

# CDER Small Business and Industry Assistance (SBIA)

**Renu Lal, Pharm.D.**

CDER Small Business and Industry Assistance (SBIA)

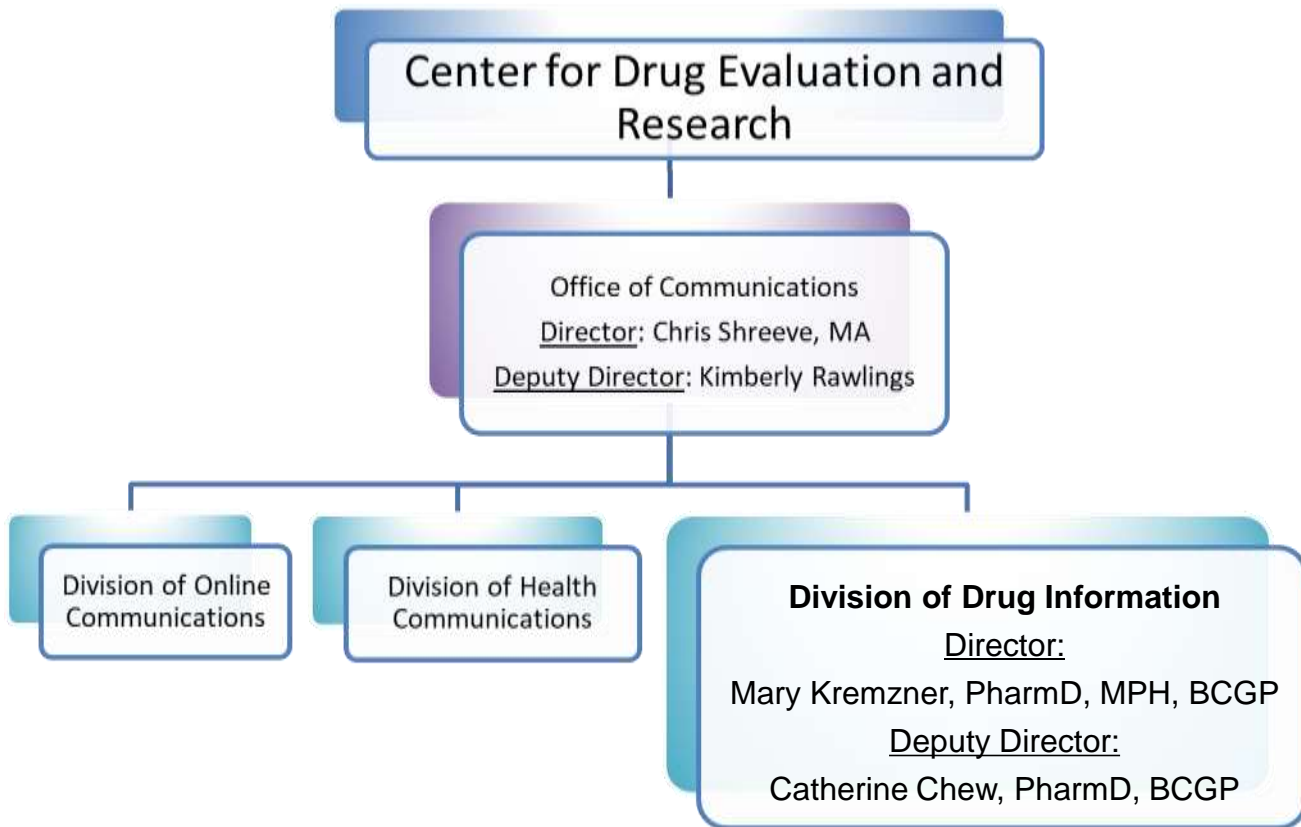
Division of Drug Information (DDI)

Center for Drug Evaluation and Research

Food and Drug Administration

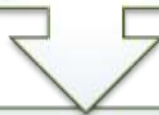
May 2018

# 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

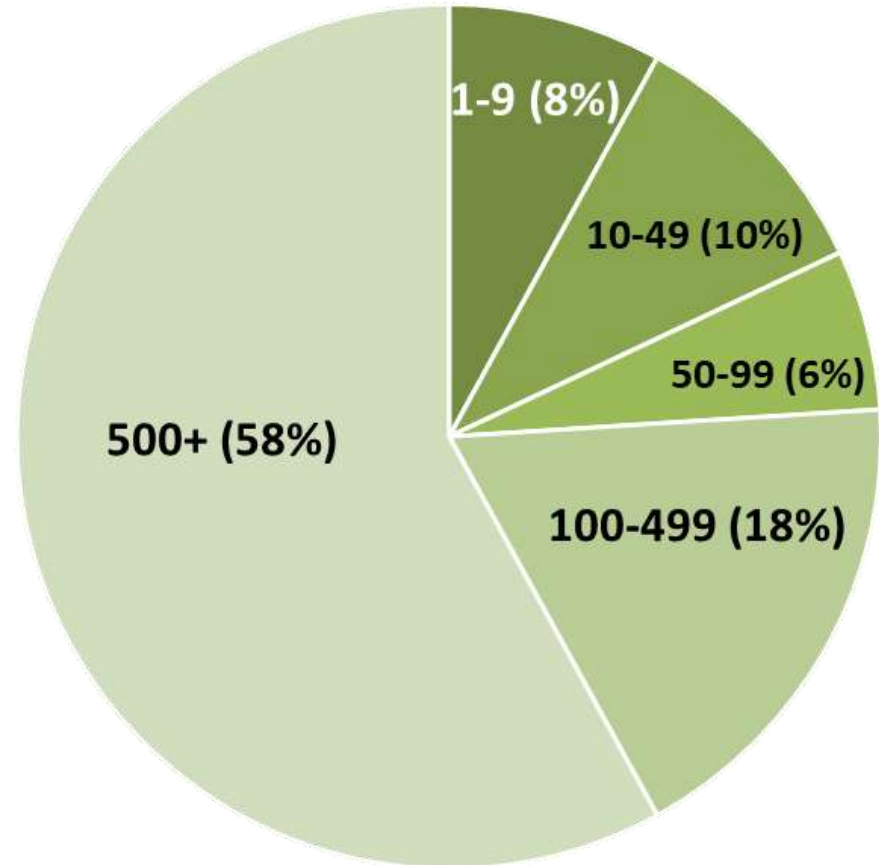


To engage with small pharmaceutical business and industry by providing timely and accurate information on human drug development and regulation

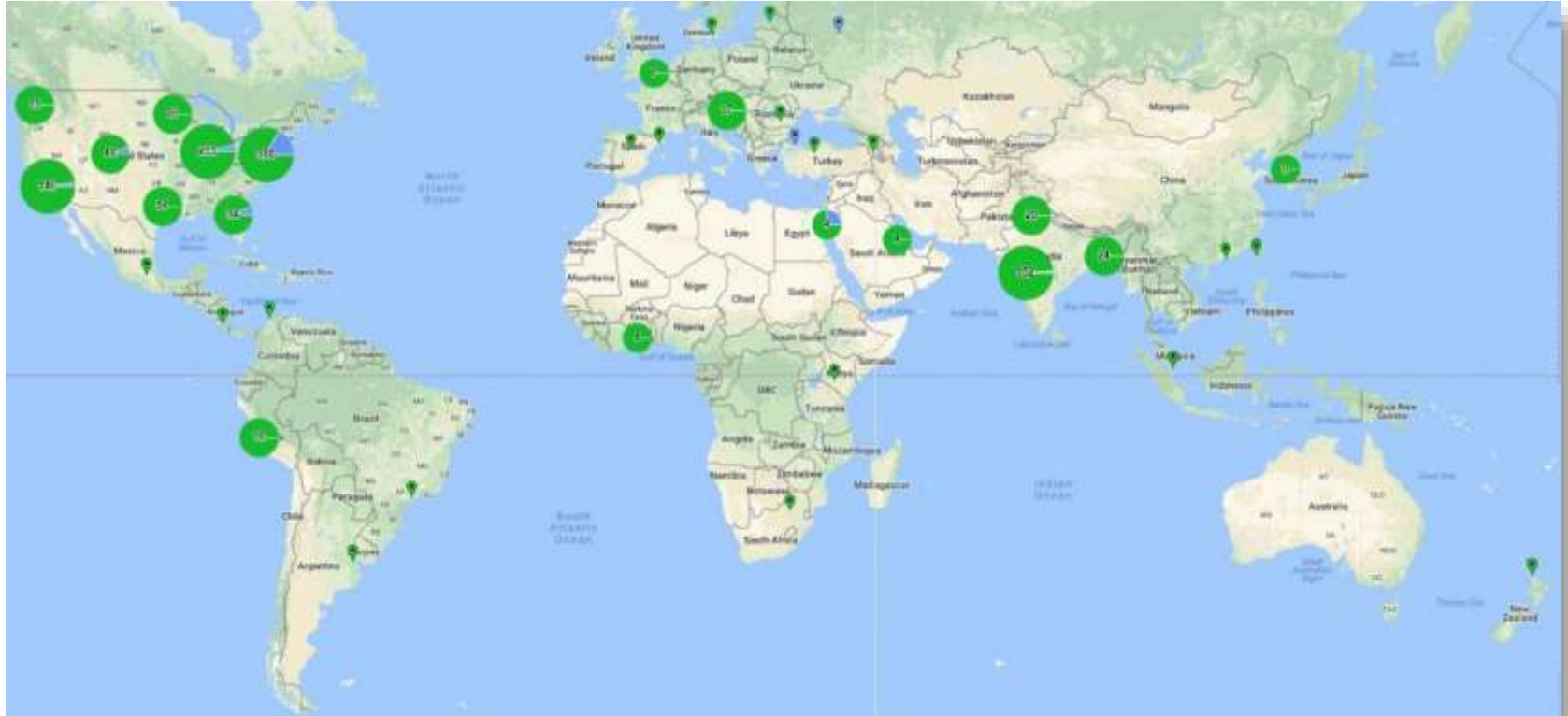
# Our Audience



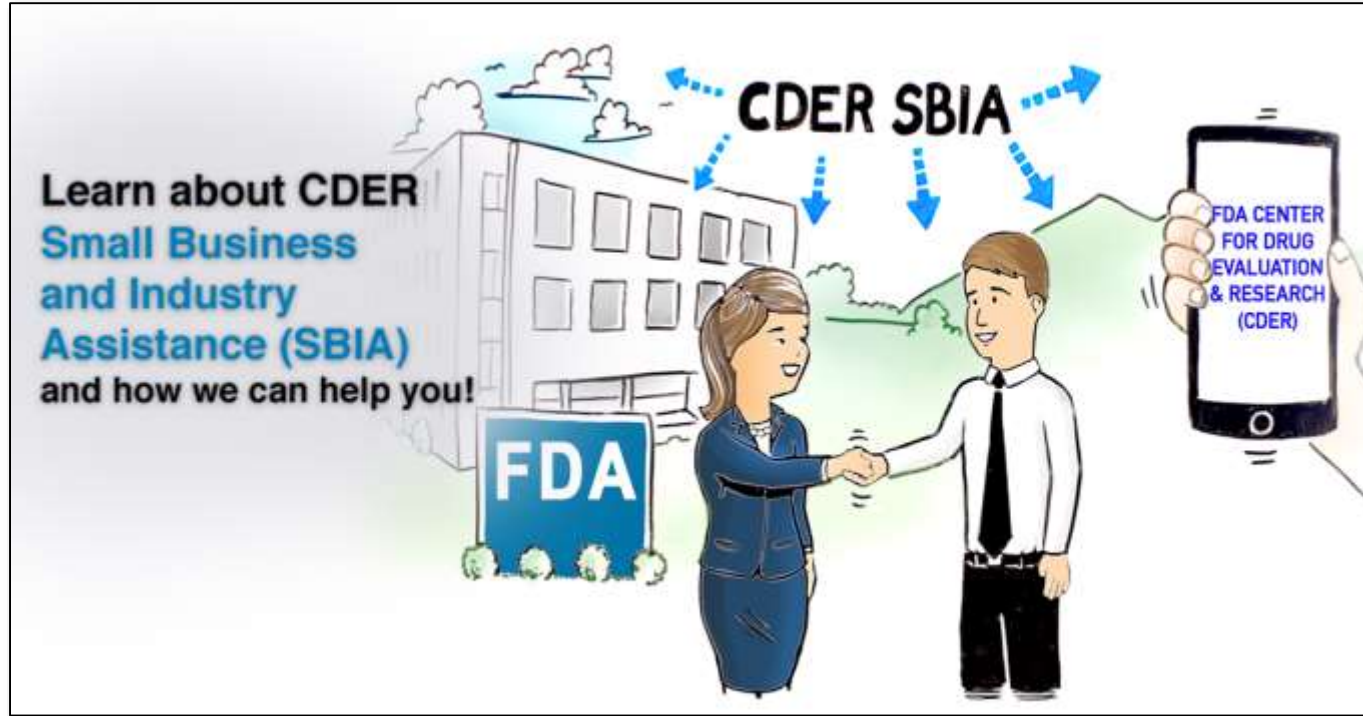
**Company size  
(# of employees)**



# Our Audience



# What We Do



[https://www.youtube.com/watch?time\\_continue=16&v=5l\\_lhdFaIGY](https://www.youtube.com/watch?time_continue=16&v=5l_lhdFaIGY)



#### Spotlight

- Optimizing Your Study Data Submissions to FDA: Office of Vaccines Research and Review (OVR) Data Submission - May 8, 2018
- FDA Regulatory Education for Industry (REdI) Spring, May 15-16, 2018
- Generic Drugs Forum 2018 – April 11-12
- "A New Era for Homeopathic Drug Product Regulation" March 22, 2018 Issue
- Office of Pharmaceutical Quality Annual Report 2017 (PDF - 10.2MB)
- "FDA Helping the Generic Industry Submit Complete Applications" February 6, 2018 Issue
- Office of Generic Drugs (OGD): NEW webinars
- 12-04-17 Webinar: REMS Integration Initiative: An Overview

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FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

SMALL BUSINESS & INDUSTRY ASSISTANCE



#### Drug Development

*Pre-Clinical through Investigational New Drug Application (IND)*

#### New Drug Application(NDA)/Biologic License Application (BLA)

*Submission of the Marketing Application*

#### Generic Drug Review

#### Over-the-Counter (OTC) Drug Review

#### Biosimilars

#### Rare Diseases and Orphan Drugs

#### Drug Safety

[www.fda.gov/cdersbia](http://www.fda.gov/cdersbia)



## Learning Resources

- Webinars
- Conferences and Workshops
- Small Business and Industry Education Series
- CDERLearn Training and Education
- CDER SBIA Chronicles
- SBIA Resources in Chinese 中文信息
- CORH Learn

## CDER SBIA Learn

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Welcome to CDER SBIA Learn. We offer a variety of multimedia resources to provide information that is comprehensive, interactive, and easily accessible to small pharmaceutical business and industry. Our offerings are organized by topic below.

[Over-the-Counter Drug Regulation](#)[New Drug Development and Safety](#)[Regulatory Submissions](#)[Generic Drugs](#)[Registration and Listing](#)[Drug Supply Chain](#)[Import-Export](#)[Drug Quality](#)[Additional Topics](#)[BioResearch Monitoring Program](#), [Drug Master File](#), [Compounding](#), [Drug Shortages](#)[Related Presentations and Webinars](#)

# 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](https://SBIAevents.com) and [www.fda.gov/cdersbialearn](https://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

A graphic featuring a stylized world map in shades of blue and green. Overlaid on the map is a light blue banner with a right-pointing arrow. The banner contains the text "CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA) WEBINAR SERIES" in dark blue, bold, sans-serif capital letters.

## CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA) WEBINAR SERIES

**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](http://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



[www.fda.gov/cdersbialearn](http://www.fda.gov/cdersbialearn)

# 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](http://www.fda.gov/cdersbia)

## CDER SBIA

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cdcr-small-business-and-industry-assistance](https://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:**

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



[@FDA\\_Drug\\_Info](https://twitter.com/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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