CDER Small Business and Industry Assistance (SBIA)

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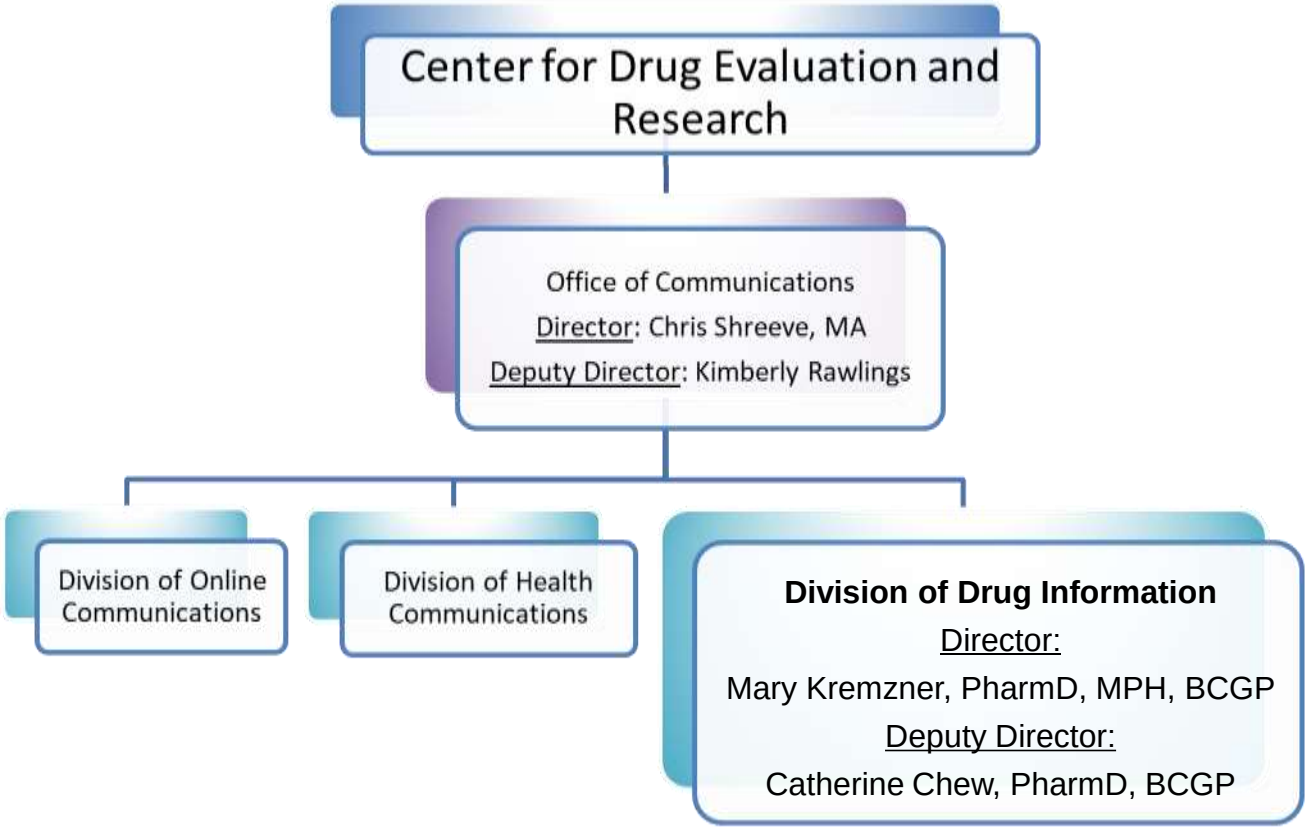
CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research
Food and Drug Administration
May 2018

Organizational Chart



FDA Small Business

FDA recognizes that regulated small business and industry may encounter some difficulties in working through the complex regulatory process

Each medical product Center has established a small business assistance office

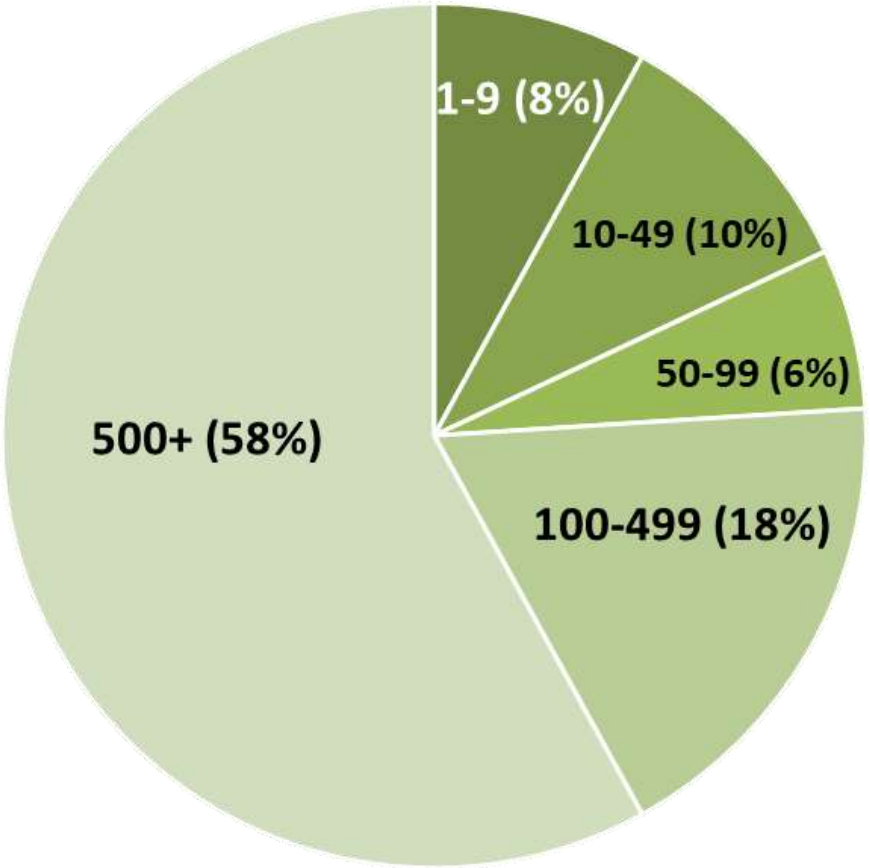
Provide technical assistance and an efficient channel through which small business and industry can acquire information from the FDA.

Mission

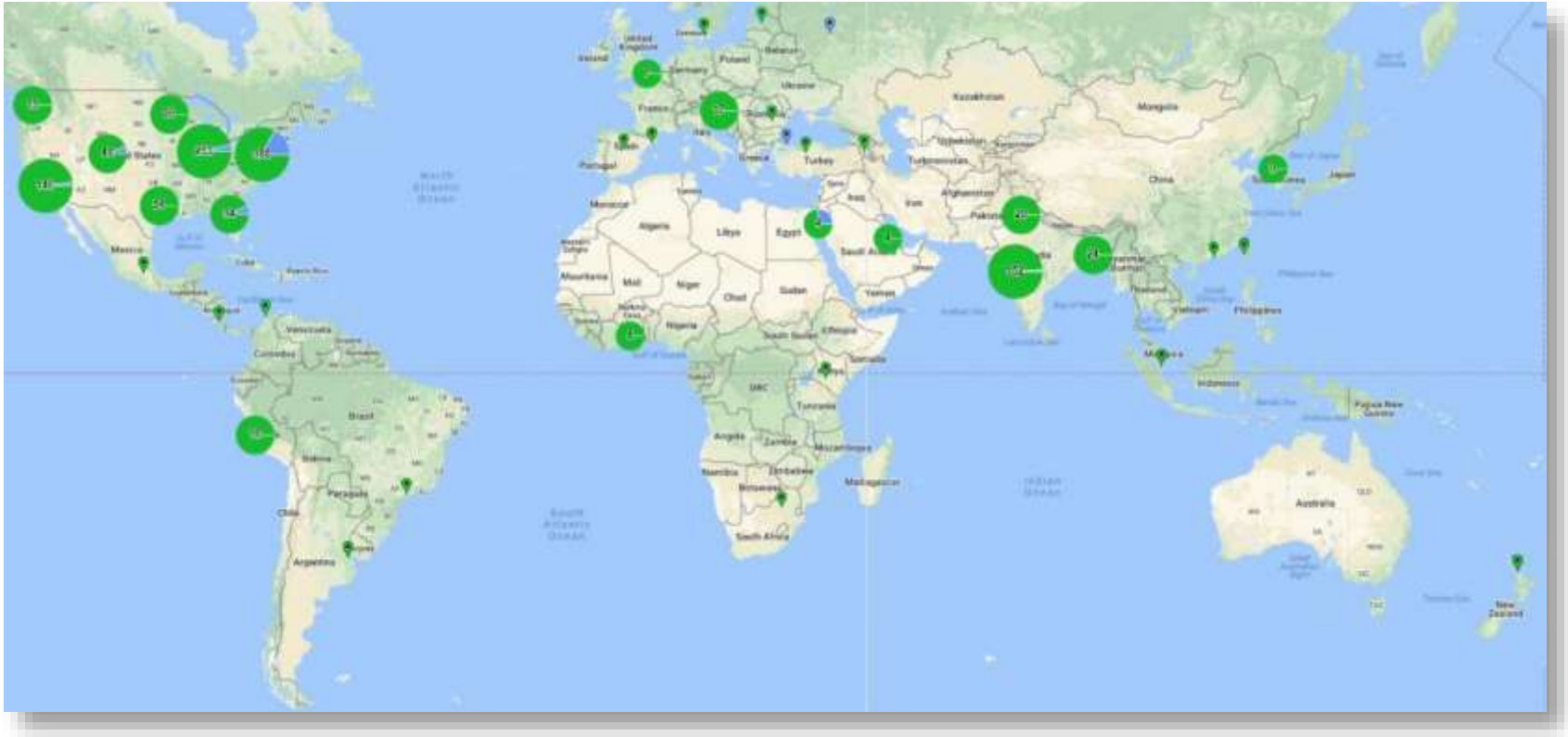
To engage with small pharmaceutical business and industry by providing timely and accurate information on human drug development and regulation

Our Audience

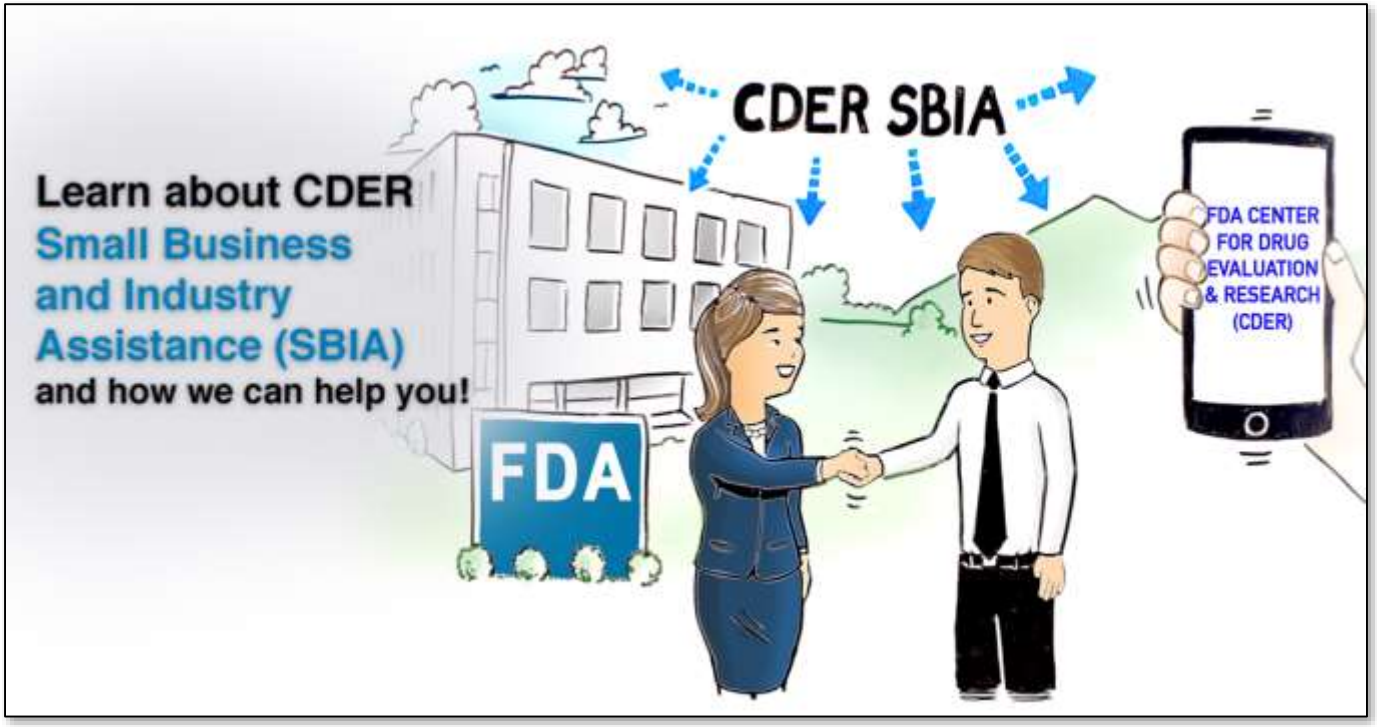
Company size (# of employees)



Our Audience

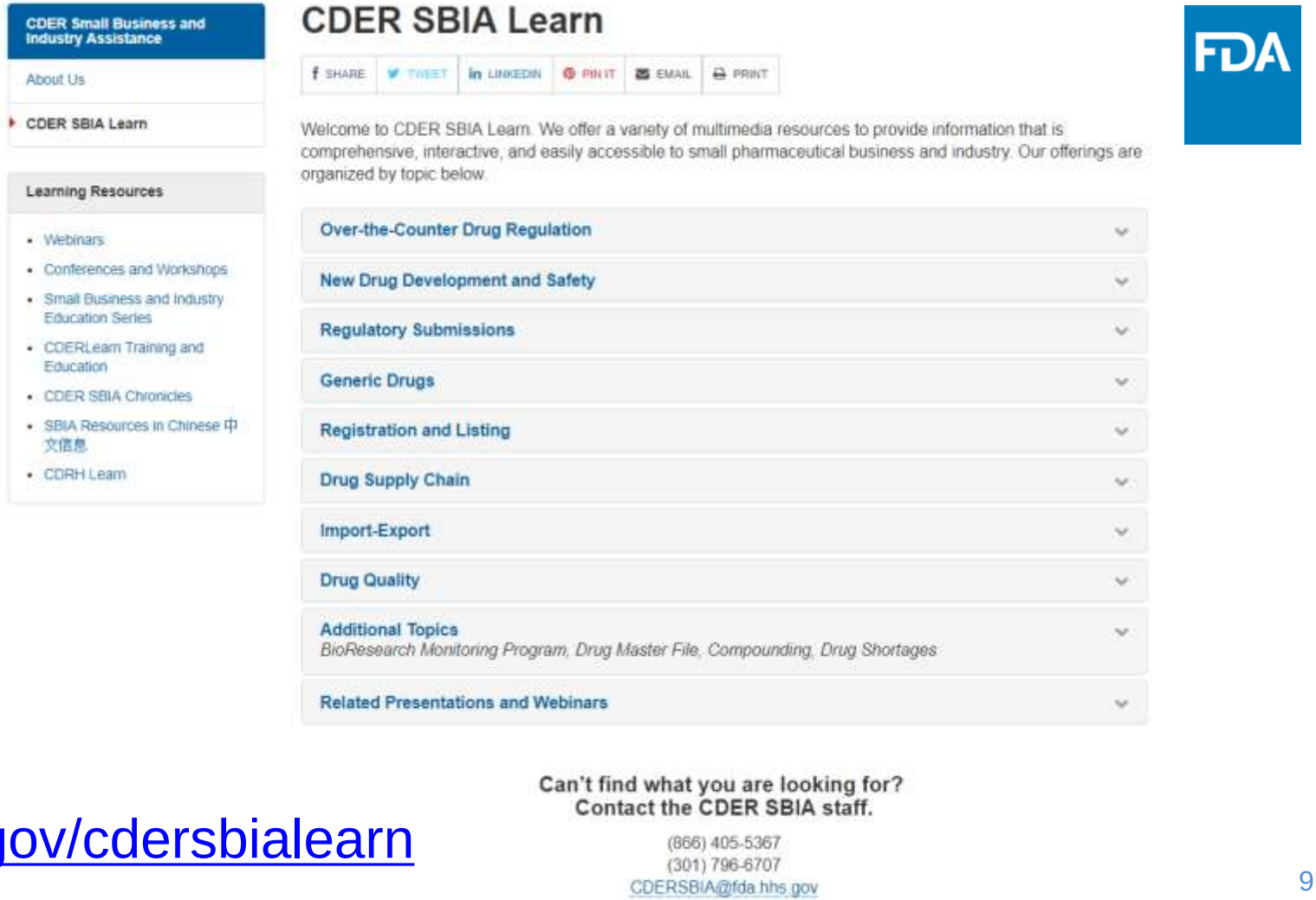


What We Do



https://www.youtube.com/watch?time_continue=16&v=5I_lhdFaIGY

www.fda.gov/cdersbia



www.fda.gov/cdersbialearn

Workshops and Conferences

Regulatory Education for Industry (REdI) Conferences

- Dual-Track REdI Conferences that combine CDER & CDRH
- Topic-Specific REdI Conferences presented by CDER experts
- All are FREE
- Available for in-person or online attendance

- Regulatory Affairs Certification (RAC) credits available to attendees

Workshops and Conferences

General REdI Conferences:

- Chemistry, Manufacturing Controls Requirements for an IND Application
- Benefit-Risk Considerations During Drug Product Development
- Good Manufacturing Practices from an IND Perspective
- Pre-Approval Manufacturing Site Inspections

Topic-specific Conferences:

- Pharmaceutical Quality Symposium
- Generic Drugs Forum
- Prescription Drug Labeling – Challenges and Issues
- Focus on GMPs and FDA Inspections
- GDUFA and You
- Clinical Investigator Training Course (CITC)

Recordings available at SBIAevents.com and www.fda.gov/cdersbialearn

Presentations & Exhibits

- Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Conference
- Conduct other presentations per request
- Exhibit at conferences to increase outreach and increase visibility

Webinars

Tool to communicate directly with industry

Extends SBIA's reach globally

Video and Audio Archive (mp3)

Regulatory Affairs Certification (RAC) credits available to live webinar attendees

Webinars

Examples of past webinars:

- REMS Integration Initiative: An Overview
- Optimizing Your Study Data Submissions to FDA –Study Data Technical Conformance Guide October 2017 Version
- Draft Guidance for Industry: Determining Whether to Submit an ANDA or 505(b)(2) Application
- The Ins and Outs of Presenting Clinical Pharmacology Information in Prescription Drug Labeling
- CDER Microbiology Issues: A Deeper Dive

Foreign Regulators & Publications

Interactions with Foreign Regulators

- Meet with foreign regulators explain FDA process
- Work with Office of International Programs
- SBIA Resources in Chinese

Publications

- FDA Voice Blog: FDA Helping Small Businesses Get Big Results
- Am J Health Systems Pharmacy: FDA Application of the USP Salt Policy
- Pharmaceutical Executive: FDA's Helping Hand to Small Pharma
- Pharmaceutical Manufacturing: ANDA Tips from the FDA

www.fda.gov/cdersbiachronicles

Short electronic newsletter and audio podcast, highlighting a specific regulatory issue every other month in an easy to read format.

Examples of recent issues:

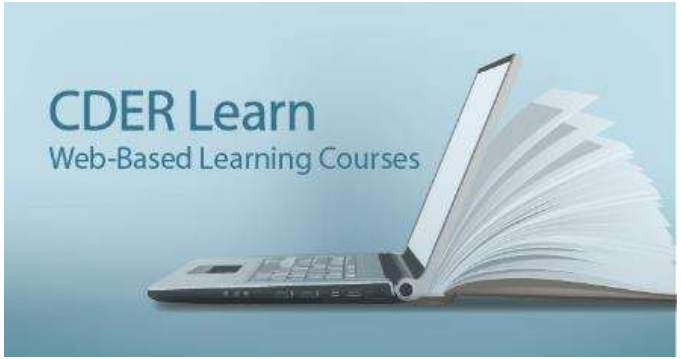
- A New Era for Homeopathic Drug Regulation
- FDA Helping the Generic Industry Submit Complete Applications
- PDUFA VI – A Time for Change
- Real-World Data and Evidence in Drug Development
- Submitting Master Files in eCTD Format: When and How to Comply
- The Complexities of Compounding
- FDA Addresses Small Business Concerns in GDUFA II

CDERLearn – SBIA Education Series

Web-based learning tutorials aimed at educating small pharmaceutical business and industry on topics relating to drug regulation and review.

Courses Offered:

- Bringing an Over-the-Counter (OTC) Drug to Market
- Chemistry, Manufacturing, and Controls (CMC) Perspective of the IND
- Electronic Common Technical Document (eCTD)
- Engaging with the FDA During New Drug Development
- Human Drug Establishment Registration and Drug Listing Compliance
- Overview of the Generic Drug User Fee Amendments of 2012 (GDUFA)
- GDUFA Self-Identification (SPL) Submission – Parts 1&2



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Stay Connected:
The Small Biz Buzz (Email Updates)

CDER SBIA email updates:

- New regulations and Federal Register announcements
- New guidance documents
- Upcoming meetings, conferences, and workshops
- Upcoming webinars
- New web-based learning courses

Sign up at:
www.fda.gov/cdersbia

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www.linkedin.com/company/cder-small-business-and-industry-assistance

Showcase page for SBIA audience off the main FDA LinkedIn Company page

Follow to receive information about:

- Conferences & Workshops
- Webinars
- New Guidances
- FDA and Federal Register Notices
- E-newsletters & podcasts
- CDERLearn courses
- And more!

@FDA_Drug_Info

Can't attend a conference?

Follow to receive live updates during SBIA conference Twitter chats

Direct Communication Services

In 2017, we responded to:

- 6,556 Emails
- 3,713 Phone Calls

CDER SBIA Contact Information:

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Email: **CDERSBIA@fda.hhs.gov**

Monday – Friday, 8 AM – 4:30 PM ET

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