Poll: How Familiar are you with Federal regulatory sources?

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

- 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?

- 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

<table>
<thead>
<tr>
<th><strong>Federal Register Act (1935)</strong></th>
<th><strong>Administrative Procedure Act (1946)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal structure for regulatory system</td>
<td>Added due process – public participation</td>
</tr>
<tr>
<td>Single publication – Federal Register – allowed for central filing/public inspection</td>
<td>Agencies must give notice of proposed rules in the FR</td>
</tr>
<tr>
<td>Includes Proposed/Final Rules, Notices, Presidential Documents</td>
<td>Agencies must receive and take action on public comments</td>
</tr>
<tr>
<td>Code of Federal Regulations- codification of the Federal Register – added in 1937</td>
<td>Rules need to state the legal basis and purpose</td>
</tr>
<tr>
<td></td>
<td>Rules effective only after 30 days – sometimes longer</td>
</tr>
</tbody>
</table>
Sources: Tangible and Electronic
What Triggers Rulemaking?

- Congressional Branch
- Executive Branch
- Judicial Branch
- Other Petitions for Rulemaking

http://forgottenmanblog.blogspot.com/
Some Federal Register & CFR Contributors

- United States Environmental Protection Agency
- U.S. Securities and Exchange Commission
- Food and Drug Administration
- NASA
- Department of Transportation
- OSHA
- U.S. Department of Homeland Security
- Internal Revenue Service
- U.S. Department of Homeland Security
- Transportation Security Administration
- Consumer Product Safety Commission
- United States Department of Agriculture
- Bureau of the Census
- Department of Defense
- Department of Health & Human Services
- Federal Energy Regulatory Commission
Organization in the FR & CFR

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 – ¼ 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

- Preliminary Rulemaking – advanced notices, petitions, and negotiated rulemaking

- Proposed Rules – also known at 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
Also Included in Rule (but not shown here) are:

- Addresses
- For further information contact
- Supplementary Information
Federal Register Content
Final Rules

- 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
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

Example of Direct Final Rule – no proposed rule – FDA is trying to increase its own transparency
List of CFR Sections Affected (LSA)

- 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
  - 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

- 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
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.
<table>
<thead>
<tr>
<th>Title</th>
<th>Title</th>
<th>Title</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General Provisions (Cover Only)</td>
<td>17</td>
<td>Commodity and Securities Exchanges</td>
</tr>
<tr>
<td>2</td>
<td>Grants and Agreements</td>
<td>18</td>
<td>Conservation of Power and Water Resources</td>
</tr>
<tr>
<td>3</td>
<td>The President</td>
<td>19</td>
<td>Customs Duties</td>
</tr>
<tr>
<td>4</td>
<td>Accounts</td>
<td>20</td>
<td>Employees' Benefits</td>
</tr>
<tr>
<td>5</td>
<td>Administrative Personnel</td>
<td>21</td>
<td>Food and Drugs</td>
</tr>
<tr>
<td>6</td>
<td>Domestic Security</td>
<td>22</td>
<td>Foreign Relations</td>
</tr>
<tr>
<td>7</td>
<td>Agriculture</td>
<td>23</td>
<td>Highways</td>
</tr>
<tr>
<td>8</td>
<td>Aliens and Nationality</td>
<td>24</td>
<td>Housing and Urban Development</td>
</tr>
<tr>
<td>9</td>
<td>Animals and Animal Products</td>
<td>25</td>
<td>Indians</td>
</tr>
<tr>
<td>10</td>
<td>Energy</td>
<td>26</td>
<td>Internal Revenue</td>
</tr>
<tr>
<td>11</td>
<td>Federal Elections (Cover Only)</td>
<td>27</td>
<td>Alcohol, Tobacco Products and Firearms</td>
</tr>
<tr>
<td>12</td>
<td>Banks and Banking</td>
<td>28</td>
<td>Judicial Administration</td>
</tr>
<tr>
<td>13</td>
<td>Business Credit and Assistance</td>
<td>29</td>
<td>Labor</td>
</tr>
<tr>
<td>14</td>
<td>Aeronautics and Space</td>
<td>30</td>
<td>Mineral Resources</td>
</tr>
<tr>
<td>15</td>
<td>Commerce and Foreign Trade</td>
<td>31</td>
<td>Money and Finance:Treasury</td>
</tr>
<tr>
<td>16</td>
<td>Commercial Practices</td>
<td>32</td>
<td>National Defense</td>
</tr>
<tr>
<td></td>
<td></td>
<td>33</td>
<td>Navigation and Navigable Waters</td>
</tr>
<tr>
<td>34</td>
<td>Education</td>
<td>36</td>
<td>Parks, Forests, and Public Property</td>
</tr>
<tr>
<td>37</td>
<td>Patents, Trademarks, and Copyrights</td>
<td>38</td>
<td>Pensions, Bonuses, and Veterans' Relief</td>
</tr>
<tr>
<td>39</td>
<td>Postal Service</td>
<td>40</td>
<td>Protection of Environment</td>
</tr>
<tr>
<td>41</td>
<td>Public Contracts and Property Management</td>
<td>42</td>
<td>Public Health</td>
</tr>
<tr>
<td>43</td>
<td>Public Lands: Interior</td>
<td>44</td>
<td>Emergency Management and Assistance</td>
</tr>
<tr>
<td>45</td>
<td>Public Welfare</td>
<td>46</td>
<td>Shipping</td>
</tr>
<tr>
<td>47</td>
<td>Telecommunication</td>
<td>48</td>
<td>Federal Acquisition Regulations System</td>
</tr>
<tr>
<td>49</td>
<td>Transportation</td>
<td>50</td>
<td>Wildlife and Fisheries</td>
</tr>
</tbody>
</table>
Federal Deposit Insurance Corporation

§ 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

[Regulation text continues]
Citations

Federal Register

- 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

  - Government Printing Office

  - National Archives and Records Administration, Office of the Federal Register Office

  - National Archives and Records Administration, Office of the Federal Register Office

  - Government Printing Office and the Office of the Federal Register

  - Environmental Protection Agency, eRulemaking Program Management Office

  - Office of Management and Budget, Office of Information and Regulatory Affairs

- Agency docket rulemaking participation
Federal Digital System (Fdsys) Basic Search
Code of Federal Regulations Browse Search

Browse VS. Basic/Adv.

- Titles by Subject
- Searching through 200 volumes when performing basic/adv search
- Ability to Drill Down
- Could get to answers faster
Participate Today!

Submit your comments on proposed regulations and related documents published by the U.S. Federal government. You can also use this site to search and review original regulatory documents as well as comments submitted by others.

Help improve Federal regulations by submitting your comments.

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

What's Trending

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Request for Comments
Closing on Apr 14, 2014

Guidance for Industry GFI #213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated...
ELECTRONIC CODE OF FEDERAL REGULATIONS


e-CFR Data is current as of April 10, 2014

USER NOTICE


Browse: Select a title from the list below, then press "Go".

Title 1 - General Provisions

Go

For questions or comments regarding e-CFR editorial content, features, or design, email ecf@nara.gov.
OMB’s Regulatory Information

Executive Order 12866 directs agencies to follow certain principles in rulemaking, such as consideration of alternatives and analysis of benefits and costs, and

The Unified Agenda and Regulatory Plan provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal

ICR DASHBOARD
INFORMATION COLLECTIONS REVIEW PEND
BY TYPE
Agency Dockets

EPA Docket Center

EPA docket provide the public with access to agency information in a wide variety of rulemaking and non-rulemaking are serve as a source of current and historical information on agency activities, including comments received from to public to decisions.

Basic Information
Learn more about EPA docket.

Regulations.gov
Find how to access all EPA docket materials electronically and offer comment through the multi-agency docket system: Regulations.gov.

Frequent Questions about Dockets
Get answers to frequently asked questions about docket and related topics.

Contact Information for EPA Dockets
Find the contact information for the EPA Docket Center or a particular program office docket (e.g., Air, Water...).
For Fee/Subscription Tools

- Proquest Congressional

- Formerly LexisNexis and CIS

- Much greater coverage for both titles
  - Federal Register – 1980- current (updated daily)
  - Code of Federal Regulations – 1981-current (updated weekly)

- Greater searching capabilities
Congressional (Proquest)

Advanced Search

Federal Register & Code of Federal Regulations

Search by Number (Citation)

Federal Register & Code of Federal Regulations
Conclusion

- **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

Contact Information:

Lisa S. Nickum
Government Publications and Reference Librarian
Colorado School of Mines
Golden, Colorado 80401

Ph: 303-273-3695
Email: lnickum@mines.edu