

FDA Communication Pathways During Drug Development

Rachel Kichline

Regulatory Affairs Team

Immediate Office, Office of New Drugs

Center of Drug Evaluation and Research

September 27, 2017

FDA's Communication Philosophy

- FDA and IND sponsors have a shared goal of early availability of safe, effective, and high-quality drugs
- different primary responsibilities



FDA's Communication Philosophy

Sponsors' Primary IND Responsibilities



- Managing the overall drug development
- Soliciting input and guidance from FDA
- Determining the nature and timing of regulatory submissions
- Providing well-organized and complete submissions for review

FDA's Communication Philosophy

FDA's Primary IND Responsibilities

- Ensuring
 - safety and rights of subjects
 - quality of the scientific evaluation of drugs
- Enforcing
 - good clinical practice
 - enforcing human subject protection requirements



FDA's Communication Philosophy

FDA's Primary IND Responsibilities Cont'd

- Reviewing IND submissions
- Providing feedback on trials and development programs
- Taking regulatory actions



FDA's Communication Philosophy

FDA's Primary IND Responsibilities Cont'd

- Promoting the advancement of regulatory science by:
 - authoring FDA and international guidances
 - conducting and participating in public workshops
 - collaborating with academia
 - publishing in medical and trade journals
 - presenting at professional conferences

Communication Pathways







Resources for Sponsors

FDA develops and maintains Web pages, portals, and databases, and participates in interactive media as a means of providing self-service tools for its stakeholders.

Sponsor use of these tools allows for more effective utilization of limited FDA resources in providing advice on scientific and regulatory issues that fall outside of established guidance, policy, and procedures.

Resources for Sponsors

- FDA Guidances
- FDA Policy and Procedures
- FDA Basics for Industry
- FDA Interactive Media
- FDA Presentations
- FDA Labeling and Approvals
- FDA Rules and Regulations
- FDA-Funded Scientific Research Results
- Code of Federal Regulations





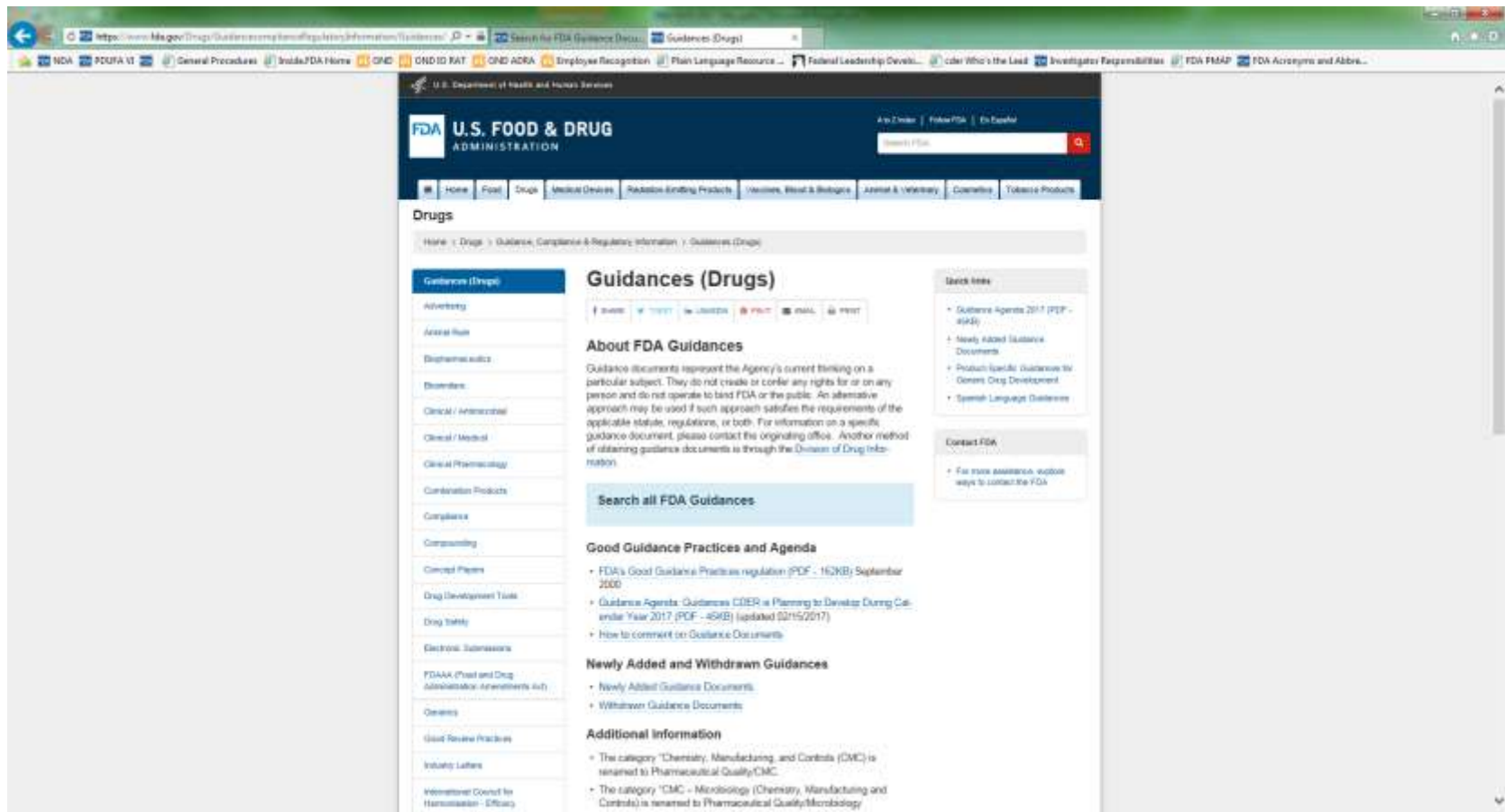
FDA Guidances

Guidance documents explain our current thinking on policy, scientific, and/or regulatory issues.

FDA Guidance web page

<https://www.fda.gov/Drugs/GuidancecomplianceRegulatoryInformation/Guidances/default.htm>

How to Search for a Guidance



The screenshot shows the FDA website's 'Guidances (Drugs)' page. The browser address bar displays the URL: <https://www.fda.gov/drugs/guidances/regulatory-information/guidances>. The page features a search bar at the top right with the text 'Search FDA'. The main content area is titled 'Guidances (Drugs)' and includes a section 'About FDA Guidances' which states: 'Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office. Another method of obtaining guidance documents is through the Division of Drug Information.' Below this is a search bar labeled 'Search all FDA Guidances'. The page also includes a sidebar with navigation links, a 'Quick links' section, and a 'Contact FDA' section.

Guidances (Drugs)

About FDA Guidances

Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office. Another method of obtaining guidance documents is through the Division of Drug Information.

Search all FDA Guidances

Good Guidance Practices and Agenda

- FDA's Good Guidance Practices regulation (PDF - 162KB) September 2000
- Guidance Agents: Guidances CDER is Planning to Develop During Calendar Year 2017 (PDF - 49KB) (updated 02/15/2017)
- How to comment on Guidance Documents

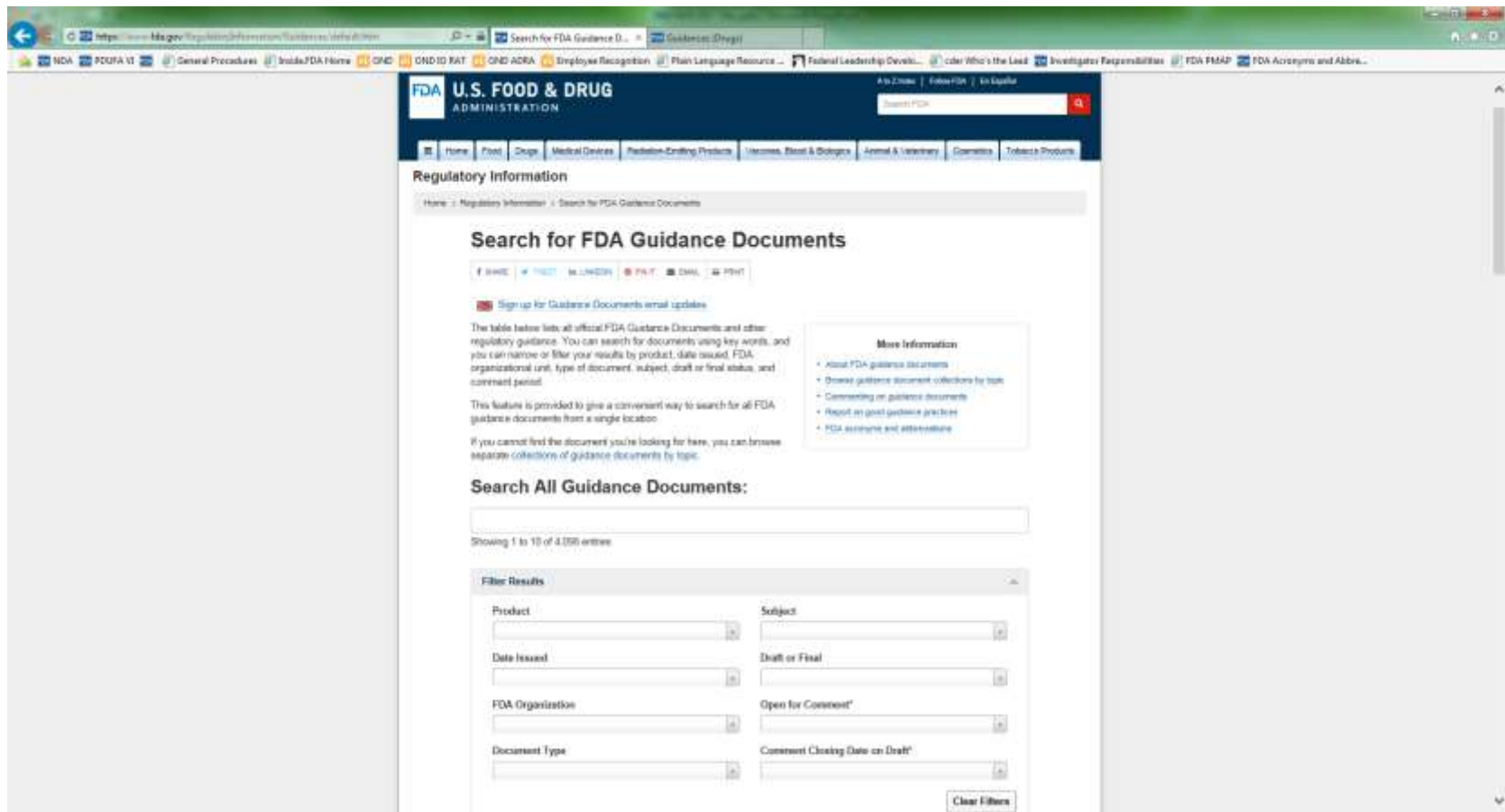
Newly Added and Withdrawn Guidances

- Newly Added Guidance Documents
- Withdrawn Guidance Documents

Additional Information

- The category "Chemistry, Manufacturing, and Controls (CMC)" is renamed to Pharmaceutical Quality/CMC.
- The category "CMC - Microbiology (Chemistry, Manufacturing and Controls)" is renamed to Pharmaceutical Quality/Microbiology.

How to Search for a Guidance Cont'd



The screenshot shows the FDA's 'Search for FDA Guidance Documents' page. The page has a blue header with the FDA logo and navigation tabs. Below the header, there's a search bar and a section titled 'Regulatory Information'. The main content area is titled 'Search for FDA Guidance Documents' and includes a search bar, a 'Sign up for Guidance Documents email updates' link, and a 'More Information' box. Below this, there's a 'Search All Guidance Documents:' section with a search bar and a 'Filter Results' section with various filters.

Search for FDA Guidance Documents

Sign up for Guidance Documents email updates

The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

This feature is provided to give a convenient way to search for all FDA guidance documents from a single location.

If you cannot find the document you're looking for here, you can browse separate collections of guidance documents by topic.

Search All Guidance Documents:

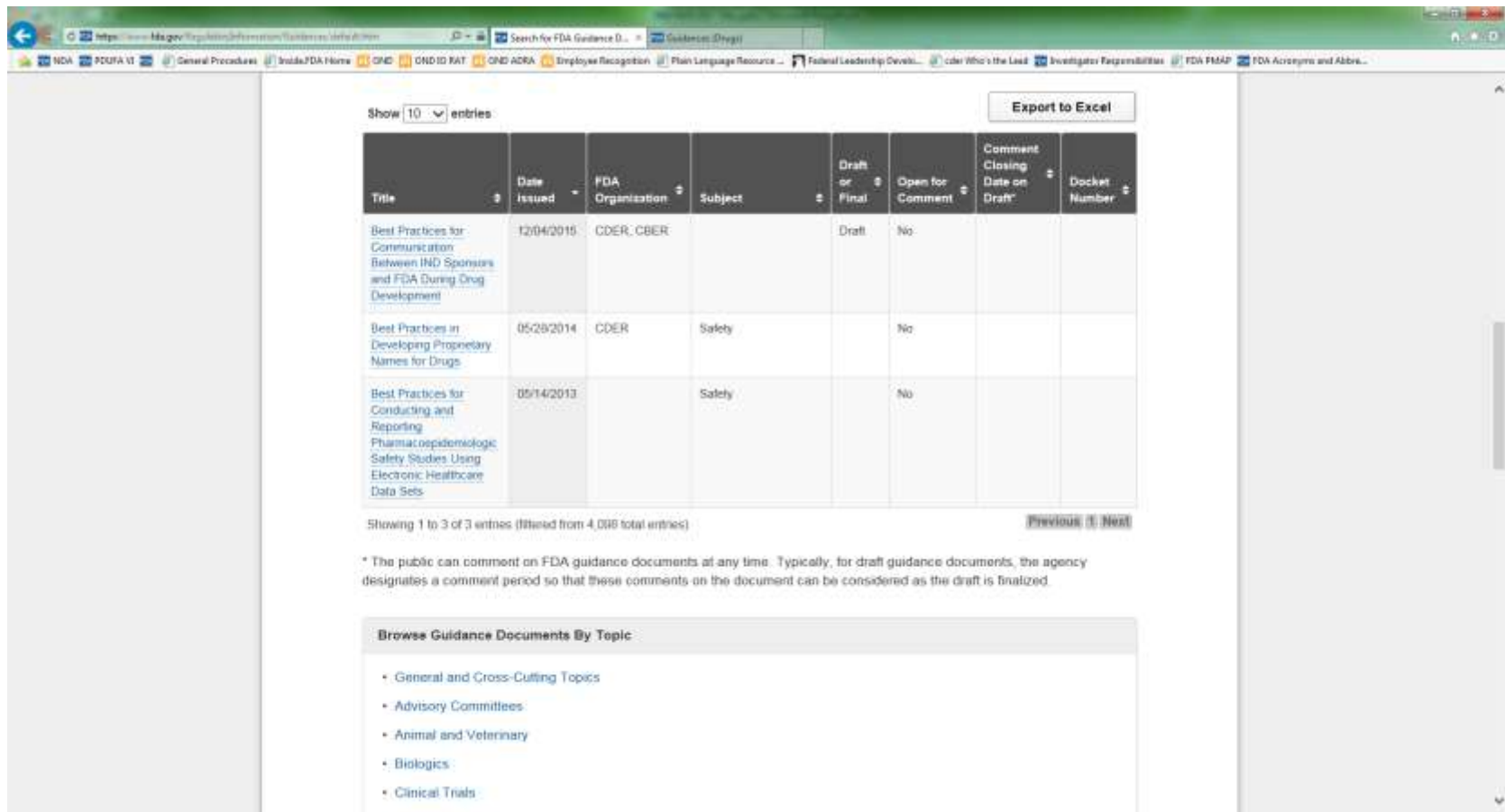
Showing 1 to 10 of 4,056 entries

Filter Results

Product	Subject
Date Issued	Draft or Final
FDA Organization	Open for Comment*
Document Type	Comment Closing Date on Draft*

Clear Filters

How to Search for a Guidance Cont'd



The screenshot shows the FDA's public guidance search results page. At the top, there's a search bar and navigation links. Below the search bar, a table lists search results. The table has columns for Title, Date Issued, FDA Organization, Subject, Draft or Final, Open for Comment, Comment Closing Date on Draft, and Docket Number. Three results are shown, all from CDER. Below the table, there's a note about the public's ability to comment on draft guidance documents. At the bottom, there's a section titled 'Browse Guidance Documents By Topic' with a list of categories.

Search for FDA Guidance Documents

Export to Excel

Title	Date Issued	FDA Organization	Subject	Draft or Final	Open for Comment	Comment Closing Date on Draft	Docket Number
Best Practices for Communication Between IND Sponsors and FDA During Drug Development	12/04/2015	CDER, CBER		Draft	No		
Best Practices in Developing Proprietary Names for Drugs	05/28/2014	CDER	Safety		No		
Best Practices for Conducting and Reporting Pharmacovigilance Safety Studies Using Electronic Healthcare Data Sets	05/14/2013		Safety		No		

Showing 1 to 3 of 3 entries (filtered from 4,000 total entries)

* The public can comment on FDA guidance documents at any time. Typically, for draft guidance documents, the agency designates a comment period so that these comments on the document can be considered as the draft is finalized.

Browse Guidance Documents By Topic

- [General and Cross-Cutting Topics](#)
- [Advisory Committees](#)
- [Animal and Veterinary](#)
- [Biologics](#)
- [Clinical Trials](#)



773

774 **H. Use of Out-of-Office Messages by FDA and Sponsors**

775

776 IND sponsors and FDA staff should alert others to their unavailability by using email and

777 voicemail out-of-office messages. The messages should include an expected return time and


778 contact information for other staff that may be able to assist in the interim, particularly for time-

779 sensitive communications (e.g., notification of clinical hold). FDA project managers should also

780 include contact information for their division's CPMS in CDER or the alternative project

781 management staff in CBER.

782

783 **I. Resources for Sponsors** 

784

785 To disseminate a broad range of information in a manner that can be easily and rapidly accessed

786 by interested parties, FDA develops and maintains Web pages, portals, and databases, and

787 participates in interactive media as a means of providing self-service tools for its stakeholders,

788 including IND sponsors. Sponsor use of these tools allows for more effective utilization of

789 limited FDA resources in providing advice on scientific and regulatory issues that fall outside of

790 established guidance, policy, and procedures.

791

792 *1. FDA Guidances*

793

794 FDA uses guidance documents to explain its current thinking on policy, scientific, and/or

795 regulatory issues.³⁴ FDA guidances are useful for industry and other stakeholders and FDA staff

796 that may refer to them to address such matters as the design, manufacturing, and testing of

797 regulated products; scientific issues; content and evaluation of applications for product

798 approvals; and inspection and enforcement policies. In general, FDA guidances do not establish

799 legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a

800 topic and should be viewed only as recommendations, unless specific regulatory or statutory

FDA Policy and Procedures

CDER MAPPs and CBER SOPPs describe internal policies and procedures.

CDER MAPPs web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>

CBER SOPPs web page

<https://www.fda.gov/biologicsbloodvaccines/guidancecomplianceandregulatoryinformation/proceduressopps/default.htm>



Want to learn more about CDER's IND Review Process?

Check out MAPP 6030.9- Good Review Practice: Good Review Management Principles and Practices for Effective IND Development Review



FDA Basics for Industry

Provides basic information about FDA regulatory processes and resources to better understand how to work with FDA.

Subject Areas:

- Topics A-Z Index
- Popular Content
- Submit Questions and Comments
- Industry Frequently Asked Questions

FDA Basics for Industry web page

<https://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm>



https://www.fda.gov/industry/fda-basics-for-industry/faq/industry-frequently-asked-questions

FDA Basics for Industry > fa...

NDA PDUA IT General Procedures Inside FDA Home OND OND ID FAT OND ADRA Employee Recognition Plain Language Resource Federal Leadership Devic... oder Who's the Lead Investigator Responsibilities FDA PMAP FDA Acronyms and Abbre...

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | Go Global

Search FDA

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

For Industry

Home > For Industry > FDA Basics for Industry

FDA Basics for Industry

- Guidance
- Registration and Listing
- Regulatory Process
- Product Application and Petition Review Process
- Stay Informed with FDA Program Alerts
- Search Databases
- Popular Content
- Industry Frequently Asked Questions**
- Educational Resources
- Compliance and Enforcement
- For Trade and Industry Groups: Requesting Cross-Agency Speakers From FDA
- Infographics
- Related Questions and Comments

Industry Frequently Asked Questions

Facebook Twitter LinkedIn YouTube Email RSS Print

Below are frequently asked questions and the associated answers sorted by topic area. Please rate the answers to the questions in order to help us to better meet your needs.

Drugs

Drugs

Drug Review

What information is provided to sponsors during the human drug product application review process?

How is a sponsor of a product application that is subject to PDUA target dates informed about whether the review of its product application is on track to meet the target date for FDA action on the application?

Drug Approval

How can I better understand Patents and Exclusivity?

I wish to market an OTC drug product - where do I start?

I own a small pharmaceutical business. Am I eligible for, and if so, how do I apply for a PDUA waiver?

How do I go about getting a drug approved?

I am a small business owner, where can I find information specific for me?

Import and Export

What must I do to import a human drug product that has been approved by the FDA into the US?

What must I do to export a human drug product from the US?

FDA Interactive Media

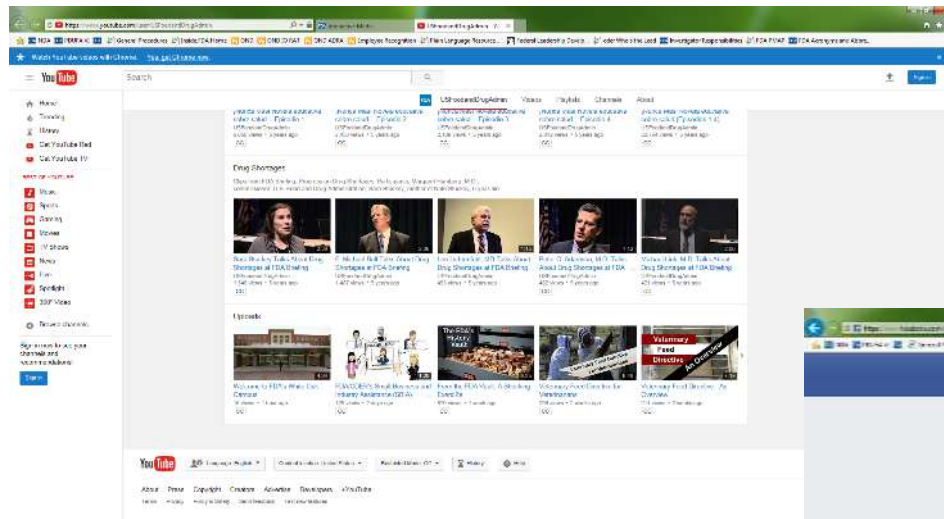
FDA uses interactive media to communicate information about:

- emerging science
- new policies and procedures
- public advisory committee meetings
- workshops

Interactive Media web page

<https://www.fda.gov/NewsEvents/InteractiveMedia/default.htm>

FDA on YouTube, Facebook, and Twitter



FDA Presentations - CDER

Topics can range from:

- users fees
- to drug advertising and marketing
- to genomics
- to over-the-counter products

Meeting Presentations (Drugs) web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm>

FDA Presentations - CBER

Presentations about the work performed at CBER in the oversight of biological products.

<https://www.fda.gov/biologicsbloodvaccines/internationalactivities/ucm273267>

FDA Labeling and Approvals - CDER



CDER's Drugs@FDA database contains information about CDER regulated FDA-approved products.

- search by drug, active ingredient, or application
- browse by drug
- drug approval reports by month
 - ✓ original NDAs and BLAs
 - ✓ supplements to NDAs and BLAs
 - ✓ original ANDAs
 - ✓ tentative approvals

Drugs@FDA database web page

<https://www.accessdata.fda.gov/scripts/cder/daf/>



FDA Labeling and Approvals - CBER

CBER's web page contains information about:

- listing of product approvals and clearances with supporting documents
- product/manufacturer lists
- reports (e.g. postmarketing)

Biologics Products & Establishments web page

<https://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm>

FDA Rules and Regulations

Web page contains information about:

- notice and comment on rulemaking
- review of proposed and final rules
- related resources (e.g. what FDA regulates)

FDA Rules and Regulations web page

<https://www.fda.gov/regulatoryinformation/rulesregulations/default.htm>



The scope of FDA's regulatory authority is very broad.

- **Center for Drug Evaluation and Research**
 - prescription and non-prescription drugs
- **Center for Biologics Evaluation and Research**
 - vaccines, allergenics, blood and blood products, cellular and gene therapy products, tissue and tissue products

Note: Both Centers regulate biologic and biosimilar biological products



- **Center for Food Safety and Applied Nutrition**
 - bottled water, dietary supplements, infant formulas, food additives
- **Center for Devices and Radiological Health**
 - tongue depressors, pacemakers, dental devices, surgical implants
- **Center for Tobacco Products**
 - cigarettes, roll your own and smokeless tobacco

FDA-Funded Scientific Research Results

Philosophy:

- broad availability of scientific information and underlying data allow for the critical review, replication, and verification of findings
- accessible and analyzable findings and supporting digital data promote robust and open communication
- bolsters scientific credibility and regulatory decision making based on those findings



FDA-Funded Scientific Research Results Cont'd

In the future the web page will provide educational resources about public access policies and the tools for complying.

Public Access to Results of FDA-Funded Scientific Research web page

<https://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm433459.htm>

Code of Federal Regulations

The Code of Federal Regulations (CFR) codifies the Federal Government rules published in the Federal Register.



Electronic Code of Federal Regulations

The e-CFR is an unofficial compilation of CFR material and Federal Register amendments.

e-CFR web page

<https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

How to Search the eCFR

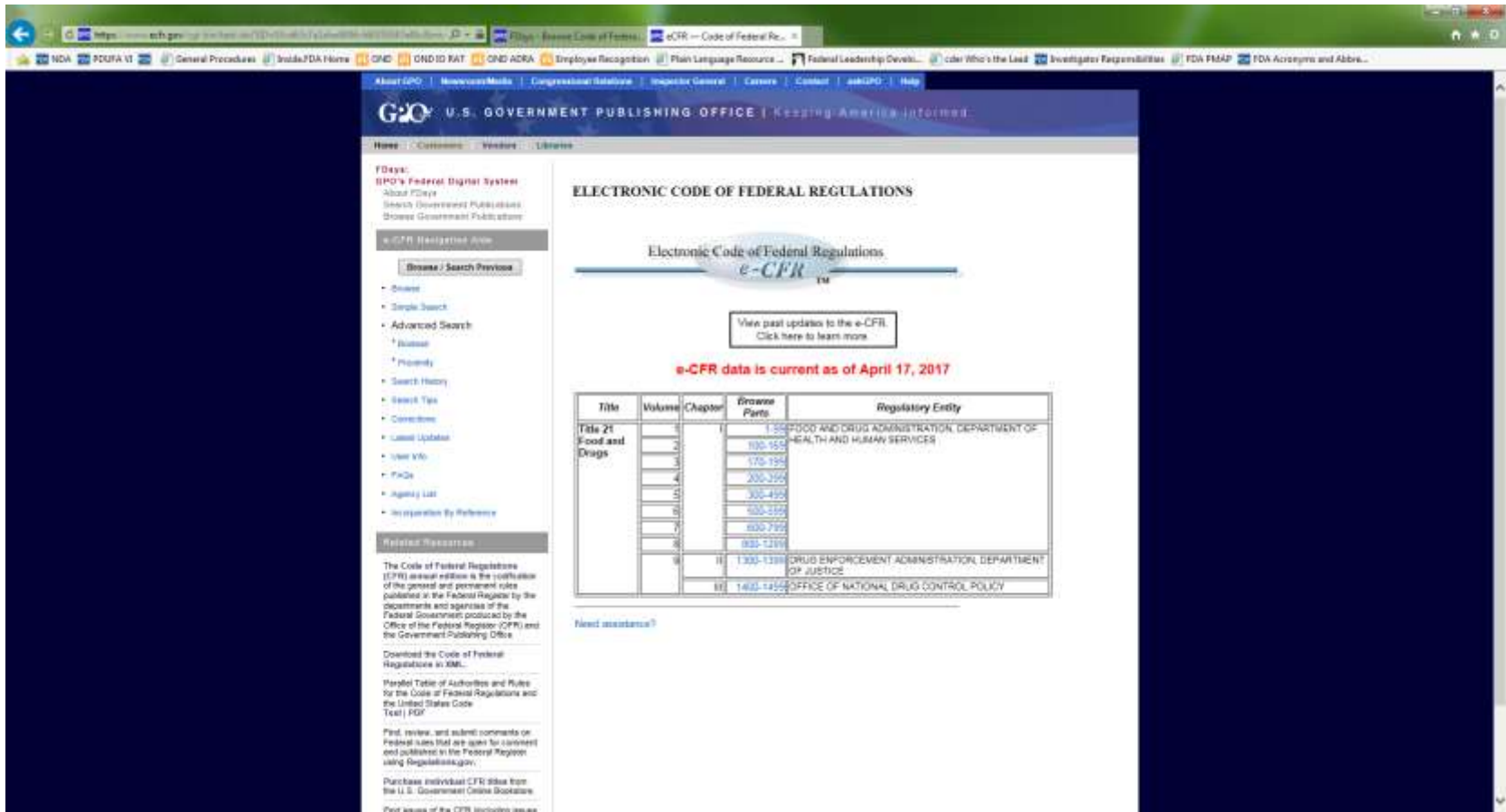
The screenshot displays the eCFR website, which is the official online version of the Code of Federal Regulations. The browser's address bar shows the URL <https://www.ecfr.gov/cgi-bin/cfr.cgi?open=home>. The website header features the GPO (Government Publishing Office) logo and the text "U.S. GOVERNMENT PUBLISHING OFFICE | Keeping America Informed". A navigation bar at the top lists various links such as "About GPO", "How to Use Media", "Congressional Relations", "Inspector General", "Careers", "Contact", "Ask GPO", and "Help".

The main content area is titled "ELECTRONIC CODE OF FEDERAL REGULATIONS" and "Electronic Code of Federal Regulations e-CFR". A button labeled "View past updates to the e-CFR. Click here to learn more." is visible. Below this, a red banner states "e-CFR data is current as of April 17, 2017". A "USER NOTICE" section explains that the e-CFR is a currently updated version of the Code of Federal Regulations (CFR), which is not an official legal edition. It mentions that amendments are produced by the National Archives and Records Administration's Office of the Federal Register (OFR) and the Government Publishing Office (GPO). The notice also states that the OFR updates the material in the e-CFR on a daily basis and that the current update status appears at the top of all e-CFR web pages. A link "More" is provided for further information.

Below the user notice, there is a search section titled "Browse: Select a title from the list below, then press 'Go'". A dropdown menu shows "Title 21 - Food and Drugs" selected, and a "Go" button is next to it. A link "Need assistance?" is also present.

The left sidebar contains several sections: "FDays: GPO's Federal Digital System" with links for "About FDays", "Search Government Publications", and "Browse Government Publications"; "e-CFR Navigation Area" with links for "Browse / Search Previous", "Simple Search", "Advanced Search", "Search History", "Search Tips", "Connections", "Latest Updates", "User Info", "FAQs", "Agency List", and "Organization by Reference"; and "Related Resources" with links for "The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office", "Download the Code of Federal Regulations in XML", "Parallel Table of Authorities and Rules for the Code of Federal Regulations and the United States Code Text | PDF", "Find, review, and submit comments on Federal rules that are open for comment and published in the Federal Register using Regulations.gov", "Purchase individual CFR titles from the U.S. Government GSA Bookstore", and "Find issues of the CFR (including issues".

How to Search the eCFR



The screenshot shows the eCFR website interface. The main heading is "ELECTRONIC CODE OF FEDERAL REGULATIONS". Below it, the text "Electronic Code of Federal Regulations" and "e-CFR" are displayed. A button labeled "View past updates to the e-CFR. Click here to learn more." is present. A red banner states "e-CFR data is current as of April 17, 2017".

A table titled "Regulatory Entity" is shown, listing various entities and their corresponding CFR parts. The table has columns for Title, Volume, Chapter, Browse Parts, and Regulatory Entity.

Title	Volume	Chapter	Browse Parts	Regulatory Entity
Title 21 Food and Drugs	1		1-350	FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
	2		350-650	
	3		650-1000	
	4		1000-1500	
	5		1500-2000	
	6		2000-2500	
	7		2500-3000	
	8		3000-3500	
		9	3500-4000	DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
		10	4000-4500	
		11	4500-5000	OFFICE OF NATIONAL DRUG CONTROL POLICY
		12	5000-5500	

Below the table, there is a link "Need assistance?".

On the left side of the page, there is a sidebar with the following sections:

- FDays:**
 - BPD's Federal Digital System
 - About FDays
 - Search Government Publications
 - Browse Government Publications
- e-CFR Navigation Area:**
 - Browse / Search Previous
 - Simple Search
 - Advanced Search
 - Business
 - Recently
 - Search History
 - Search Tips
 - Connections
 - Latest Updates
 - View Info
 - FAQs
 - Agency List
 - Organization by Reference
- Related Resources:**
 - The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office (GPO).
 - Download the Code of Federal Regulations in XML.
 - Parallel Table of Authorities and Rules for the Code of Federal Regulations and the United States Code Text | PDF
 - Find, review, and submit comments on Federal rules that are open for comment and published in the Federal Register using Regulations.gov.
 - Purchase individual CFR titles from the U.S. Government Online Bookstore.
 - Find issues of the CFR (including issues...

How to Search the eCFR

[NDA](#)
[PDFA V1](#)
[General Procedures](#)
[Inside FDA Home](#)
[OND](#)
[OND ID RAT](#)
[OND ADRA](#)
[Employee Recognition](#)
[Plain Language Resource](#)
[Federal Leadership Develop](#)
[eCFR Who's the Lead](#)
[Investigator Responsibilities](#)
[FDA FMAP](#)
[FDA Acronyms and Abbrev](#)

FDPA's Federal Digital System

About FDPA's
Search Government Publications
Browse Government Publications

eCFR Navigation Tools

[Browse / Search Previous](#)

- Browse
- Simple Search
- Advanced Search
 - * Boolean
 - * Proximity
- Search History
- Search Tips
- Connections
- Latest Updates
- View Info
- FAQs
- Agency List
- Organization By Reference

Related Resources

The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office.

Download the Code of Federal Regulations in XML.

Parallel Table of Authorities and Rules for the Code of Federal Regulations and the United States Code Text | PDF

Find, review, and submit comments on Federal rules that are open for comment and published in the Federal Register using [Regulations.gov](#).

Purchase individual CFR titles from the U.S. Government Online Bookstore.

Find issues of the CFR (including issues prior to 1996) at a free Federal depository library.

[42]

ELECTRONIC CODE OF FEDERAL REGULATIONS

Electronic Code of Federal Regulations
e-CFR

View past updates to the e-CFR.
Click here to learn more.

e-CFR data is current as of April 17, 2017

[Title 21](#) — [Chapter 1](#) — [Subchapter D](#)

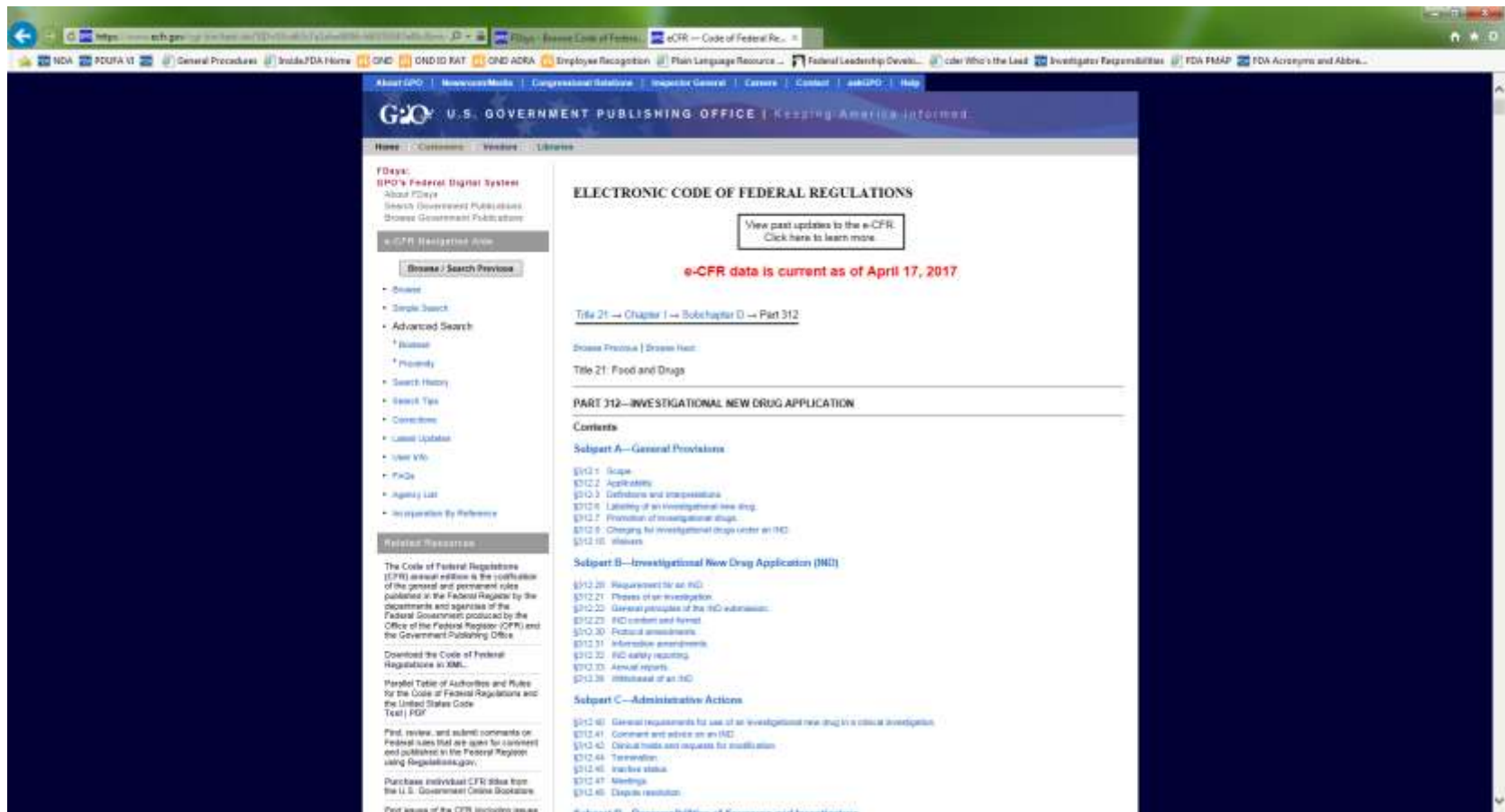
TITLE 21—Food and Drugs

CHAPTER 1—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

SUBCHAPTER D—DRUGS FOR HUMAN USE

Part	Table of Contents	Headings
300	300.50 to 300.100	GENERAL
310	310.3 to 310.540	NEW DRUGS
312	312.1 to 312.330	INVESTIGATIONAL NEW DRUG APPLICATION
314	314.1 to 314.650	APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG
315	315.1 to 315.6	DIAGNOSTIC RADIOPHARMACEUTICALS
316	316.1 to 316.52	ORPHAN DRUGS
317	317.1 to 317.2	QUALIFYING PATHOGENS
320	320.1 to 320.67	BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS
328	328.1 to 328.50	OVER-THE-COUNTER DRUG PRODUCTS INTENDED FOR ORAL INGESTION THAT CONTAIN ALCOHOL
329	329.100	NONPRESCRIPTION HUMAN DRUG PRODUCTS SUBJECT TO SECTION 700 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

How to Search the eCFR



The screenshot displays the eCFR website interface. At the top, there is a navigation bar with links to various resources. Below this, the main header identifies the U.S. Government Publishing Office. The left sidebar contains a search section with options like 'Browse / Search Previous', 'Simple Search', and 'Advanced Search'. The main content area is titled 'ELECTRONIC CODE OF FEDERAL REGULATIONS' and includes a link to 'View past updates to the e-CFR'. Below this, it states 'e-CFR data is current as of April 17, 2017'. The content is organized into sections: 'Title 21 - Chapter I - Subchapter D - Part 312', 'PART 312—INVESTIGATIONAL NEW DRUG APPLICATION', 'Contents', 'Subpart A—General Provisions', 'Subpart B—Investigational New Drug Application (IND)', 'Subpart C—Administrative Actions', and 'Subpart D—Responsibilities of Sponsors and Investigators'. Each section lists specific regulatory provisions with their corresponding CFR numbers.

FDA - Additional Contacts



Use for basic or procedural drug development questions ***not*** directly linked to an existing or planned development program.



CDER - Additional Contacts



- Controlled Substance Staff
- Division of Drug Information
- Division of Pediatric and Maternal Health
- Emerging Technology Team
- Enhanced Communication Team
- Import/Export
- Office of Pharmaceutical Quality
- Ombudsman
- Rare Diseases Program
- Small Business & Industry Assistance
- Therapeutic Biologics and Biosimilars Staff
- Biomarker Qualification Program

Controlled Substance Staff

Responds to inquiries about the drug scheduling process and the study of abuse potential in animal and human studies.

Controlled Substance Staff web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm180753.htm>

Division of Drug Information

Provides expert advice and guidance regarding all aspects of CDER activities to consumers, health care professionals, insurance companies, regulated industry, academia, law enforcement, FDA, and other government agencies.

Division of Drug Information web page

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm082585.htm>

Division of Pediatric and Maternal Health

Collaborates with internal and external stakeholders to develop clinically relevant, evidence-based labeling and other communications that facilitate informed use of medicines in children and women of childbearing potential.

- Pediatric email: pedsdrugs@fda.hhs.gov
- Maternal health email: cder.pmhs@fda.hhs.gov

Emerging Technology Team

Responds to external inquiries on novel product design and manufacturing technologies likely to improve product safety, identity, strength, quality, and purity.

Emerging Technology Team web page

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm523228.htm>

Enhanced Communication Team

- Responds to general questions about the drug review process
- Clarifies which OND review division to contact
- Provides assistance resolving communication challenges with the review team

Enhanced Communication Team web page

<https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm>

Import/Export

Responds to questions related to:

- general import compliance
- export certificate
- Compliance

Import Export Compliance Branch web page

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm>



Office Of Pharmaceutical Quality

Responds to product quality related inquiries.

Office of Pharmaceutical Quality web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm418347.htm>



Ombudsman

Provides:

- informal advice
- assistance with issues that arise in the context of the regulatory process
- feedback about CDER's programs and overall performance

Note: Upon request, communication with the Ombudsman will be kept confidential.

CDER Ombudsman web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm>

Rare Diseases Program

- Exchanges scientific and regulatory information with international regulatory agencies
- Promotes the development of treatments by collaborating with internal and external rare disease stakeholders

Rare Diseases Program web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm221248.htm>



Small Business and Industry Assistance

Provides human drug product development and regulation information.

Small Business and Industry Assistance web page
www.fda.gov/cdersbia

Therapeutic Biologics and Biosimilars Staff

Ensures consistency in the scientific and regulatory approach and advice regarding development programs for therapeutic biologics and for proposed biosimilar products.

email:

ONDTherapeuticBiologicsandBiosimilarsPMStaff@fda.hhs.gov

Information on Biosimilars web page

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>

Biomarker Qualification Program

Encourages biomarker development by providing a framework for development and regulatory acceptance.

Biomarker Qualification Program web page

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/ucm20086360.htm>

CBER - Additional Contacts

- Manufacturers Assistance and Technical Training Branch
- Ombudsman



Manufacturers Assistance and Technical Training Branch

Provides assistance in many areas including:

- clinical investigator information
- adverse event reporting
- electronic submissions
- how to submit an IND

Manufactures Assistance web page

<https://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/manufacturingquestions/default.htm>



Ombudsman

Provides:

- informal advice or referrals
- assistance with issues that arise in the context of the regulatory process
- feedback about CBER's programs and overall performance

Note: Upon request, communication with the Ombudsman will be kept confidential.

CBER Ombudsman web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122881.htm>



Office of Special Medical Programs – Additional Contacts

Office of Special Medical Programs

- Advisory Committee Oversight and Management Staff
- Office of Combination Products
- Office of Good Clinical Practice
- Office of Orphan Products Development
- Office of Pediatric Therapeutics

Advisory Committee Oversight and Management Staff

Provides guidance and assistance on the establishment, staffing, and management of public advisory committees.

- calendars
- meeting materials

Advisory Committees web page

<https://www.fda.gov/AdvisoryCommittees/default.htm>

Office of Combination Products

- Addresses premarketing review and postmarketing regulation questions
- Provides combination product training to FDA staff and industry
- Classifies products

Office of Combination Products web page

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm2018184.htm>

Office of Good Clinical Practice

- Plans and conducts training and outreach programs
- Responds to good clinical practice and human safety protection questions

Office of Good Clinical Practice web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.htm>

Office of Orphan Products Development



Programs:

- Orphan Drug Designation
- Humanitarian Use Device
- Rare Pediatric Disease Priority Review Voucher
- Orphan Products Grants
- Pediatric Device Consortium Grants
- Orphan Products Natural History Grants

Office of Orphan Products Development web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018190.htm>



Office of Pediatric Therapeutics

Programs:

- Scientific Activities
- Ethics
- Safety
- International
- Neonatology

Office of Pediatric Therapeutics web page

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018186.htm>

Communication Pathways



Review Division Regulatory Project Manager

The review division regulatory project manager (RPM) is the primary point of contact for communications between a sponsor and FDA during the life cycle of drug development.





Phone calls to RPMs are suitable for general or administrative questions.



RPMs can respond to general questions via non-secure email.

FDA communications via non-secure email should not contain confidential information (e.g. trade secrets or patient information).



RPMs typically send a courtesy copy of FDA correspondence via secure email when the correspondence communicates a regulatory action or is time sensitive.

For more information on establishing a Secure Electronic Mail link with CDER, contact SecureEmail@fda.hhs.gov



RPMs can send a courtesy copy of FDA correspondence via fax when secure email has not been established and the correspondence communicates a regulatory action or is time sensitive.



The following types of questions are best addressed in a meeting or submission to FDA:

- complex scientific/technical
- policy
- regulatory



Please complete the session survey:
surveymonkey.com/r/DRG-D1S02

