FDA Assistance to Industry

Marie Falcone

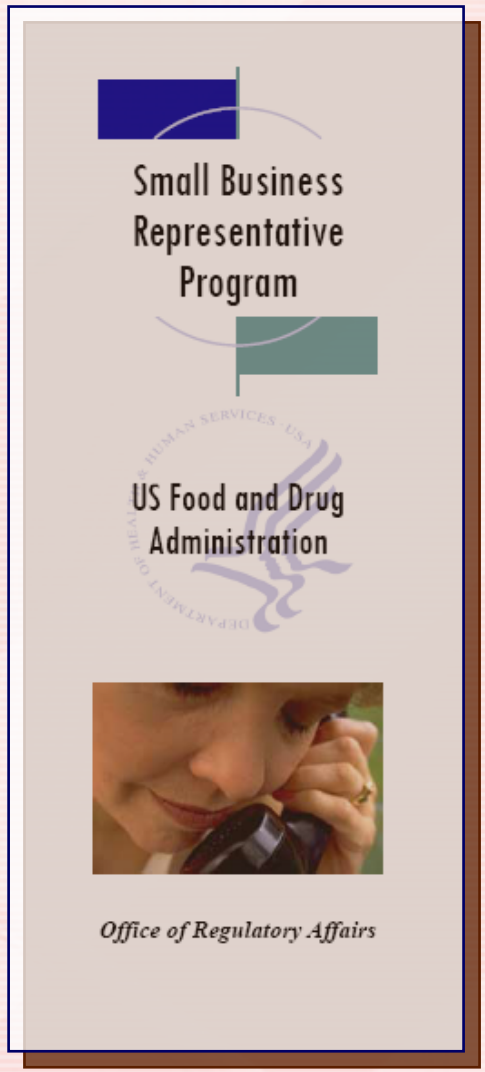
FDA ORA CER Small Business Representative

Presentation Agenda

1. The Small Business Representative
2. Staying informed
3. Solving problems
4. Communicating your views to the agency

The Small Business Representative

- Assist industry and entrepreneurs
  - Facilitate access to guidance, policies, regulations, and laws enforced by FDA
  - Provide technical assistance
  - Act as liaison

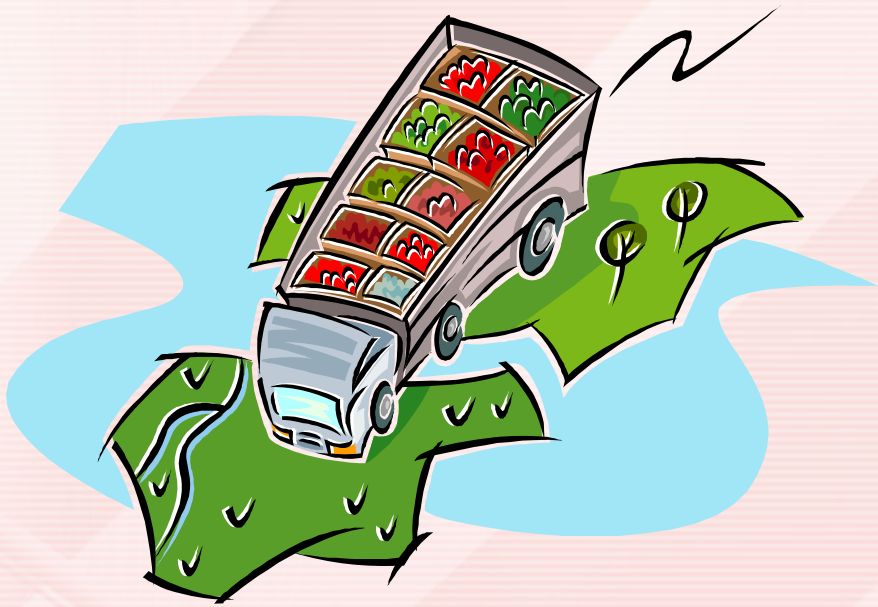


SBR Customers

- Small businesses
- Entrepreneurs
- Start-ups
- Professional associations
- Industry associations
- Consultants
- Corporations

FDA Jurisdiction

- Foods
- Drugs
- Biologics
- Cosmetics
- Medical devices
- Veterinary products
- Radiation-emitting products



SBR On-Site Visits

- Voluntary review
- At industry's request
- Confidential
- Cursory, brief
- Limited by schedule and budget

SBR Confidentiality

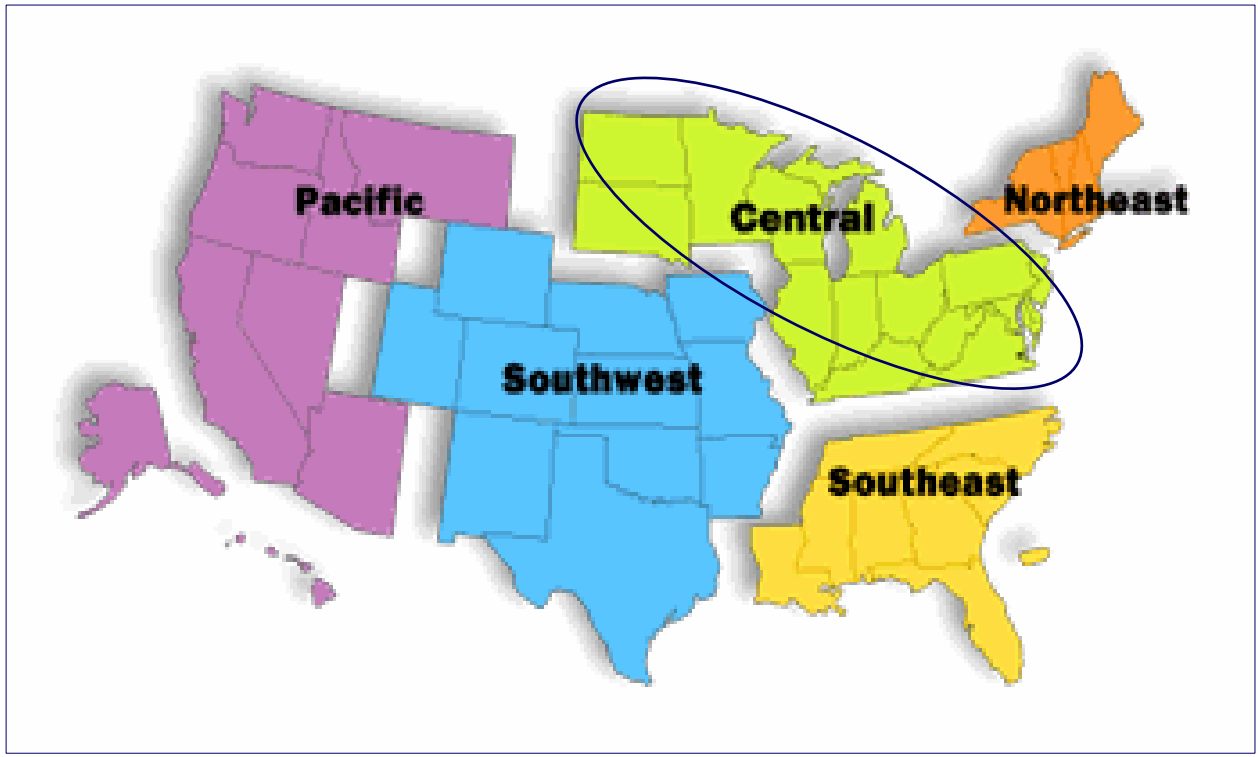
- All FDA employees are prohibited by law from divulging trade secret or confidential information

SBR Limitations

- Not available when an open inspection reveals conditions that may warrant enforcement action
  - FDA 483 objectionable observations
  - Warning letter
  - Import detention

SBR Geographical Limitations

- Delaware
- District of Columbia
- Illinois
- Indiana
- Kentucky
- Maryland
- Michigan
- Minnesota
- New Jersey
- North Dakota
- Ohio



- Pennsylvania
- South Dakota
- Virginia
- West Virginia
- Wisconsin

Federal State Relations
Small Business Guide
Introduction
Federal Register
How to Comment
Obtain Agency Docs
Statutes and Regs
How to Petition FDA
Decision Making
What to do When
Who to Contact
Small Business Reps
District Offices
FDA Center Contacts
Obtain Assistance
Freq Called Numbers
Related FDA Pages...
Consumer Information
Industry Assistance
Recall

Small Business Guide to FDA
(last revised on 03/31/04)

SMALL BUSINESS REPRESENTATIVES (SBRs)

Small Business Representative (HFR-NE17) Marilyn Corretto
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FAX (718) 662-5434
Email: oranersbr@ora.fda.gov

Small Business Representative (HFR-CE5) Marie T. Falcone
FDA, Central Region (DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV)
U.S. Customhouse
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Philadelphia, PA 19106
Phone (215) 597-2120, ext. 4003
FAX (215) 597-5798
Email: mfalcone@ora.fda.gov

Small Business Representative (HFR-SE17)
FDA, Southeast Region (AL, FL, GA, LA, MS, NC, PR, SC, TN, VI)

U.S. Food and Drug Administration

Department of Health and Human Services

http://www.fda.gov/

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A-Z Index

Site Map

Products FDA Regulates

Food
Foodborne Illness, Nutrition, Dietary Supplements...

Drugs
Prescription, Over-the-Counter, Generic...

Medical Devices
Pacemakers, Contact Lenses, Hearing Aids...

Biologics
Vaccines, Blood Products...

Animal Feed and Drugs
Livestock, Pets...

Cosmetics
Safety, Labeling...

FDA NEWS

New Product Approved to Treat Smallpox Vaccination Complications

FDA/NCI Program to Bridge Research, Regulation in Cancer Product Development

New Improvements in FDA's Drug Safety Monitoring Announced

President Nominates Dr. Lester Crawford to be FDA Commissioner

- White House Announcement
- Statement by HHS Secretary Leavitt
- Dr. Crawford's Biography

Cellular, Tissue and Gene Therapies Advisory Committee to Meet March 3-4

Recalls, Product Safety

Product Approvals

More FDA News - Press Releases, Meetings, Congressional Testimony, Speeches, More

Food Industry

- Register a Facility
- Prior Notice of Imports

Hot Topics

- Flu Information
- PPA
- Losing Weight
- Cell Phones
- Imported Drugs
- Counterterrorism
- Bioterrorism Act
- Buying Medicines Online
- Counterfeit Drugs
- **More Hot Topics...**

FDA Activities

- About FDA
- Advisory Committees
- Clinical Trials
  - Consumers
  - Professionals
- Commissioner's Page
- Field Operations
- Freedom of Information
- Imports
- International
- Major Initiatives

Radiation-Emitting Products
Cell Phones, Lasers, Microwaves...

Combination Products

Subscribe to FDA's Free E-mail Newsletters

Sign up for any of more than 20 lists.

Let Us Hear From You

- Report a Problem with a Product
- Comment on Proposed Regulations
- Petition FDA
- Job Opportunities
- Contact FDA

Reference Room

- Laws FDA Enforces
- Code of Federal Regulations
- Federal Register
- Guidance Documents
- Forms
- Dockets
- Warning Letters
- Manuals and Publications

www.healthfinder.gov FIRSTGOV.gov

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5600 Fishers Lane, Rockville MD 20857-0001
1-888-INFO-FDA (1-888-463-6332)

- MedWatch
- Pediatrics
- *Progress and Priorities 2004*
- Science
- Toxicological Research
- User Fees
  - Animal Drugs
  - Human Drugs
  - Medical Devices

Information For

- Consumers
- Patients
- Health Professionals
- Health Educators
- State/Local Officials
- Industry
- Press
- Women
- FDA Alumni
- Español
- Teens
- KIDS

FDA *Consumer*

Current Issue

Straight Talk on Braces

Take Our Quiz

Subscribe

Information for FDA-Regulated Industry

Industry Information by Subject

- Drugs
- Foods
- Dietary Supplements
- Medical Devices
- Biologics
- Animal Feed & Drugs
- Cosmetics
- Radiation-Emitting Products
- Combination Products Program

Small Business

- Small Business Guide to FDA
- Small Business Representatives
- Input on Rulemaking

Adverse Event Reporting

- MedWatch (medical products)
- Biologic Product Deviation
- Special Nutritionals/Dietary Supplements
- Animal Drugs
- Vaccines
- Blood Transfusions/ Donations

Compliance and Enforcement

- Warning Letters
- Forms
- Federal Register
- Unified Agenda of Federal Regulatory and Deregulatory Actions
- Code of Federal Regulations
- Guidance Documents
- FDA Enforcement Activities
- Laws Enforced by FDA
- FDA Dockets
- Science References
- Imports
- Inspection References
- Compliance References
- Industry Guidance: Product Recalls, Removals, Corrections
- Model for Recall Press Releases
- Ethics Program

Contact FDA

- Contact FDA Online
- Comment on FDA Regulations
- Field Offices
- Employee Directory
- Ombudsman

What's New

- Extension of Pilot Program for Evaluation of Globally Harmonized Medical Device Premarket Applications
- Nanotechnology at FDA
- FDA News
- Federal Register (Pre-publication)
- Recalls/Safety Alerts
- Approvals
- Hot Topics
- Subscribe to FDA Email Lists

Food Industry

- Register a Facility
- Prior Notice of Imports

Meetings/Workshops

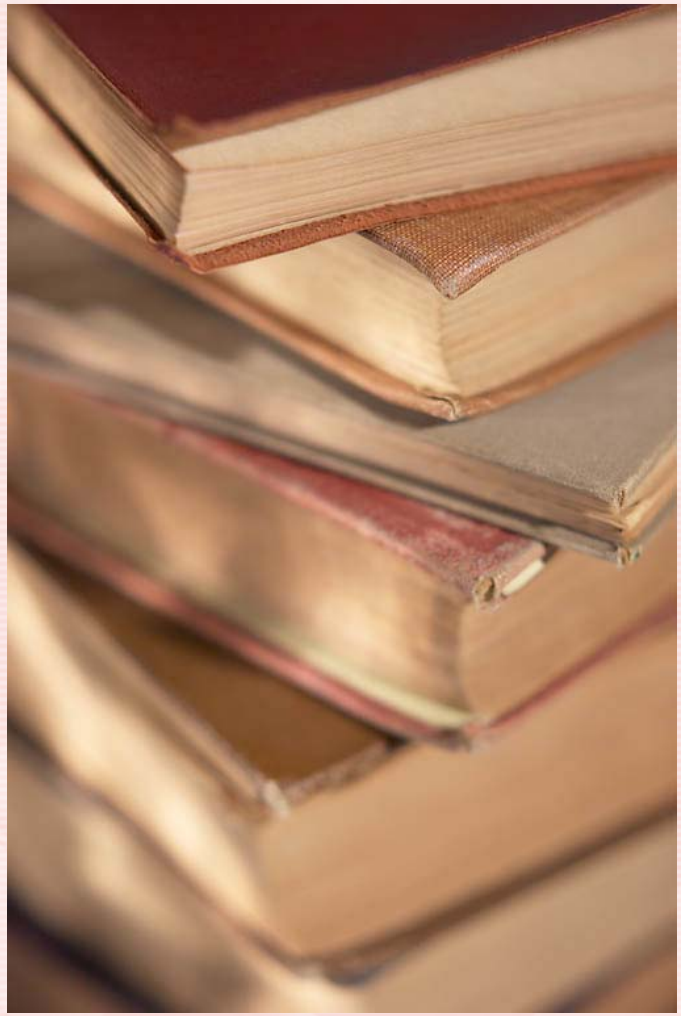
- Upcoming Meetings
- Advisory Committees
- FDA Center Meetings
- FDA Regional Meetings

Small Business Guide to the FDA

- How to obtain statutes, regulations, and agency documents
- How to use the Federal Register
- How to comment on proposed regulations
- How to petition the FDA
- What to do when marketing a new product, undergoing FDA inspection, recalling violative products, etc.

Build a Regulatory Library

- Laws
- Regulations (CFR)
- Federal Register
- Guidance Documents
- Forms
- Dockets
- Warning Letters
- Manuals and Publications
- Email Subscriptions



U.S. Food and Drug Administration

Department of Health and Human Services

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Let Us Hear Fr

Report a Problem w
Product

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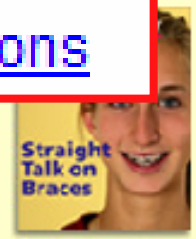

Straight Talk on Braces

Take Our Quiz

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What are Laws?

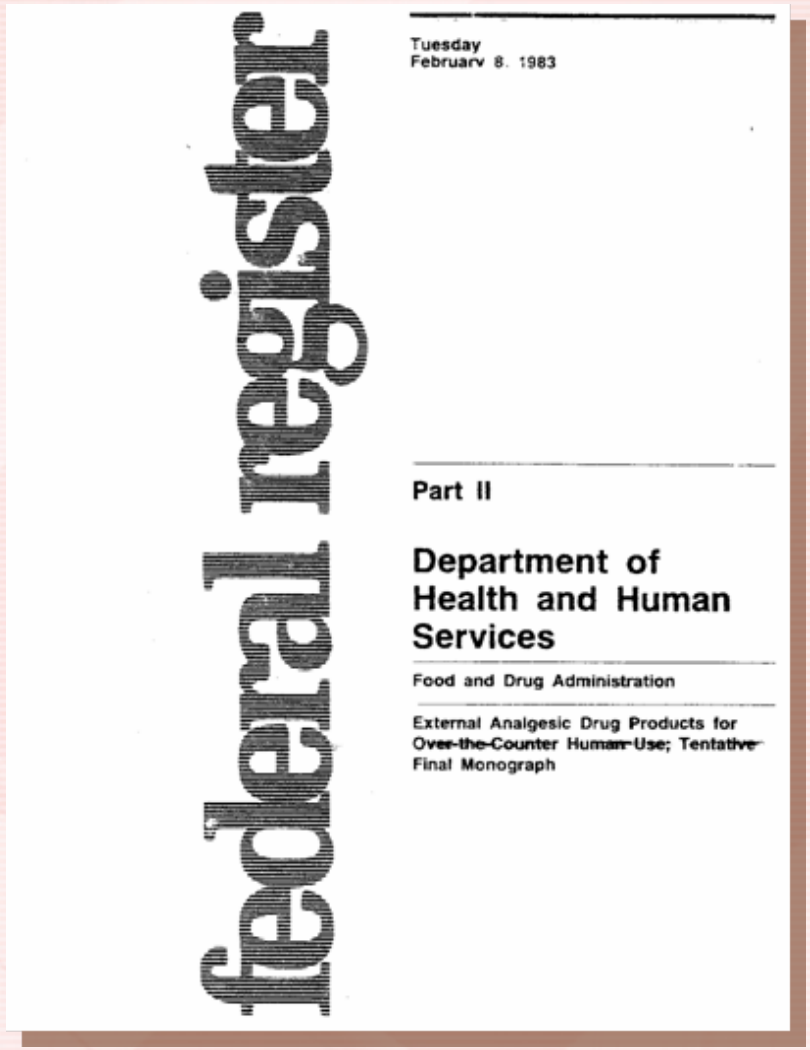
- The basic enabling authority enacted by Congress
  - Food, Drug and Cosmetic Act (FD&C)
  - FDA Modernization Act (FDAMA)
  - Orphan Drug Act
  - Prescription Drug User Fee Act (PDUFA)
  - Medical Device User Fee and Modernization Act (MDUFMA)

What are Regulations?

- Implement the provisions of the law based on the authority provided by the law
- The development of regulations must follow specific procedures that allow public notice and comment
- Legally binding on industry and the agency

The Federal Register

- Official daily publication
  - Notices
  - Proposed Rules
  - Final Rules
- Free online through http://www.gpo.gov or http://www.fda.gov
- GPO subscription



The Code of Federal Regulations

- Title 21
  Food and Drugs
- Published yearly
- Free online through
  - http://www.gpo.gov
  - http://www.fda.gov
- Order through GPO at 1-866-512-1800

Semi-Annual Unified Agenda

- Identifies regulations under development throughout the federal government
- Primarily ANPRM, NPRM, and Final Rule expected in the next 12 months
- Published twice a year
  - http://www.gpoaccess.gov/ua/
- Most recently on December 11, 2006
  - FR Vol. 71, No. 237

Semi-Annual Unified Agenda

- Status of regulation
  - Pre-Rule Stage: agency to determine whether or how to initiate rulemaking
  - Proposed Rule Stage: NPRM not issued yet
  - Final Rule Stage: Final or Interim Final Rule not issued yet
  - Long Term Actions

FDA Semi-Annual Unified Agenda

- The FDA portion of the Semi-Annual Unified Agenda
- http://www.fda.gov/oc/industry/unifiedagenda/agenda.html
- 2000-2006

Guidance Documents...

...Policy Statements and Advisory Opinions

- Serve to provide the Agency's interpretation of the law and applicable regulations
- The preamble to a regulation has the status of an advisory opinion
- Are not legally binding on the public or the agency

Applicable Guidance

- FDA Comprehensive List of Guidance Documents, FR 3/28/2006
  - Volume 71 No. 59
  - http://www.fda.gov/opacom/morechoices/industry/guidedc.htm
- Additional listings under each Center web site
- CDER Comprehensive List of Guidances http://www.fda.gov/cder/guidance/CompList04_2007.pdf dated 4/2/07

Obsolete Guidance

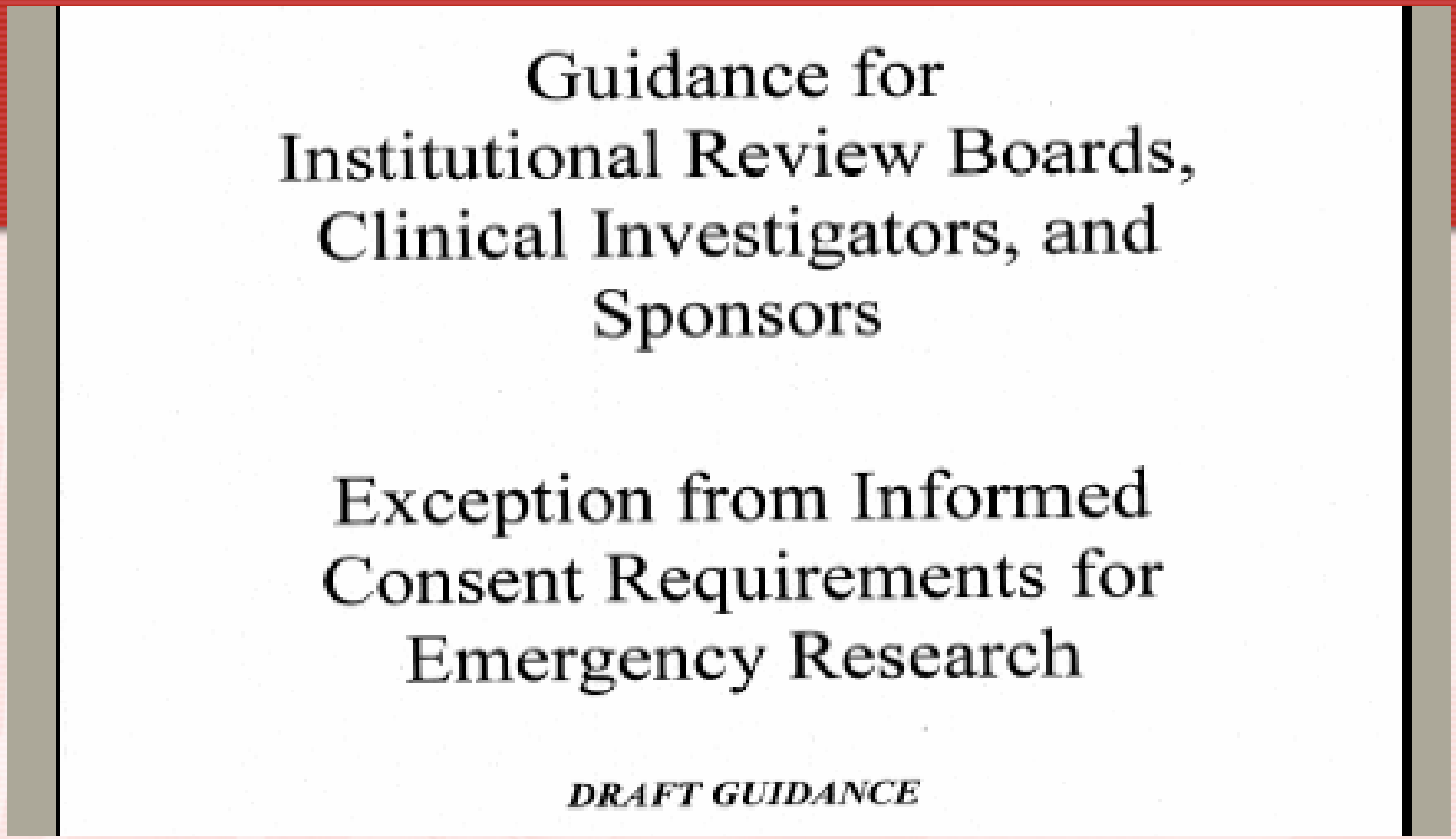
- Watch out for new, revised, and withdrawn guidance documents
- Expired documents remain online for historic reference
- Most documents will state if they have been superceded by newer or revised documents

Expected Guidance

- FDA Annual Guidance Agenda
  - **Most recent published on the Federal Register of September 1, 2006**
    - **Volume 71, No. 170**
    - **Docket 2004N-0234**
  - **Contains possible guidance topics**
  - **Organized by Center, then category**

FDA Annual Guidance Agenda

- Example from 9/1/06 annual guidance agenda, Office of the Commissioner:
- Guidance for Institutional Review Boards, Clinical Investigators and Sponsors, Exception from Informed Consent Requirements for Emergency Research



Draft Published in FR of August 29, 2006

Docket No. 2006D-0331

60 day comment period

FDA Public Meetings and Workshops

- Announced in the Federal Register
- Posted in many professional and industry association web sites and newsletters
- Broadcasted in various FDA mailing lists
- Publicized throughout the FDA and Center web sites

On the FDA Web Site

http://www.fda.gov/

- opacom/hpmeetings.html
- cder/calendar/
- cdrh/dsma/workshop.html
- cber/meetings.htm
- cfsan.fda.gov/~lrd/vidtel.html

FDA Mailing List Subscriptions

- Free e-mail newsletters
- Most are listed here:
  - http://www.fda.gov/emaillist.html
- FDA GCPP mailing list:
  - http://www.fda.gov/oc/gcp/
- CDER Small Business mailing list:
- http://www.fda.gov/cder/about/smallbiz/default.htm

Documents Through FOIA

- Documents not originally prepared for public distribution are available under the Freedom of Information Act
- Documents are purged of confidential and trade secret information
- FDA assesses fees to cover costs of document research, redaction, reproduction, and mailing
- No phone or e-mail requests

Freedom of Information Requests

- Use the “Handbook for FOI Requests”
  - http://www.fda.gov/opacom/backgrounders/foiahand.html
- Mail to:
  FDA FOI Staff (HFI-35)
  5600 Fishers Lane
  Rockville, MD 20857
- Fax to:
  301-443-1726

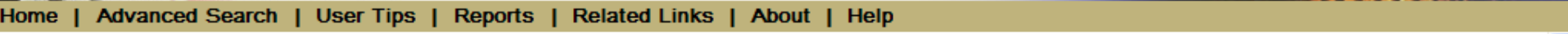
Contacting the Centers

- Visit the GCP contacts page at www.fda.gov/oc/gcp/contactogcp.html
- CDER Organizational Charts and Directories http://www.fda.gov/cder/cderorg.htm
- Division of Drug Information

  301-827-4570
- Contact your regional Small Business Representative for referral information

Comment on Proposed Rules, etc.

- Visit the Division of Dockets Management at http://www.fda.gov/ohrms/dockets/
- Search using the docket number or browse the dockets list by year
  - Use the list of dockets with comment periods closing in the next 2 months
  - Insert Docket Number into Federal Register search box to get comment closing date
- Comment electronically online



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On this U.S. Government Web site you can find, view and comment on regulations for all Federal agencies.

Use the search options to the right only to access Federal actions **open for comment**.

Click on the Advanced Search Tab above to find Federal actions no longer open for comment or to further refine your search.

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- All Documents Open for Comment
- All Documents Published for Comment Today
- Regulations by Topic
- Comments Due Today

Search Regulations and Federal Actions Open for Comment

*** indicates Agency posts Federal Register documents, supporting materials and public submissions on this site.**

Agency - ALL -

And

Document Type - All Document Types -

And

Keyword

Exact Phrase **Any Word**

Submit

www.regulations.gov

Solving Problems

1. Communicate with the FDA Investigator
2. Contact the Supervisor
3. Contact the Branch Director
4. Contact the District Director
5. Contact the Regional Office
6. Contact the FDA Ombudsman
7. Contact the National Ombudsman

Contact Information Resources

- Directory of FDA District and Regional Offices

  http://www.fda.gov/ora/Inspect_ref/iom/IOMORADIR.html

- HHS Employee Directory

http://directory.psc.gov/employee.htm

- Your Regional Small Business Representative


Address http://directory.psc.gov/employee.htm
Go
Links
Google
Search
213 blocked
Check
AutoLink
AutoFill
Options
United States Department of Health & Human Services
Leading America to Better Health, Safety and Well-Being
HHS Home
Questions?
Contact Us
Site Map
Search the HHS Employee Directory
Browse HHS Organizations | Where to Send Corrections
Do Search
Clear Form
Help
Last name..: begins with
First name.: begins with
Agency.....: equal to
Other org..: contains
Job title..: begins with
Keywords...: contains
Bldg.....: equal to
City.....: begins with
Phone.....: equal to
E-mail.....: equal to
Return no more than 100 rows (maximum 500).
Internet
start
Inbox - Micros...
Microsoft Powe...
2 Internet Ex...
2003 LINK LIST...
1:16 PM

FDA Ombudsman

- The FDA Ombudsman explores complaints and assist in resolving disputes between companies or individuals and agency offices
  - http://www.fda.gov/oc/ombudsman/homepage.htm
  - Telephone: 301-827-3390
  - Facsimile: 301-480-8039
  - E-mail: ombuds@oc.fda.gov

National Ombudsman Fair Enforcement of Federal Regulations

Mission

To assist small businesses with unfair and excessive federal regulatory enforcement, such as repetitive audits or investigations, excessive fines, penalties, retaliation or other unfair regulatory enforcement action by a federal agency.

The National Ombudsman receives complaints and comments from small business concerns and acts as a"trouble shooter" between them and federal agencies. Small business comments are forwarded to federal agencies for a high level review and federal agencies are requested to consider the fairness of their action.

Highlights & Headlines

- SBPRA 2004 Task Force Report
- Calendar of Events
- Success Stories
- File a Complaint or Comment
- How to File a Complaint or Comment
- National Ombudsman
- Annual Report
- E-Blast Sign-Up

www.sba.gov/ombudsman

File a Comment (PDF Version)

My Contact Information

- Marie Falcone
  Small Business Representative
  FDA Central Region
  Room 900 U.S. Customhouse
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  Philadelphia, PA 19106
- Telephone: (215) 717-3703
- Fax: (215) 597-5798
- E-mail: marie.falcone@fda.hhs.gov