FDA Communication Pathways During Drug Development

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Center of Drug Evaluation and Research

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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


WWW


24/7
HOURS
SERVICE

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

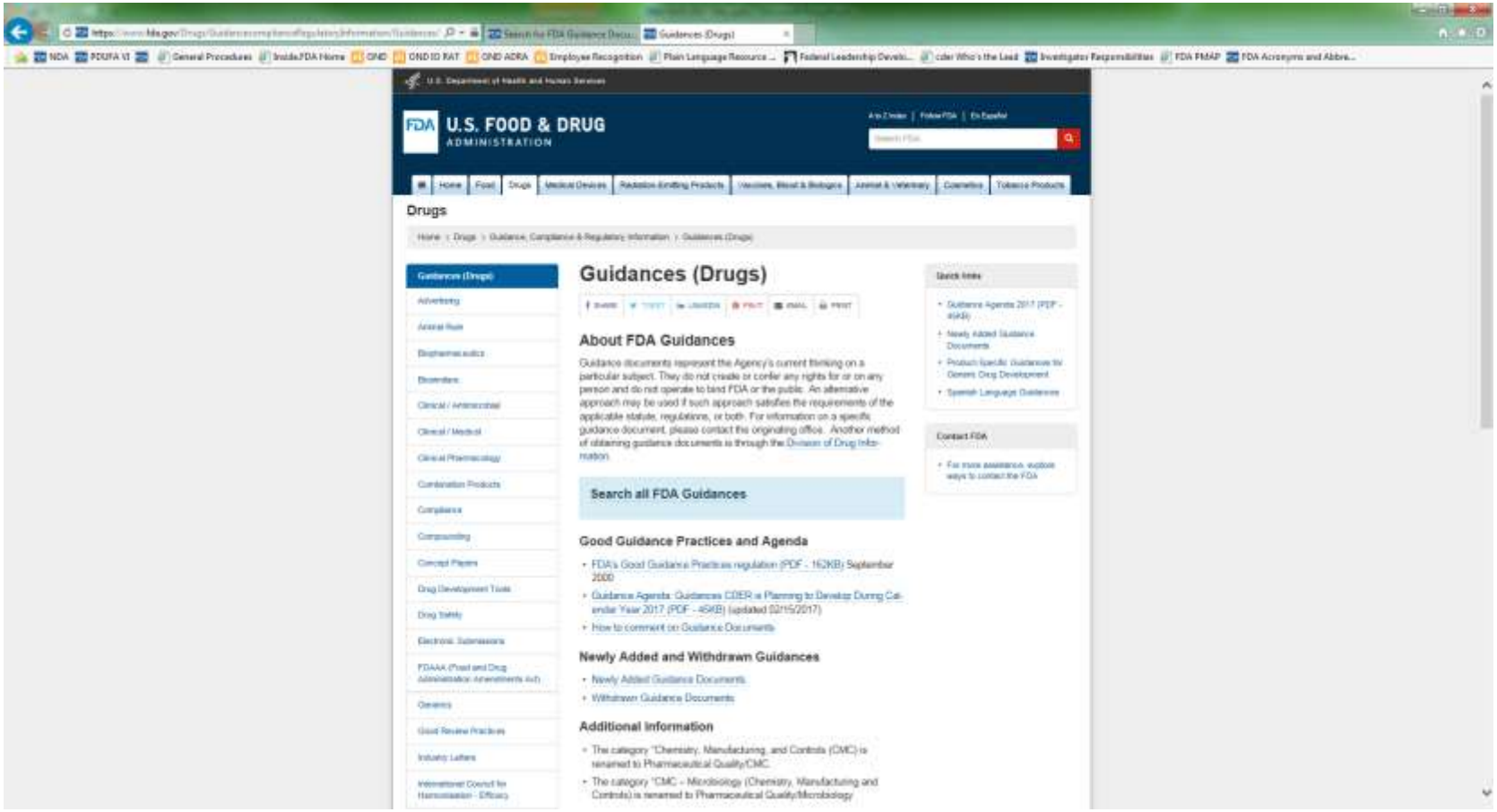
FDA Guidances

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



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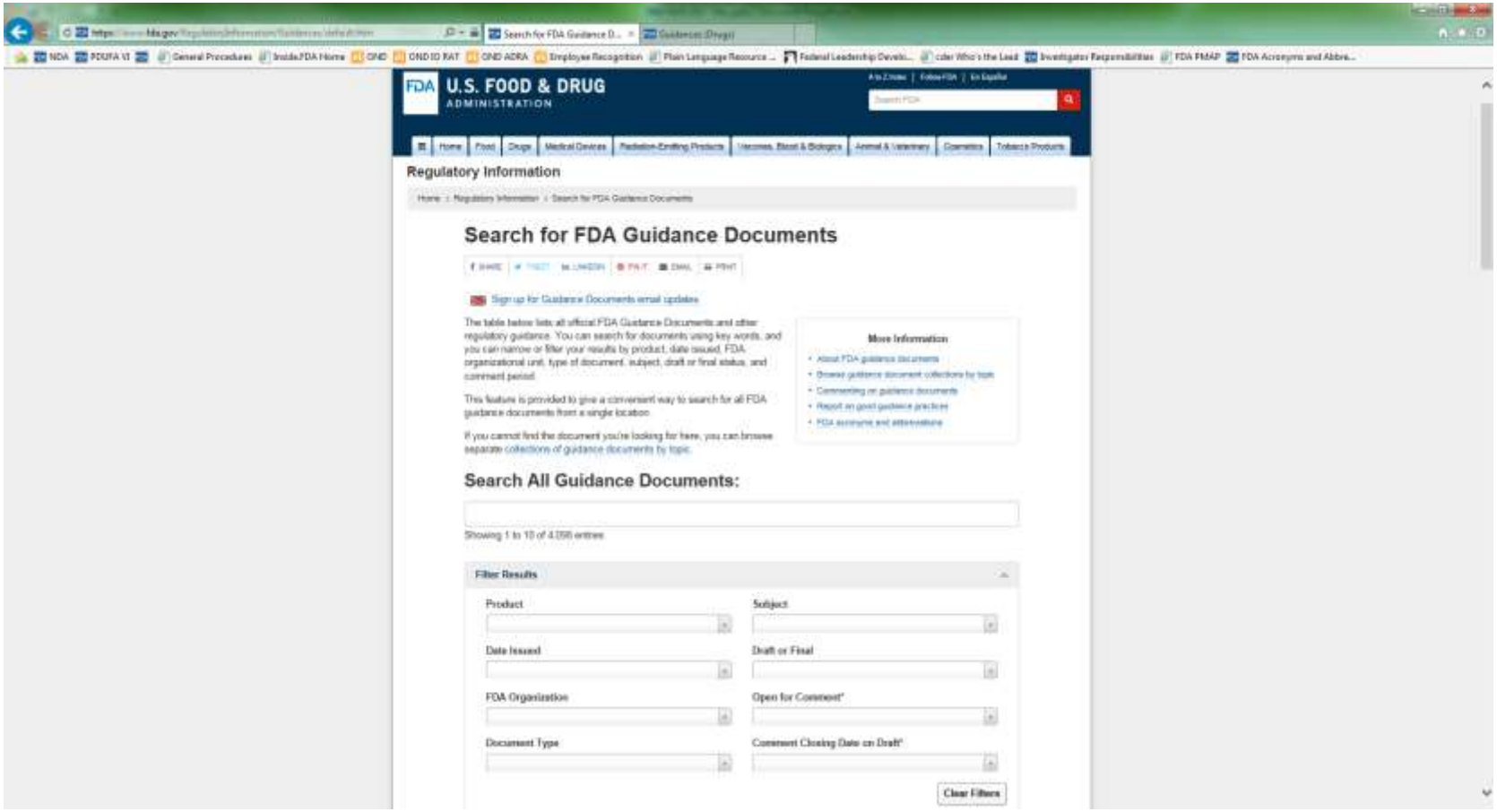
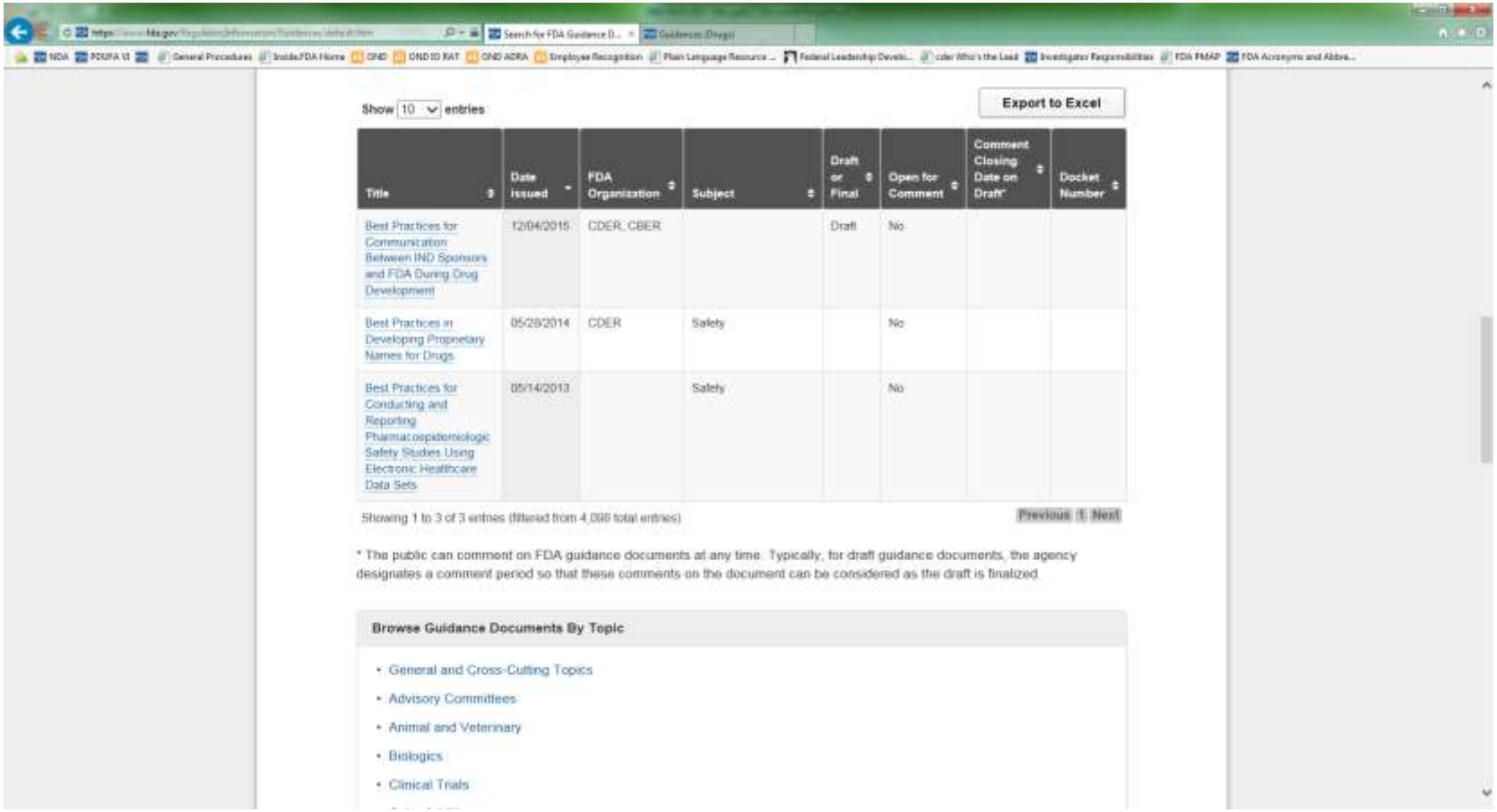


How to Search for a Guidance Cont'd



Show 10 entries

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 Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets	05/14/2013		Safety		No		

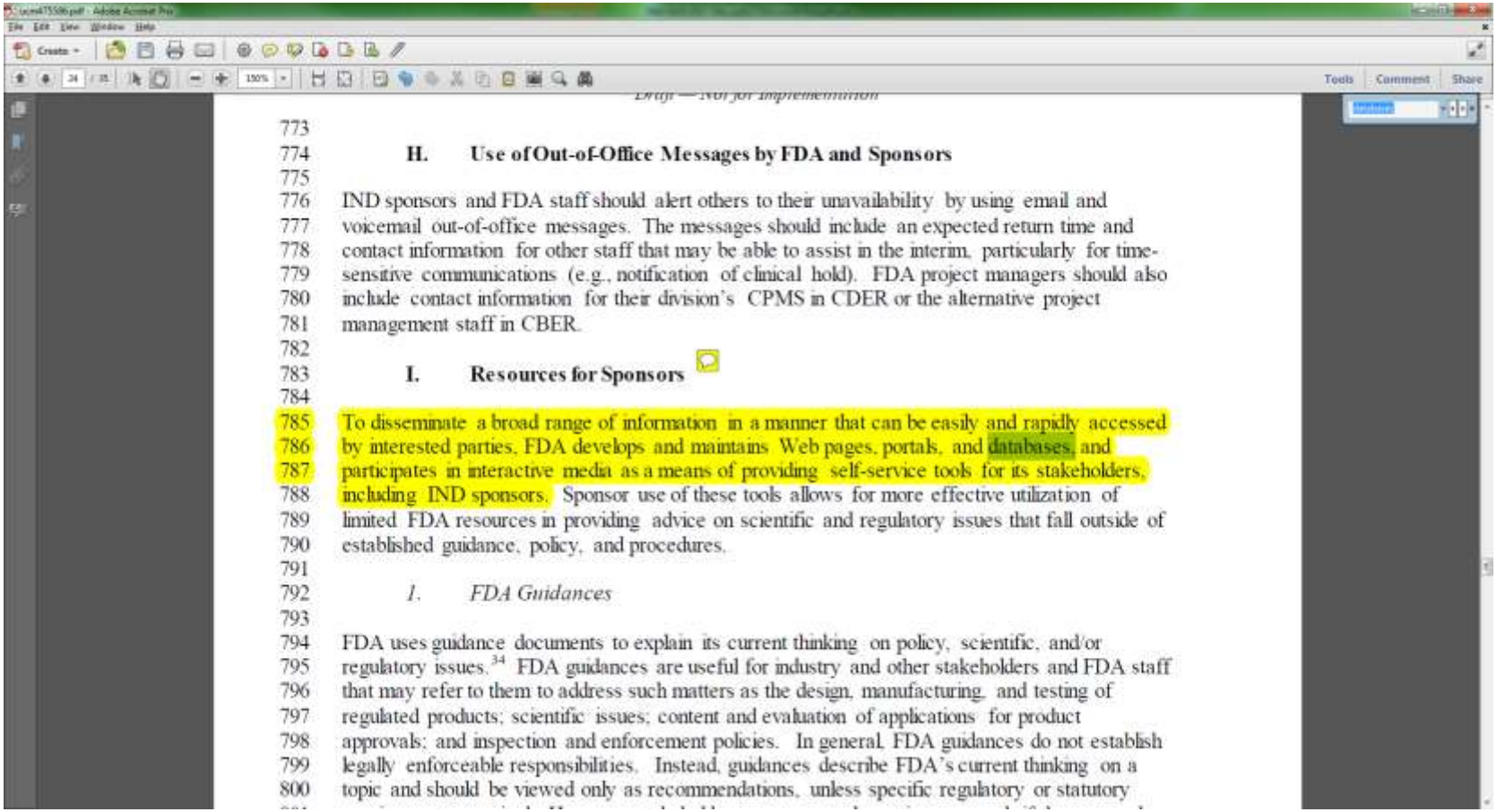
Showing 1 to 3 of 3 entries (filtered from 4,098 total entries)

Previous 1 Next

* 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



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

IND sponsors and FDA staff should alert others to their unavailability by using email and voicemail out-of-office messages. The messages should include an expected return time and contact information for other staff that may be able to assist in the interim, particularly for time-sensitive communications (e.g., notification of clinical hold). FDA project managers should also include contact information for their division's CPMS in CDER or the alternative project management staff in CBER.

I. Resources for Sponsors

To disseminate a broad range of information in a manner that can be easily and rapidly accessed by interested parties, 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, including IND sponsors. 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.

1. FDA Guidances

FDA uses guidance documents to explain its current thinking on policy, scientific, and/or regulatory issues.[34] FDA guidances are useful for industry and other stakeholders and FDA staff that may refer to them to address such matters as the design, manufacturing, and testing of regulated products; scientific issues; content and evaluation of applications for product approvals; and inspection and enforcement policies. In general, FDA guidances do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a 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/guidancecomplianceregulatoryinformation/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

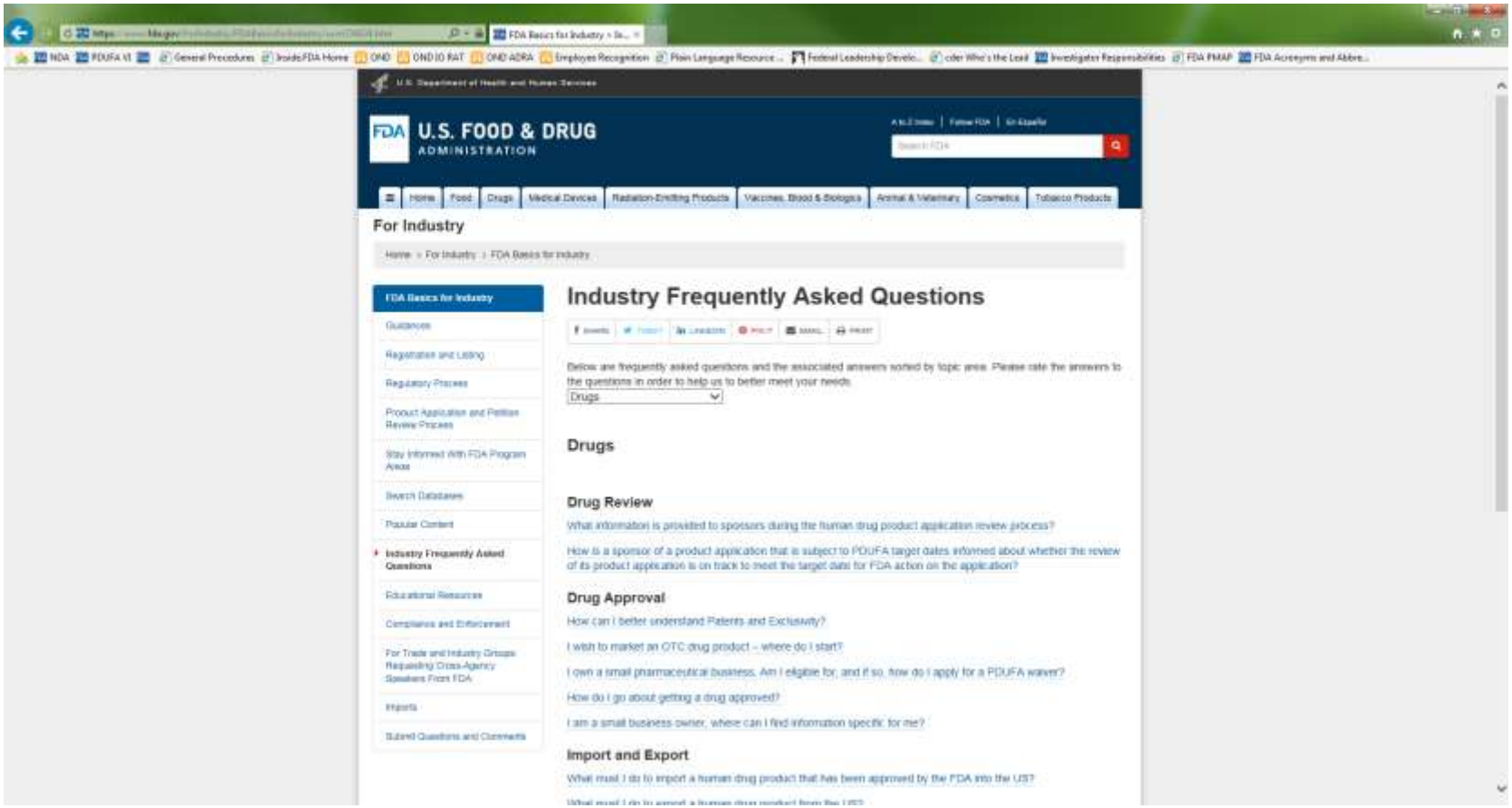
Provides basic information about FDA regulatory processes and resources to better understand how to work with FDA.

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


U.S. FOOD & DRUG ADMINISTRATION
For Industry
Industry Frequently Asked Questions
Drugs
Drug Review
Drug Approval
Import and Export

FDA Interactive Media

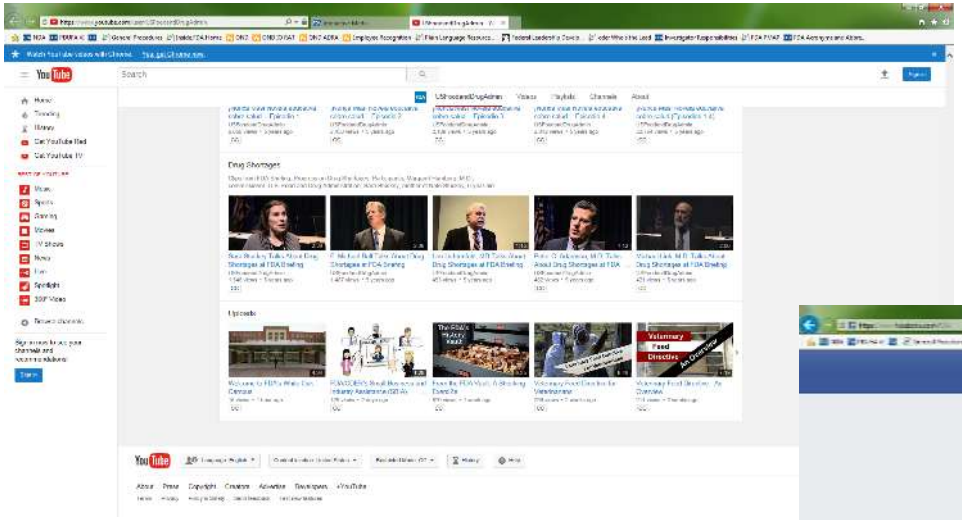
FDA uses interactive media to communicate information about:

- 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.

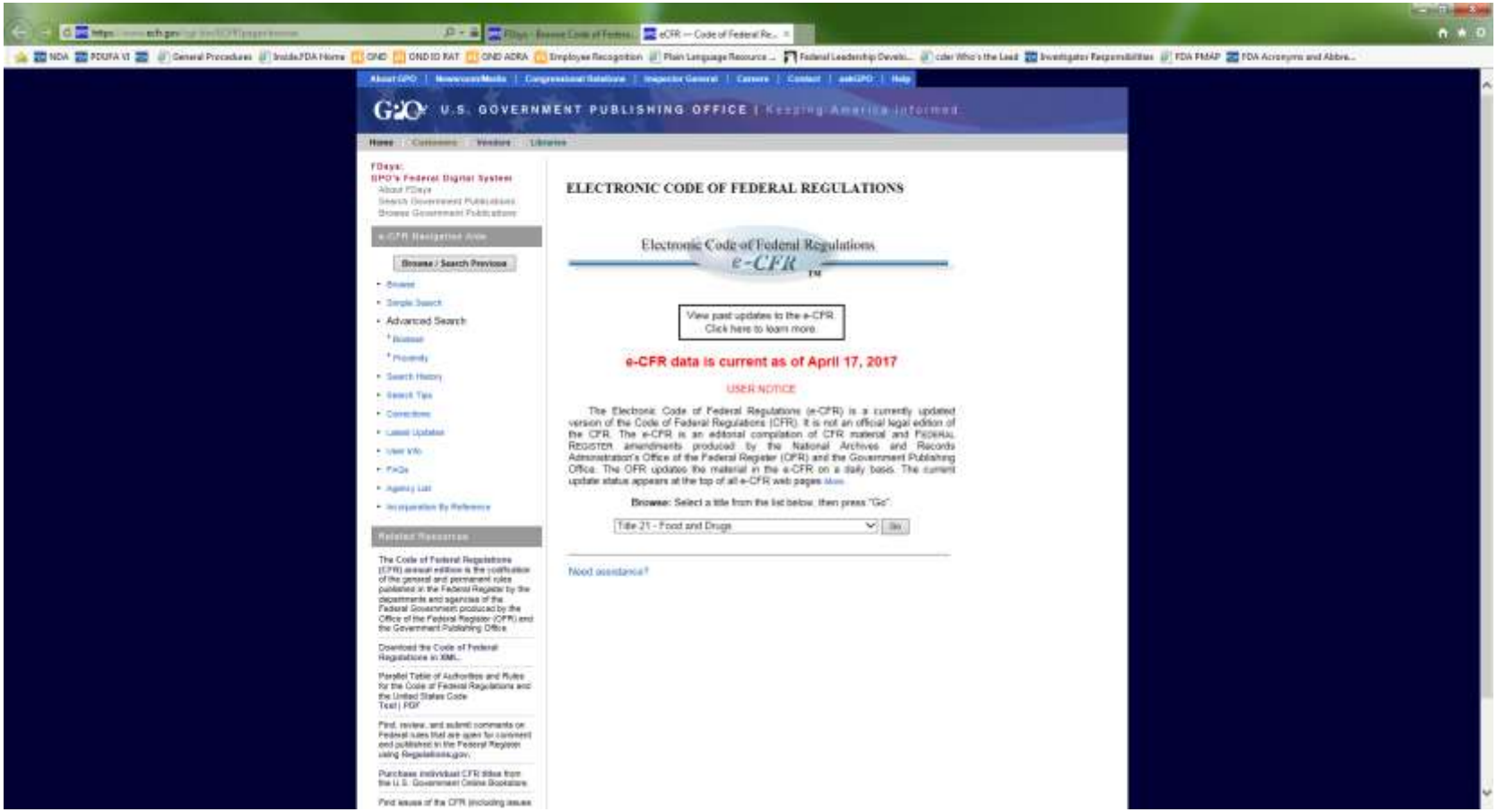
Electronic Code of Federal Regulations

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



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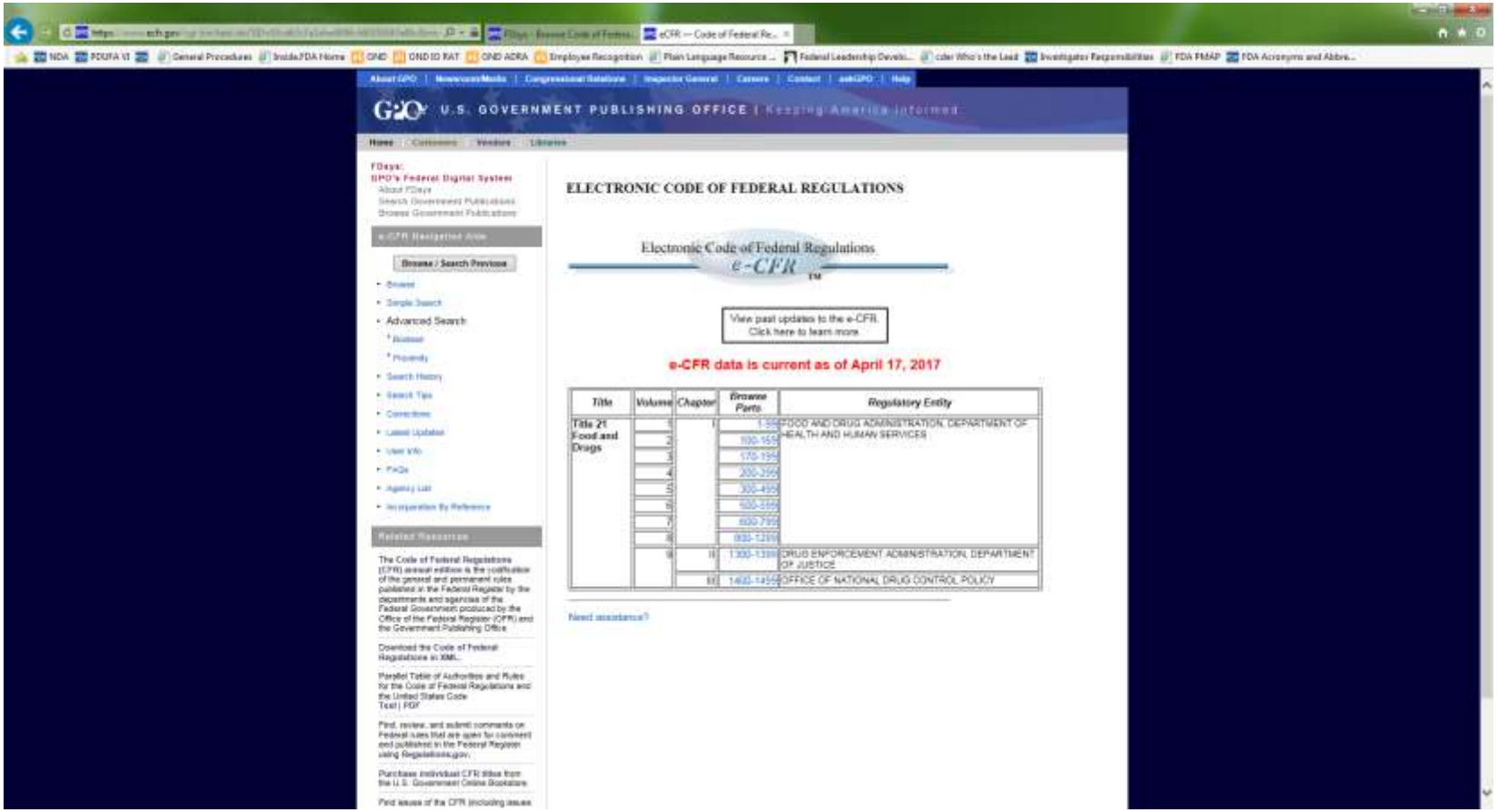

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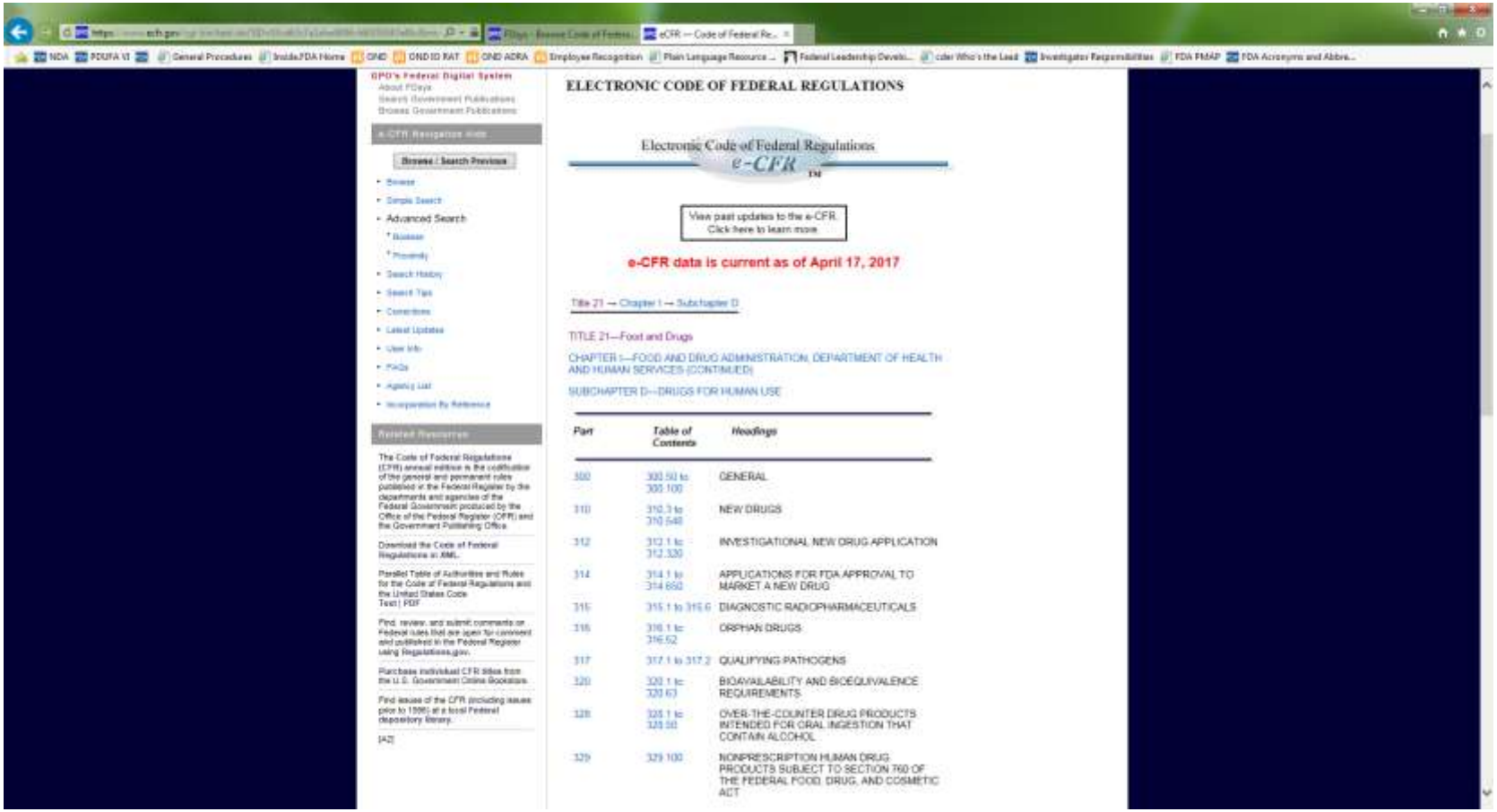

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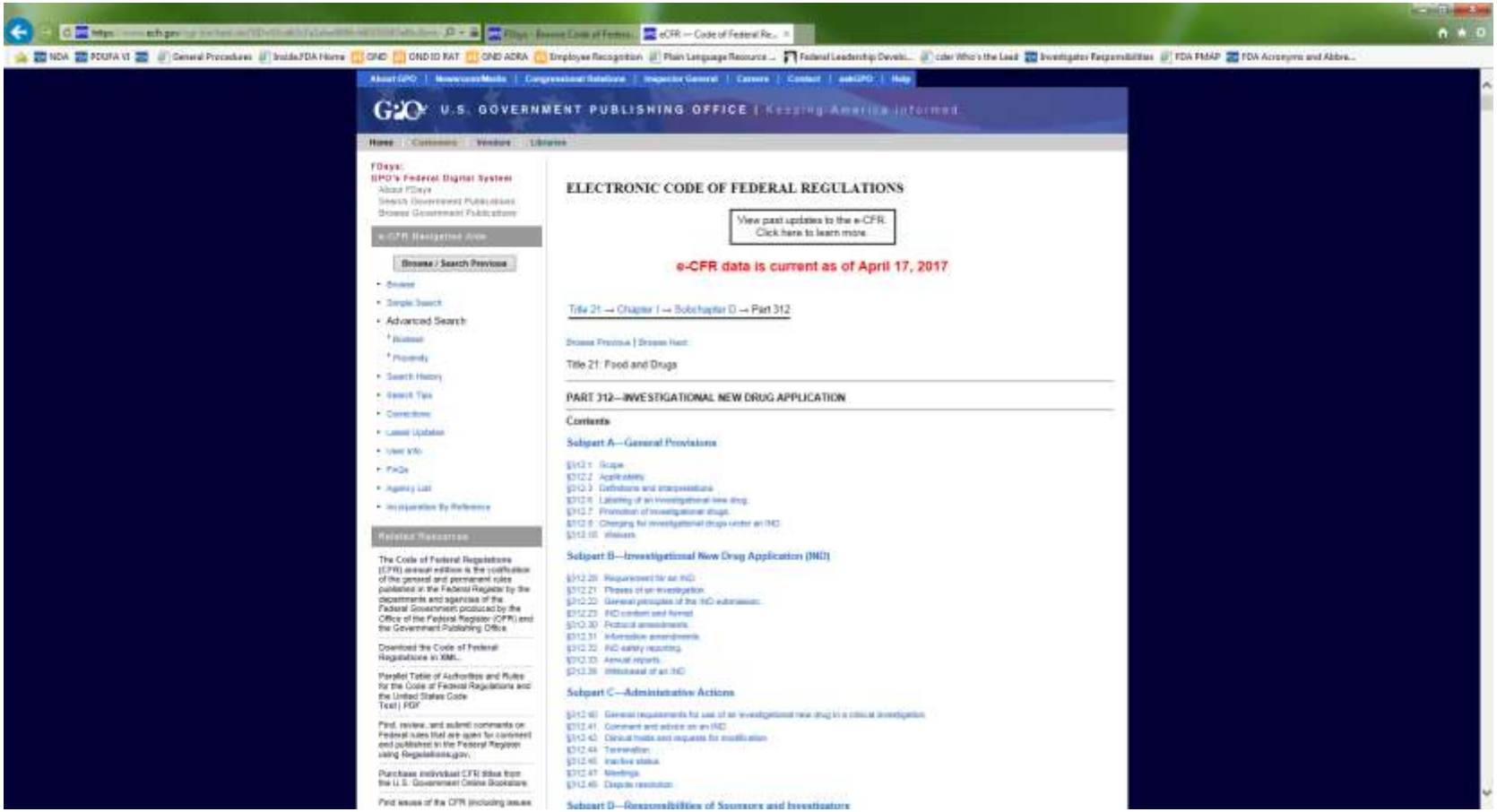


FDA - Additional Contacts

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 technologies.

Email: CDER-ETT@fda.hhs.gov

To learn more, see the *Draft Guidance for Industry: Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base*.

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
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm

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.

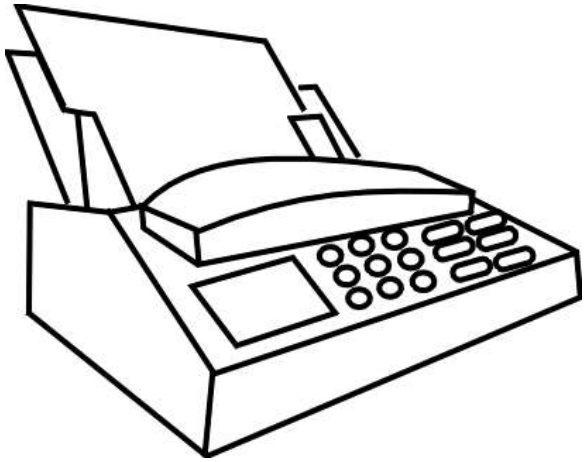
Phone calls to RPMs are suitable for general or administrative questions.

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-D2S08


THank
YOU!