About FOI Services, Inc.

FDA Regulatory Resources

2002-2003

foi online™

User's Guide

General Information

FOI Services, Inc. was founded in 1975 to facilitate the flow of information under the Freedom of Information Act (FOIA). Since its inception, FOI has specialized in Food & Drug Administration information, providing a wide range of products and services. FOI maintains the world's largest private library of FDA documents, containing over 160,000 documents and 6 million pages.

FOI's basic services include:

- Document delivery for all categories of FDA documents
- Reference Books & Subscription Publications
- The online database DIOGENES®

Hours & Contact Information

FOI Services, Inc. is an independent, privately-held corporation located near FDA headquarters in the Washington, D.C. suburb of Gaithersburg, Maryland.

We are open Monday through Friday from 9:00am until 5:00pm, Eastern Time. We are closed on all Federal Holidays and the day after Thanksgiving.

Contact us at: **FOI Services, Inc.**
11 Firstfield Road
Gaithersburg MD 20878-1704
Phone: 301-975-9400
Fax: 301-975-0702
EMail: infofoi@foiservices.com
Web: *www.foiservices.com*

Table of Contents

FOI's FDA information products are featured on the pages with Green Headers.

FOI's FDA document types are described on the pages with Purple Headers.

Immediate Gratification

Many of the FDA documents in FOI Services' library can now be searched and downloaded from our website in convenient PDF format.

Searching is Free!

Entering your search term(s) here lets you search the indexing for 75,000+ FOI Services documents as well as selected documents from other leading publishers for FDA-regulated industry.

Types of Documents Include:

- Drug Summary Bases of Approval
- FDA Drug Approval Reviews
- PMA Summaries & 510(k)s
- EIRs & 483s
- FDA/Industry Correspondence & Meeting Minutes
- Guidelines
- Topical Regulatory & Market Reserch Reports from Advamed, Espicom, IDRAC & Theta Reports

General Information about FOI Services

Click here for current shipping and payment policies, frequently asked questions and our event calendar.

A Free Document Each Week

Click here every Monday for a new FREE document of interest to FDA-regulated industry. Past free documents have included:

- Cloning
- Bioterrorism
- FDA testimony before Congress
- Clinical trial subject selection
- Internet advertising
- Trade with China
- And more!

foi online™

www.foiservices.com

Boolean Searching

Begin your search by typing your search terms into the box on the home page:

```
venous catheter
```

The system will default to the "AND" operator i.e., it will look for documents containing the indexing words venous AND catheter.

To look for documents containing either word, use the "OR" operator.

Phrase Searching

To look for an exact phrase, enclose the terms in double quotes.

```
"venous catheter"
```

Pattern Searching

If you're not sure how a word is spelled, or would like to account for possible variations in spellings (e.g. British versus American English), you may want to try Pattern Searching.

To turn on pattern searching, go to the Query Type box on the home page and choose Pattern:

Query Type: 3. Pattern

Enter your search terms into the search box without operators – FOI Online will look for words and phrases similar to those you've entered and rank your results accordingly.

Pattern searching is a little slower than Boolean searching, but offers very high recall and precision.

Truncation and Wildcards

FOI Online automatically looks for plurals of entered terms. To specify a truncation to match any character or nothing, use the asterisk (*):

```
Pharma*
```

The asterisk can also be used as a wildcard within a search term; e.g. orthop*edic will retrieve orthopedic or orthopaedic.

Date Searching

Search for a specific date by entering it in the format mm/dd/yyyy:

```
04/28/2000
```

Search for a date range using a hyphen:

```
01/01/2000 - 12/30/2000
```

Advanced (Fielded) Searching

To restrict terms to a particular indexing field (such as the title or generic name), go to advanced search by clicking the "Advanced Search" button on the home page. Browse the indexing fields by scrolling down the page. Hints for entering terms into a particular field are available by clicking on the field name.

Note: Not every record contains every indexing field. We recommend using Advanced Search only when a simple search yields too many results.

Your Results

Your results will list descriptive titles for documents that contain your search terms. For more information about a particular document, highlight the title and click the "More Detail About This Document" button. The entire document description will be displayed, including the page count and price. For example:

Document Description

Document Number: 5200563 – B 142 Pages US$ 105.40
Title: LNR International, Hauppauge, NY, USA: Establishment Inspection Report (EIR); 483; Company Response 12/11/1998 – 12/18/1998
Occurrence Date: 12/11/1998
Begin Date: 12/11/1998
End Date: 12/18/1998
Company Name: LNK International
Address:
100 Riceland Lane
Hauppauge, NY USA
People Involved: Pankaj Chudgar, LNK International Contact; Thomas Mooney, FDA Investigator
Log number: 0020735
Subfile: Inspection
Category: Drug
Contents: Establishment Inspection Report (EIR); 483; Company Response
Subject Enhancement: Over the counter drug manufacturer; follow-up to Assignment #10545 regarding 200 mg tablets. Deficiencies: lack of assurance on uniform mixtures; revoked batches; labeled shelf life; revised formulation; test methods

If you want the document, click the "Add to Cart" button. You'll be offered the opportunity to return to searching to look for more documents or proceed to check-out to download the document(s) you've chosen.

Checking Out

When your cart contains the documents you need, click the "Check-Out" button and follow the on-screen directions. After entering a credit card number, you'll be given an opportunity to download your documents immediately. You will also receive an email with links to the documents you've ordered. The links remain valid for 72 hours after placing the order.

FOI Services open account holders may opt to charge their FOI accounts. Please call us first at 301-975-9400 during regular business hours to enable this feature.

Pricing on Documents from our Library of FDA-Related Files

Each document is individually priced. Prices may be determined by clicking the "More Detail About This Document" button on our website or by calling us.

There are no additional charges for downloaded documents; a nominal shipping & handling fee applies to orders for printed copies.

Pricing for Custom Document Retrieval

FOI Service Fee
$39 for FDA requests
$65 for other agencies

An FOI Service Fee is charged for each custom document retrieval request made. This fee is non-refundable.

In addition to the above charge, customers will be billed for content, shipping charges, and any charges assessed by the government.

Shipping Rates
A nominal shipping & handling charge is added.

$10 surcharge for same-day and non-standard shipping requests.

Electronic Delivery
A nominal charge is added.

Fax Delivery
$10 for up to 5 pages;
$1 for each additional page.

Double the fax delivery rates outside the U.S. & Canada.

FOI Offers Two Options for Ordering FDA Documents:

1 Search and Download Documents from the Web

Most of the FDA documents in our huge library of over 6 million pages are indexed and available for sale and immediate downloading from our website in convenient PDF format. And, each week, there's a new, free document available for downloading!

2 Custom Document Retrieval

If you can't find the document you need, or if you'd simply prefer that we check our holdings for you, just contact us. There's no charge for us to search our in-house database, and we can advise you as to the scope of documents available, cost, and delivery time. If we don't already have the document you need, we can place a request to the government for you. With over 25 years of experience using the Freedom of Information Act, we'll construct a request that contains the information the government needs to efficiently process the order. If requests similar to yours have previously yielded no information, we'll let you know up-front, before you've waited in vain.

Of course, we hold every inquiry confidential. Every request carries the FOI name…so no one knows the products, processes, and companies you're researching.

Document Retrieval Terms & Conditions

On custom document retrieval orders, an FOI Service Fee is charged for each order and is non-refundable, regardless of the outcome of the request. In addition you will be charged for the cost of the document, government-assessed search fees and shipping charges. Please see the Price List at left for additional pricing information.

Unless specified otherwise, all of the documents have been released by the U.S. Government under the provisions of the Freedom of Information Act and are therefore available to the general public. FOI Services, Inc. does not guarantee the accuracy of any of the information in the documents it provides; the documents will be copies of the information supplied to FOI Services, Inc. by the government.

Documents and books are not sold on a "trial" basis, and are not returnable. If you receive an incorrect or illegible document, please give us a call. We can usually provide the correct information without requiring document return.

Frequently Asked Questions about FOI Services' Document Retrieval Services

Why use FOI Services to obtain Freedom of Information Act (FOIA) documents?

While any person can file a FOIA request, it frequently makes more sense to have FOI Services process the request. First, FOI Services offers convenience. FOI Services has filed over 160,000 FOIA requests…we know exactly how a request should be phrased, where to submit a request, and lots of other knowledge born of long experience. We often already have exactly the document you need…saving you months of waiting. FOI Services also keeps all requests confidential. Every request submitted to the Federal government is a matter of public record. When FOI Services requests a document, no one knows that you initiated a request…allowing you to keep your research projects confidential.

Is information about individuals available?

FOI Services does not process FOIA requests for information about private (non-government) individuals, nor do we process requests of a personal nature, as they are subject to the provisions of The Privacy Act and must be signed by the individual in question. If you would like to request this information yourself, a list of government FOI addresses is available at:

www.usdoj.gov/foia/foiacontacts.htm

Are FOI Services documents available full-text online?

Of course. In addition to FOI Online, many of our more substantive documents are available full-text on DIOGENES®, available on Dialog, DataStar and STN. See page 8-9 for details.

How long does it take?

If FOI Services has the document you need, and you request traditional delivery rather than download it yourself, it will normally be shipped to you within two business days; express delivery is available upon request. If the document you need must be ordered from the FDA, turnaround time depends on the type of information requested. Some documents are available within a few weeks. Device Premarket Notifications [510(k)s] have the longest fulfillment time; some take up to 36 months.

What do these documents look like?

If you're requesting a FOIA document for the first time you might be surprised by its appearance…unlike monographs and journal article reprints, these documents don't contain neat titles, abstracts, publication date and source, and other familiar hallmarks of the literature. The documents you receive were not prepared for publication, and are simply photocopies of correspondence, reviewers notes, handwritten observations, etc. They may be purged of confidential content with broad swipes of black ink. In the case of microfiche, material is withheld by physically cutting it off the film. That said, while these documents may not look attractive, they provide a wealth of information unattainable elsewhere.

Subscription Pricing

FDA Freedom of Information Request Log
$549/year

FDA Log on Disk
$549/year
$275/year with print version

Index of FDA Warning Letters
$399/year

RegiFax
$739/year
in U.S., Canada & U.K.
$999/year in rest of world

Sample Editions of Subscription Items

Contact us for free sample editions of our print publications or download them from our website:

www.foiservices.com/brochure/subscriptions.html

A free sample edition of ***FDA Log on Disk*** is available for you to try on your own computer. Call us at 301-975-9400 or email *infofoi@foiservices.com* for a copy.

FDA Freedom of Information Request Log

Each year, over 30,000 Freedom of Information Act (FOIA) requests are submitted to the Food and Drug Administration. The information requested covers the entire spectrum of FDA authority.

The *FDA Freedom of Information Request Log*, printed weekly, lists all FOIA requests received by the FDA. It includes, for each request, the date, name and affiliation of the requestor, and the request subject.

Use this publication to see who is requesting information about your company and products. This is a valuable tool for keeping abreast of the documents that are currently popular, and following the trends of industry requests.

FDA Log on Disk

The monthly *FDA Log on Disk* enables you to track all FDA requests electronically.

With just an IBM-compatible computer and virtually any database software (which you probably already have), you can easily load each month's request data and instantly have an electronic database of all requests made to FDA.

Index of FDA Warning Letters

The *Index of FDA Warning Letters* provides a weekly listing of all of the warning letters issued by the agency, including the company and products involved, as well as the alleged violation. This enables the reader to track those areas of FDA regulatory interest, as well as keeping track of what is happening to the competition.

RegiFax

RegiFax is the quick way to keep track of FDA *Federal Register* notices. Published daily and sent to you by fax, *RegiFax* abstracts each notice to appear in the next day's edition of the *Federal Register*. This means that you'll know about each notice up to a week earlier than if you waited to receive your copy by mail.

foi DIOGENES®

DIOGENES® – FDA Regulatory Information Online

DIOGENES is the only online database offering instant access to a full range of FDA information needed by the regulatory affairs community. Unlike other databases, which concentrate on published clinical information, DIOGENES gives you unpublished FDA documents online — full-text and as citations — as well as full-text news articles. With over one million records, DIOGENES provides a unique information resource, unduplicated anywhere.

DIOGENES contains the full-text of thousands of FDA documents generated by the regulatory process. These include Advisory Committee Minutes, FDA Guidelines, Warning Letters, Drug Summary Bases of Approval, Device Summaries of Safety and Effectiveness, Medical Device Report (MDR) Summaries and Approved Product Listings for Device 510(k)s and PMAs as well as Drugs and Antibiotics.

FOI Services publishes several reference books for manufacturers and others interested in the regulation of pharmaceuticals and medical devices. For more information, including pricing and complete brochures, click "Books" at www.foiservices.com

Food, Drug & Medical Device Law: Topics & Cases

Released in 2001, this textbook by Roseann B. Termini, Esq., provides a guided tour of US regulation of drugs, medical devices, dietary supplements, veterinary products, cosmetics, and biologics.

Drugs Under Patent

Drugs Under Patent brings you complete, cross-referenced lists of the 2,500+ drugs covered in the U.S. under patent law and marketing exclusivity provisions of the Waxman-Hatch Act. Eight easy-to-use indexes give you precisely the market and patent status information you need by company, trade name, generic name, expiration date, dosage form, exclusivity code, patent number and NDA number. Published every spring.

The Impact of GMPs in Pharmaceutical & Nutraceutical Manufacturing

A "how-to" of practical application of Good Manufacturing Practices to help you design or retrofit your facility. Includes a disk of forms you can adapt for your own plant. By Paul L. Simmons.

Master Procedures

This looseleaf publication provides the basics for a regulatory documentation system, including the Master Procedures for the development, implementation of programs for SOPs, equipment history files, calibration, training, change control, vendor qualification, and more. By Paul L. Simmons.

Documentation

FOI publishes a free Users Guide for DIOGENES — in addition, each system on which DIOGENES is available has a free user reference. All are linked from our website:

www.foiservices.com/brochure/diogenes.html

Database Availability

DIOGENES is publicly available from the following vendors:

Dialog File: 158
DataStar File: DIOG
STN File: DIOGENES

Contact the vendors directly for access and pricing information:

Dialog & DataStar: 800-334-2564 — *www.dialog.com*
STN: 800-753-4227 — *www.cas.org/stn.html*

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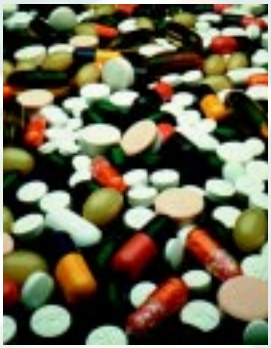

Background Regulatory Information

The Center for Drug Evaluation and Research (CDER) is the FDA division responsible for ensuring that human drugs are safe, effective, and properly labeled.

The approval process involves two stages. First, before CDER will permit a new drug to be tested on humans, the drug's sponsor must file an IND – a "Notice of Claimed Investigational Exemption for a New Drug." The IND contains the drug's structural formula, animal testing results, the proposed protocol for clinical testing, and other data.

After the trials, but before marketing, the manufacturer files a New Drug Application (NDA), which must contain full information about the product and clinical trial results. Each NDA is reviewed by various FDA scientists. In some instances, the NDA is also reviewed by a public advisory committee.

Availability

Generally Not Available

IND Documents

Except in rare circumstances, documents regarding an IND are not disclosable under the Freedom of Information Act. FDA maintains that even the acknowledgment of the existence of an IND could damage a drug sponsor's competitive position.

Full-Text NDA & ANDA Documents:

Custom Document Retrieval

FOI Online

DIOGENES® Online File (many full-text online)

Listings of New Drug Approvals (NDAs & ANDAs):

Custom Document Retrieval

DIOGENES® Online File

Patent & Marketing Exclusivity Information

Drugs Under Patent Book

DIOGENES® Online File

NDA Documents

Once the NDA is approved, information about the approval may be released under FOIA. The basic information package relating to the approval of a New Drug Application includes:

- Approval Letter, Package Insert and Labeling
- FDA Final Reviews
- Summary Basis of Approval (SBOA)

Note: SBOAs are no longer prepared for most new drug approvals. However, the same information is released in the reviews mentioned above, although not in the same format.

ANDA Documents (Generic Drugs)

When the patent and marketing exclusivity for a particular drug has expired, the drug may be manufactured by other companies as well. Manufacturers of these generic or "me-too" forms are not required to repeat the extensive preclinical and clinical testing required for new drugs. Rather, they may submit an Abbreviated New Drug Application (ANDA) documenting the bioequivalence of their formulation of the drug. The FDA reviews ANDAs to compare the generic product to the original product to ensure that comparable blood levels of active ingredients are produced. After approval, basic information about an ANDA is available:

- Approval Letter, Package Insert and Labeling
- Bioavailability and Dissolution Reviews

Icons indicate the format(s) in which FDA information is available from FOI:

Custom Document Retrieval

FOI Online: Document Retrieval on the Web

Reference Books

DIOGENES® Database

Availability

Guidelines on Drug Products & Drug Manufacturing

Designed by CDER to help industry comply with applicable regulations, drug guidelines cover virtually every phase of drug manufacture, approval and marketing.

Sample topics include:

- Adverse Experience Reporting
- Orphan Drug Designation
- Drugs for Use in the Elderly
- Transdermal Delivery Systems
- Bioequivalence Evaluation
- Sterilization Process Validation
- Prescription Drug Advertising
- Tamper-Resistant Packaging
- IND Filing

In addition, individual drug products are often covered by a specific guidance.

Drug Guidelines Full-Text

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

Adverse Reaction Reports

Adverse Reaction Reports are summaries of all of the adverse experiences with specific drug products reported to FDA. Many of these reports can be searched in-house at FOI; computer charges are applied. Our information specialists can advise you as to the current availability and cost.

Drug Adverse Reaction Reports

- Custom Document Retrieval

Biologics Documents

Biologic products are approved and regulated by FDA's Center for Biologics Evaluation and Research (CBER). Information available under FOIA regarding biologics closely follows that for drugs and devices. For drug-like products, a Summary Basis of Approval (SBOA) is prepared, generally within six months of approval, and is available along with the approval letter, package insert, and labeling. For device-like products (usually diagnostics), a biologic 510(k) is available, again generally six months after permission to enter the market is granted. As with other FDA-regulated products, information about items undergoing FDA review is not disclosable.

Guidance documents issued by the Center for Biologics Evaluation & Research are generally called Points to Consider; coverage ranges from characterization of cell lines, to clinical evaluation to labeling.

Approval Documents for Biological Products & Biologic 510(k)s

- Custom Document Retrieval
- FOI Online

Biologics Guidelines

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

Background Regulatory Information

The Center for Devices and Radiological Health (CDRH) within the FDA is responsible for ensuring the safety and effectiveness of medical devices under the authority of the 1976 Medical Device Amendments to the Federal Food Drug and Cosmetic Act. The Amendments established the system under which medical devices are brought to market.

Availability

Generally Not Available

IDE (Investigational Device Exemption) Documents

Except in rare circumstances, documents regarding an IDE are not disclosable under the Freedom of Information Act. FDA maintains that even the acknowledgment of the existence of an IDE could damage a device sponsor's competitive position.

510(k) Notifications Full-Text Copies

Custom Document Retrieval

FOI Online

510(k) Notifications Reference Listings

Custom Document Retrieval

DIOGENES® Online File

510(k) Notifications

Manufacturers of devices believed to be non-critical and substantially equivalent to devices manufactured prior to 1976 may submit a pre-market notification outlining device specifications and characteristics. These notifications, usually called 510(k)s because they are regulated by section 510(k) of the Medical Device Amendments, are reviewed by the FDA. If, after review, the FDA agrees with the manufacturer's determination, the device can be marketed. Substantial portions of the 510(k) are available through FOIA once an Agency decision has been reached.

Since 1976, over 100,000 510(k)s have been cleared for marketing. Although substantial portions of the 510(k) are available using the Freedom of Information Act, there is often a 24+ month backlog in FDA's processing time for these requests. With over 35,000 510(k)s on file, FOI Services can often provide a 510(k) immediately. To check availability of a 510(k), call us or check our website.

PMA Notifications Full-Text Summaries

Custom Document Retrieval

FOI Online

PMA Notifications Reference Listings

Custom Document Retrieval

DIOGENES® Online File

PMA Applications

Devices determined to be new and/or life supporting or otherwise critical are subject to the pre-market approval (PMA) requirements. Similar to a new drug approval, the PMA must document the device's safety and effectiveness through pre-clinical and clinical testing. The PMA undergoes scientific review by appropriate FDA personnel and advisory committees. Because of the volume of confidential business and patient information in a PMA, it is not disclosable under FOIA. Instead, a Summary of Safety and Efficacy (SS&E) is prepared and available along with the approval letter and labeling.

Availability

MDR (Device Adverse Reaction) Reports

In 1984, legislation requiring device user facility reporting was enacted by Congress to increase the amount of information FDA and device manufacturers receive about problems with medical devices.

Currently, manufacturers and importers of medical devices must report to FDA all possibly device-related deaths and serious injuries, as well as certain malfunctions. In addition, since 1991, device user facilities must report device-related deaths to the FDA and the manufacturer; serious injuries must be reported to the manufacturer.

Under FOIA, the summary of the reported incident is releasable.

MDRs
Full-Text Summaries

- Custom Document Retrieval
- DIOGENES® Online File

Medical Device Guidelines

Device guidelines, prepared by the Center for Devices and Radiological Health, cover the spectrum of device and diagnostic regulation from PMA preparation to reporting of malfunctions of marketed products. In addition to device-specific guidance documents, topics include:

- Labeling Requirements
- Biocompatability
- Statistical Methods
- Premarket Approval Inspections
- Sterilization Process Indicators
- Master Files
- Design Control
- Color Additives for Devices

Medical Device Guidelines

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

Veterinary Drugs

Drugs for use in animals fall under the jurisdiction of the Center for Veterinary Medicine (CVM) within the FDA. The approval process for New Animal Drug Applications (NADAs) closely parallels that developed for human drugs (NDAs), and requires that manufacturers prove the safety and effectiveness of products designed for use in animals. While the actual NADA is not available under the Freedom of Information Act, a Freedom of Information Summary, describing the pre-marketing studies, is generally available along with the approval letter, package insert, and labeling.

The Center for Veterinary Medicine releases guidelines pertaining to the regulation of drugs and feed additives intended for animals, especially cattle, swine, chickens, turkeys, horses, dogs and cats. Topics cover preparation of New Animal Drug Applications, Effectiveness Evaluation, Bioequivalence Determination, Labeling, and Products for Particular Animals or Conditions.

FOI Summaries for Veterinary Drugs

- CustomDocument Retrieval
- FOI Online

Veterinary Guidelines

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

Availability

Establishment Inspection Reports (EIRs) & 483s

- Custom Document Retrieval
- FOI Online

FDA Inspection Reports

FDA inspections are conducted by investigators working out of the agency's field offices and can encompass factories, warehouses, and establishments in which foods, drugs, devices, veterinary products or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce. Clinical investigators are also inspected in connection with the testing of investigational products.

All inspections generate an Establishment Inspection Report (EIR), prepared by FDA's investigator immediately after the inspection. In addition, observations of objectionable or violative conditions are recorded on a form FD-483 (483), presented to the inspected firm at the conclusion of the inspection. Both the EIR and 483 are generally disclosable under the Freedom of Information Act.

To identify a particular EIR, we generally need to know the firm name and location (city and state). We also offer the capability of searching by FDA investigator.

Advisory Committee Meeting Minutes & Transcripts

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File (minutes only)

Warning Letters

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

Speeches, Letters, Memoranda of Meetings & Phone Conversations

- Custom Document Retrieval

FDA Press Releases & Talk Papers

- Custom Document Retrieval
- DIOGENES® Online File

Other FDA Documents

FOI Services can obtain any FDA document that is disclosable under the provisions of the Freedom of Information Act. These documents include, but are not limited to:

- **Advisory Committee Minutes & Transcripts**
  FDA Public Advisory Committees are groups of experts convened to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to the FDA. Advisory Committee members tend to be drawn from the academic community, as representatives of private industry could often be seen as having conflicts of interest.

  Over 60 standing Public Advisory Committees have been formed, covering virtually every specialty regulated by the FDA.

  Although closed sessions are occasionally held, the majority of Advisory Committee meetings are open to the public and transcripts of the open sessions are available under the Freedom of Information Act. Summary minutes are also prepared for each meeting, but often are not available for one to two years after the meeting is held.
- **Warning Letters**
  Warning Letters (called Regulatory Letters or Notices of Adverse Findings before April 1991) are sent by the FDA to a firm, often following an unsatisfactory inspection. The letter details the alleged violations and gives the firm a time frame in which plans for rectifying the problem must be submitted to the FDA. Warning Letters are disclosable under the Freedom of Information Act.
- **Speeches by FDA Personnel**
- **Letters (correspondence) between industry and FDA**
- **Memoranda of Meetings & Telephone Conversations between industry and FDA**
- **FDA Press Releases & Talk Papers**

Availability

Food Documents

Articles used for food or drink (or components of food or drink, including some packaging) are regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN) to assure product safety and purity. Information available under the Freedom of Information Act includes Color Additive Petitions (CAPs), Food Additive Petitions (FAPs), and Generally Recognized as Safe (GRAS) petitions. In addition, establishment inspection reports, amendments to petitions, and guidelines for food processing and labeling can be requested from FDA.

Guidelines for food documents include information about adulteration, labeling and packaging.

Food, Color Additive, & GRAS Petitions

- Custom Document Retrieval
- FOI Online

Food & Cosmetic Guidelines

- Custom Document Retrieval
- FOI Online
- DIOGENES® Online File

foi online™

FOI Services, Inc.
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Web: *www.foiservices.com*

Ordering, Payment & Shipping Information

To order from FOI Services, visit our website or contact us at the address, phone, fax or email address indicated above.

Payment arrangements are made at the time your order is placed. Credit cards are the preferred method of payment; we accept VISA, MasterCard and American Express. We will keep your credit card number on file for use on all of your orders unless you specify otherwise. You may also use your credit card securely when shopping on our website.

In addition, deposit accounts are accepted in any amount – you will receive a statement each month showing your account activity. We also accept prepayment by check for individual orders.

Credit accounts may be established for well-rated firms in the U.S. and Canada only; contact us for a credit application.

Shipping methods are determined by the size of your order and your location. Overnight and electronic delivery are available. Outside the U.S., all orders for books and paper copies of documents are shipped via air service for prompt delivery.

Documents and books are not sold on a "trial" basis, and are not returnable. If you receive an incorrect or illegible document, please contact us. Subscription publications carry a money-back guarantee on the unexpired part of the subscription; contact us for details.

Visit Us in Person

Since FOI Services is in a business where most communication with our customers happens via telephone, fax and email, we especially value the opportunity to meet in person. We exhibit at several exhibitions and seminars each year; the following are on our regular schedule and attended annually:

Winter
Medical Design & Manufacturing West
Anaheim, California

Spring
Special Libraries Association – Pharmaceutical Division
Location varies.

Association of Clinical Reserach Professionals
Philadelphia in 2003

Summer
Special Libraries Association
Los Angeles in 2002; New York in 2003; Nashville in 2004

Drug Information Association
Chicago in 2002; San Antonio in 2003

Fall
Regulatory Affairs Professionals Society (RAPS)
Washington in 2002; Baltimore in 2003

Medical Design & Manufacturing Minnesota
Minneapolis

For exact dates, locations and additional exhibits, check our website:

www.foiservices.com/brochure/calendar.html