Center for Veterinary Medicine

- http://www.fda.gov/cvm/
- For the most up-to-date information, go to

Office of Regulatory Affairs

- http://www.fda.gov/ora/
- What's New page

FDA Enforcement Reports Index

- http://www.fda.gov/opacom/enforce.html

Compliance Policy Guides

- http://www.fda.gov/ora/compliance_ref/cpg/default.htm

Subchapter 425, Computerized Drug Processing


Inspectional Guides

- Inspectional Guides
- Guide to Inspection of Computerized Systems in Drug Establishments
- Glossary of Computer Systems Software Development Terminology
  - http://www.fda.gov/ora/inspect_ref/igs/gloss.html
- Computerized Systems in the Food Processing Industry
- #23 The Computer In FDA-Regulated Industries
- #29 The Computer in FDA-Regulated Industries: Part II, Computer Hardware

Guidance Documents

- Submission for blood establishment computer software
  - http://www.fda.gov/cber/gdlns/swreview.txt
- Center for Devices and Radiological Health (CDRH) – Medical Device Guidance
- Review of 510(k)s for computer-controlled medical devices
  - http://www.fda.gov/cdrh/k91-1.html
- Draft general principles of software validation guidance for industry