per year (Spring and Fall) as issues of the Federal Register
- ▶ Provides agency rules either under development or review – generally those with regulatory action within 12 months
- ▶ Access to the Agenda is primarily electronic through <http://reginfo.gov> (as a way to reduce printing costs)
- ▶ Regulatory Flexibility Act (1980) regulates the Agenda to contain only entries that are likely to have a significant economic impact on a substantial number of small entities
- ▶ Content includes: abstract of rule, timetable for rule development, contact information, and potential effects of rule
- ▶ Also Includes the Regulatory Plan
  - ▶ Acts as defining statement of the Administration's regulatory/deregulatory policies and priorities
  - ▶ In the fall issue of the Unified Agenda



# Code of Federal Regulations Content

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- ▶ Final rules or regulations are then codified in the Code of Federal Regulations (CFR) by broad subject categories subject to Federal regulation
- ▶ The CFR contains Federal rules that have general applicability and are for current and future effect – regulations that do not meet this stipulation will not be codified in the CFR
- ▶ Kept up to date by individual issues of the Federal Register – both need to be used to determine the latest version of a given rule



# All 50 Code of Federal Regulations Titles

- ⊕ [Title 1 - General Provisions \(Cover Only\)](#)  
Parts 1 - 500. January 1, 2013.
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- ⊕ [Title 43 - Public Lands: Interior](#)  
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- ⊕ [Title 46 - Shipping](#)  
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- ⊕ [Title 47 - Telecommunication](#)  
Parts 0 - 400. October 1, 2013.
- ⊕ [Title 48 - Federal Acquisition Regulations System](#)  
Parts 1 - 9905. October 1, 2013.
- ⊕ [Title 49 - Transportation](#)  
Parts 1 - 1580. October 1, 2013.
- ⊕ [Title 50 - Wildlife and Fisheries](#)  
Parts 1 - 697. October 1, 2013.

# Code of Federal Regulations Examples

## Title 12—Banks and Banking

(This book contains parts 300 to 499)

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| CHAPTER IV—Export-Import Bank of the United States ..... | 400 |

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303.0 Scope.

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- 303.3 General filing procedures.
- 303.4 Computation of time.
- 303.5 Effect of Community Reinvestment Act performance on filings.
- 303.6 Investigations and examinations.
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- 303.21 Filing procedures.
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- 303.23 Public notice requirements.
- 303.24 Application for deposit insurance for an interim institution.
- 303.25 Continuation of deposit insurance upon withdrawing from membership in the Federal Reserve System.
- 303.26–303.39 [Reserved]

### Federal Deposit Insurance Corporation

§ 303.24

or federally-chartered depository institution that does not operate independently but exists solely as a vehicle to accomplish a merger transaction.

(c) A request for continuation of deposit insurance upon withdrawing from membership in the Federal Reserve System shall be in letter form and shall provide the information prescribed in § 303.25.

#### § 303.22 Processing.

(a) *Expedited processing for proposed institutions.* (1) An application for deposit insurance for a proposed institution which will be a subsidiary of an eligible depository institution as defined in § 303.2(r) or an eligible holding company will be acknowledged in writing by the FDIC and will receive expedited processing unless the applicant is notified in writing to the contrary and provided with the basis for that decision. An eligible holding company is defined as a bank or thrift holding company that has consolidated assets of at least \$150 million or more; a BOPEC rating of at least “2” for bank holding companies or an above average or “A” rating for thrift holding companies; and at least 75 percent of its consolidated depository institution assets comprised of eligible depository institutions. The FDIC may remove an application from expedited processing for any of the reasons set forth in § 303.11(c)(2).

(2) Under expedited processing, the FDIC will take action on an application within 60 days of receipt of a substantially complete application or 5 days after the expiration of the comment period described in § 303.23, whichever is later. Final action may be withheld until the FDIC has assurance that permission to organize the proposed in-

written notification of the final action when the decision is rendered.

[67 FR 79247, Dec. 27, 2002, as amended at 68 FR 50459, Aug. 21, 2003]

#### § 303.23 Public notice requirements.

(a) *De novo institutions and operating noninsured institutions.* The applicant shall publish a notice as prescribed in § 303.7 in a newspaper of general circulation in the community in which the main office of the depository institution is or will be located. Notice shall be published as close as practicable to, but no sooner than five days before, the date the application is mailed or delivered to the appropriate FDIC office. Comments by interested parties must be received by the appropriate regional director within 30 days following the date of publication, unless the comment period has been extended or reopened in accordance with § 303.9(b)(2).

(b) *Exceptions to public notice requirements.* No publication shall be required in connection with the granting of insurance to a new depository institution established pursuant to the resolution of a depository institution in default, or to an interim depository institution formed solely to facilitate a merger transaction, or for a request for continuation of federal deposit insurance by a state-chartered bank withdrawing from membership in the Federal Reserve System.

#### § 303.24 Application for deposit insurance for an interim institution.

(a) *Application required.* Subject to § 303.62(b)(2), a deposit insurance application is required for a state-chartered interim institution if the related merger transaction is subject to approval by



Title 12

Part 303

Section 24

# Citations

## Federal Register

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- ▶ 68 FR 1234 – typical reference for FR
  - 68 is the volume number (annual)
  - 1234 is the page number
- ▶ Page numbers run consecutively throughout entire annual volume
- ▶ Knowing how to form proper citations makes it much easier to get to the exact information when searching.

## CFR

- ▶ 40 CFR 50.4 – typical reference for CFR
    - 40 refers to the title
    - 50 refers to a part within Title 40
    - .4 refers to a section within 40 CFR 50
  - ▶ Each title also has Chapters which generally are named with the agency responsible for the regulations. These chapters are not part of the citations.
  - ▶ The date of the CFR used should also be notated.
- 



# Free Tools

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- ▶ **FdSys – Federal Digital System** – <http://www.gpo.gov/fdsys/>
  - ▶ Government Printing Office
- ▶ **Federal Register** – <http://www.federalregister.gov/>
  - ▶ National Archives and Records Administration, Office of the Federal Register Office
- ▶ **Code of Federal Regulations** - <http://www.archives.gov/federal-register/cfr/>
  - ▶ National Archives and Records Administration, Office of the Federal Register Office
- ▶ **eCFR-** <http://www.ecfr.gov>
  - ▶ Government Printing Office and the Office of the Federal Register
- ▶ **Regulations.gov** – <http://www.regulations.gov>
  - ▶ Environmental Protection Agency, eRulemaking Program Management Office
- ▶ **RegInfo.gov** – <http://www.reginfo.com>
  - ▶ Office of Management and Budget, Office of Information and Regulatory Affairs
- ▶ **Agency dockets/rulemaking participation**





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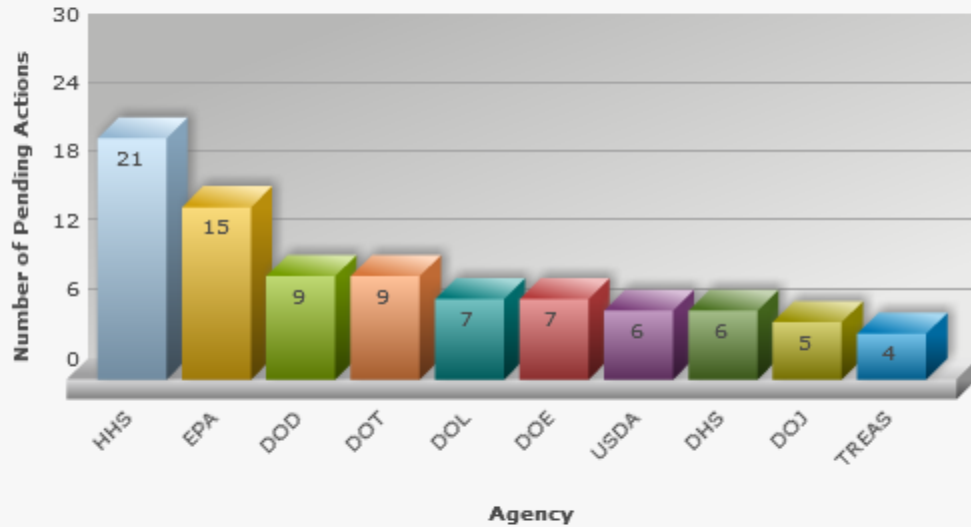
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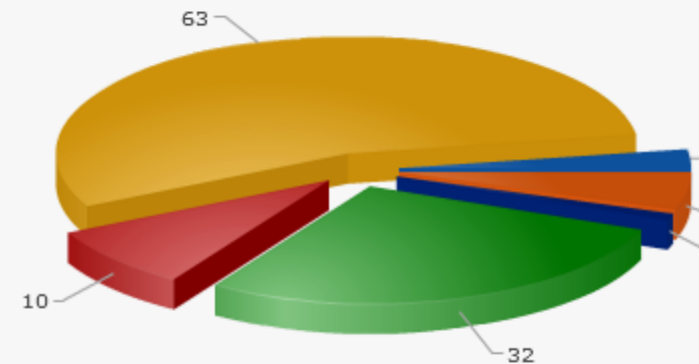
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- Proposed Rule
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- Final Rule No Material Change
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View

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Federal Register & Code of Federal Regulations

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# Conclusion

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## ▶ Good News First

- ▶ There are many free ways to find out about the Federal regulatory sources.
- ▶ There are multiple search platforms that the public can use to search the regulation sources.

## ▶ Better News Needed

- ▶ Retrospective coverage on the free sources needs to be improved (especially for the Federal Register)
- ▶ Current legislation to eliminate printing of the FR & CFR.



# Questions

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