FDA-IRAI -The FDA Information Repository for Academic Institutions & Professionals

Sign up at IRAI-ONLINE.ORG &

Download the User Manual on the FDA IRAI-ONLINE site.

1. Software Systems - Chief Features

a. **Browse** the entire content of the FDA website with additional materials from NIH and the Congressional Research Service presented with a logical table of contents organized in a structured hierarchy of folders and subfolders down to files.
b. **Search** using simple Search, Boolean Search, Advance Search (template)
c. How **Results** of a search are displayed
    a. Following a search the number of hits in each category, folder and subfolder is displayed on the left side of the Table of Contents – You may then open the folder, subfolder, down to the document & meeting the search criterial – click on the title and the document appears in the Results Window: or
    b. Following the search the document titles and an excerpt of the document showing the words searched in context is displayed in the Results window in the sequence that the software determines is likely to be most relevant. When using the advanced search feature little boxes appear adjacent to the lines of the table of contents. You may then check the boxes to limit the items that you wish to search.
    c. Documents are displayed as text (HTML), PDF, as MS Office documents, PPT, or audio visual. PDF documents will be displayed in the results window within a version of Acrobat using Acrobat features which permit searching within the document and printing the document. MS Office documents will appear within your native Office display (Word, Excel, and PPT). AV documents will open within their native software.
    d. UCM numbers. Occasionally the title of the document is a UCM number. This is due to FDA's failure to insert the document title in the metadata (documents properties). However, the text of the document does appear in the Results window.
    e. Associated PDFS and other Files. In many sections of the Table of contents, there are folder, subfolders, and documents in this folder. These are the documents that are hyperlinked from HTML documents on the FDA website (www.fda.gov) to documents on a storage site (www.access.FDA.gov.) To make these documents indexable we collect them and process them along with their HTML "parent."

2. Browsing IRAI -- KEY CONTENT – FDA Website plus Additional Relevant Information

I. Legislation:

i. Statutes: 21 USC (FDA and DEA); Amendments thereto; Other laws affecting FDA regulated products.

ii. *FDA Blue Book (1998) plus Congressional Research Service (CRS) reports. These are narrative texts describing FDA statutory functions. The CRS reports begin in 2000 and include monographs on statutory amendments as well as comprehensive summaries of major FDA programs in Drugs, Devices foods and tobacco.*

***X*II. Regulation**

i. 21 CFR in its entirety.

ii. 2015 and 2016 Proposed and Final Regulations – thus including preambles which describe the agency's reasons for the proposals as well as the agency's comments in recent two comments on the proposals including rationale for accepted changes in the proposed regulations

iii. Until 2008 FDA maintained on its website comments on FDA proposed regulations. These comments appear in IRAI at section XIII "Dockets Management" and cover 1975 thru 2008. After that time, these comments and preambles (unless reproduced on the FDA website) appear only on the Federal Register GPO website where the full text of the proposed and final regulations and the comments are not indexed.

III. FDA Overview

- **i. A Tour of FDA – AV presentation of FDA in basic terms**
- **ii. FDA History – Maintained by the FDA History Office**
- **iii. About FDA (An Overview)**
- **iv. Staff Manual Guides – (A detailed description of the function of each FDA office and their subdivisions.)**

IV. OFFICE OF COMMISSIONER

- **i. Transparency – (See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/)**
- **ii. Dispute Resolution – The functions of the FDA Ombudsman**
- **iii. FOIA (Freedom of Information Act as implemented at FDA)**

MATERIALS FROM PRINCIPAL FDA OFFICES

This includes Center and Office policies and procedures for product or component review and approval; guidelines and guidance document; lists of approved products; and other documents specific to that Center

V. OFFICE OF FOODS AND VETERINARY MEDICINE

VA. CFSAN (Center for Food Safety and Nutrition

- **i. Food**
- **ii. Cosmetics**

VB. CVM (Center for Veterinary Medicine)

VI - OFFICE OF MEDICAL PRODUCTS AND TOBACCO

VIA - OFFICE OF SPECIAL MEDICAL PROGRAMS

- **i. Office of Combination Products**
  Medical Device and a medicine
- **ii. Office of Good Clinical Practices**
  Includes training materials and responses to inquiries about clinical studies; and NIH documents relevant to clinical studies AND HUMAN PROTECTION
- **iii. Office of Orphan Products Development and incentives**
- **iv. Office of Pediatric Therapeutics Study Requirements and incentives**

VLB – CBER – CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Vaccines, Blood, Biologics

VLC - CDER - CENTER FOR DRUG EVALUATION AND RESEARCH

VLD - CDER & CBER – Overview of functions

VLE – CDRH -CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Includes Diagnostics and Laboratory Tests

VLF - CDRH RADIATION-EMITTING PRODUCTS

VLG - CENTER FOR TOBACCO PRODUCTS

VII - OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

VIIIA OFFICE OF INTERNATIONAL PROGRAMS

Relations with Foreign Countries and overseas inspection programs

VIIIB OFFICE OF REGULATORY AFFAIRS

Inspection, Compliance, Enforcement, and Criminal Investigations Criminal Investigations (Lots of FDA procedural manuals.)

Compliance Actions and Activities

For Federal, State, and Local Officials – Includes "ORA University" Programs

Import and Export Programs and Procedures

VIII. OFFICE OF EXTERNAL AFFAIRS DOCUMENTS

Speeches

Speech Archives

Meetings Conferences Workshops

Testimony

Public Health Focus

Media Contacts

Fact Sheets

Product Approval Listings

Press Announcements

Media Transcripts

Media Policies

AGENCY WIDE

IX. ADVISORY COMMITTEE MEETINGS & MATERIALS

X. BLOG (FDA Employee blogs)

XI - COLOR ADDITIVE Programs applicable to all FDA products

XII- DATABASES (Where Google Search Engines is inefficient). These are segregated databases by product area with there own search templates and documents files for retrieval.

Animal and Veterinary

Compliance and Enforcement

Medical Device Databases

Drugs

Food

Tobacco

Vaccines, Blood, Biologics Other

XIII - DOCKETS MANAGEMENT

FDA's Dockets Management website section served as the official repository for the administrative proceedings and rule-making documents for the Food and Drug Administration (FDA). This included all Federal Registers, Petitions, supporting documents and comments. On January 15, 2008, FDA transitioned from its FDA Dockets Management System (DMS) to the Federal Dockets Management System (FDMS) located at regulations.gov. The information described above is no longer compiled and reported on FDA's web site.

The Dockets Management section is now administered by the Federal Dockets Management System (FDMS) located at Regulations.gov (see FR announcing this transition). Consequently, the documents collected are no longer indexed and searchable by key word unless they are reproduced by the FDA Centers on the FDA website.

XIV - ELECTRONIC SUBMISSIONS GATEWAY

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory information for review.

The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach their final destination. It does not open or review submissions; it automatically routes them to the proper FDA Center or Office.

XV - EMERGENCY PREPAREDNESS AND RESPONSE

This section of the FDA website was created in response to bioterrorism legislation. It now includes all FDA responses to bioterrorism (counter terrorism) crisis management and other health emergencies.

XVI – RECALLS

Recalls are product removals either voluntary or mandated by FDA where the product is either misbranded or adulterated and poses adverse health consequences.

XVII - SAFETY NOTICES

Safety notices consists of Public Health Notifications, which were important message to the health care community describing a risk associated with the use of a medical device and providing recommendations to avoid or reduce the risk. They were published until 2009 when they were replaced with Safety Communications. Additional safety communications in the form of MedWatch safety alerts. MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may affect both treatment and diagnostic choices for healthcare professional and patient.

XVIII - SCIENCE RESEARCH

An overview of science and research projects across the various components of FDA; FDA Technology Transfer Program; Health Informatics; Laboratory Science - including lab manuals and procedures; science research presentations

XIX- TRAINING

We have moved most of the training materials to their Center specific sections. Where these materials cut across Centers, we retained them in this section.

XX - WARNING LETTERS

WARNING LETTER: An informal advisory to a firm communicating the agency's position on a matter but does not commit FDA to taking enforcement action. The agency's policy is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.

XXI - ADDITIONAL RESOURCES BY AUDIENCE

FDA has categorized a number of materials by audience, I. E. For Consumers, For Patents, For Health Professionals, and For Industry. We have heard the For Industry materials to their respective Center sections.

XXII - ADDITIONAL UPDATES

We endeavor to update IRAI once a month. The process of updating requires us to examine each new file and place it in its appropriate section. This takes a lot of time. Therefore, initially we place the updates in this section organized by FDA's own file structure to get an IRAI update out as soon as possible. We then editorial review the new files and place them into their proper respective locations in IRAI.

3. SEARCHING IRAI

Serendipity (Surprises) – The great benefit of seeing everywhere in IRAI where you have hits is notification about Items that you did not know existed until they pop-up in the results window or the hits numbers in the outline in sections where you may not have expected them.