U.S. FOOD & DRUG ADMINISTRATION

CDER Small Business and Industry Assistance (SBIA): Program Overview

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CDER Small Business and Industry Assistance
Division of Drug Information
Office of Communications
Center for Drug Evaluation and Research
Food and Drug Administration
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Objective

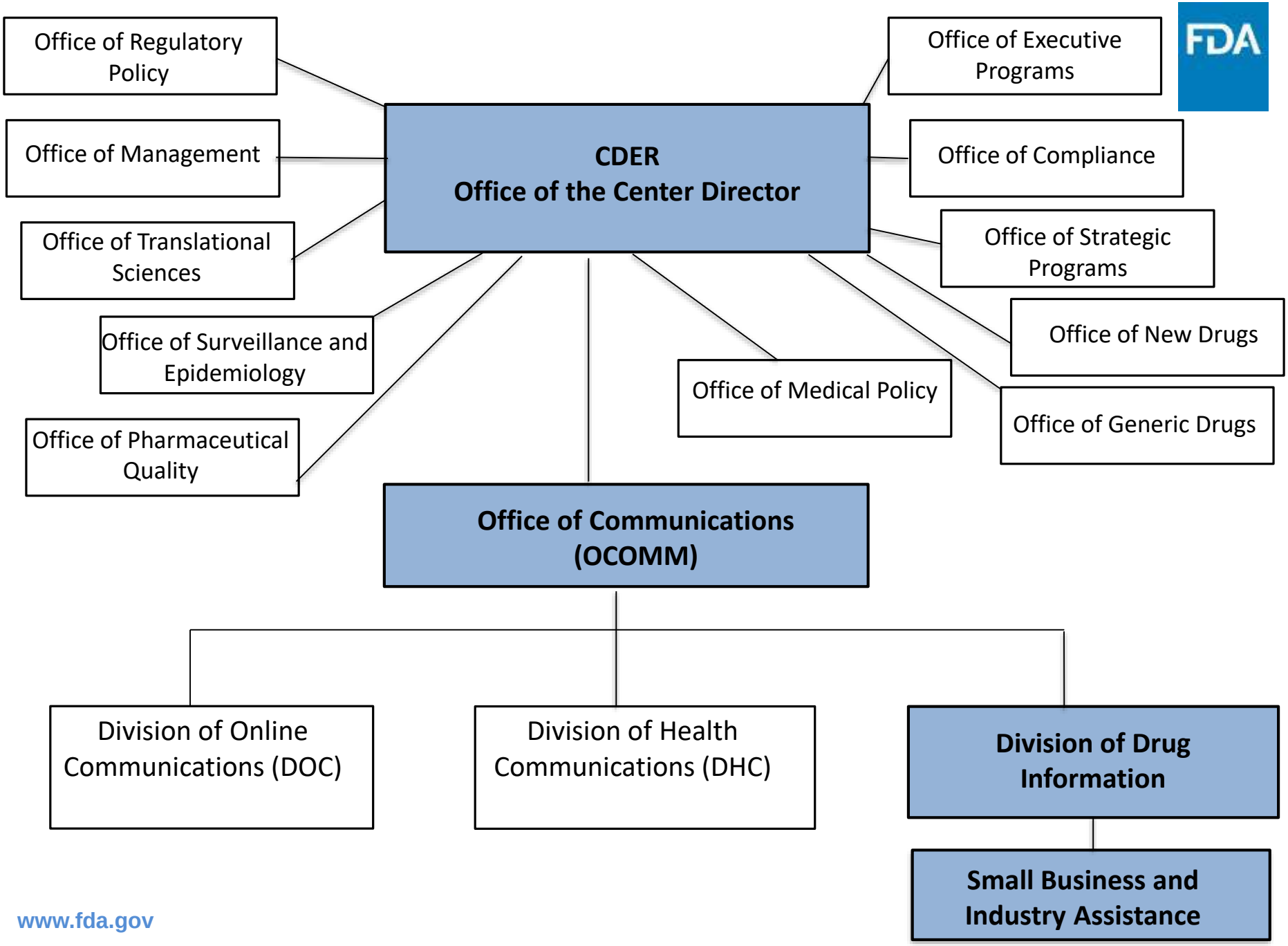
To describe the resources available via CDER's Small Business and Industry Assistance (SBIA) Program.

FDA's Philosophy

Timely interactive communication with sponsors during drug development is a core activity to help achieve our mission to **facilitate the conduct of efficient and effective drug development** programs, which can **enhance public health** by making new safe and effective drugs available to the American public in a timely manner.

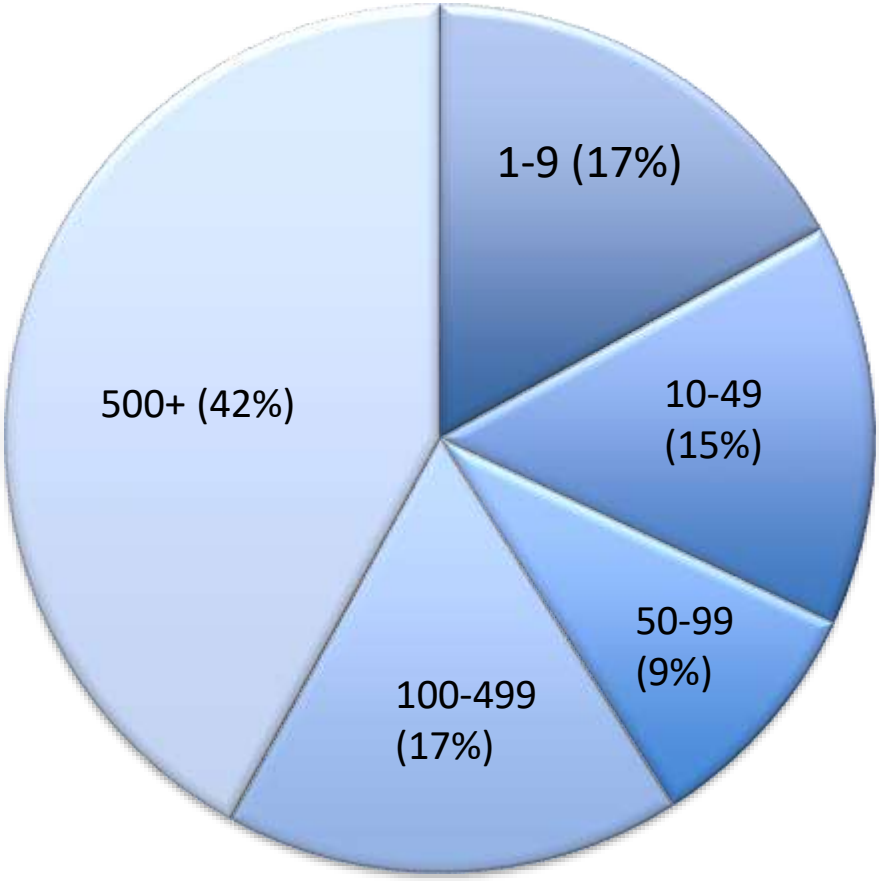
SBIA

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


Office of Regulatory Policy
Office of Management
Office of Translational Sciences
Office of Surveillance and Epidemiology
Office of Pharmaceutical Quality
CDER
Office of the Center Director
Office of Executive Programs
Office of Compliance
Office of Strategic Programs
Office of New Drugs
Office of Generic Drugs
Office of Medical Policy
Office of Communications (OCOMM)
Division of Online Communications (DOC)
Division of Health Communications (DHC)
Division of Drug Information
Small Business and Industry Assistance

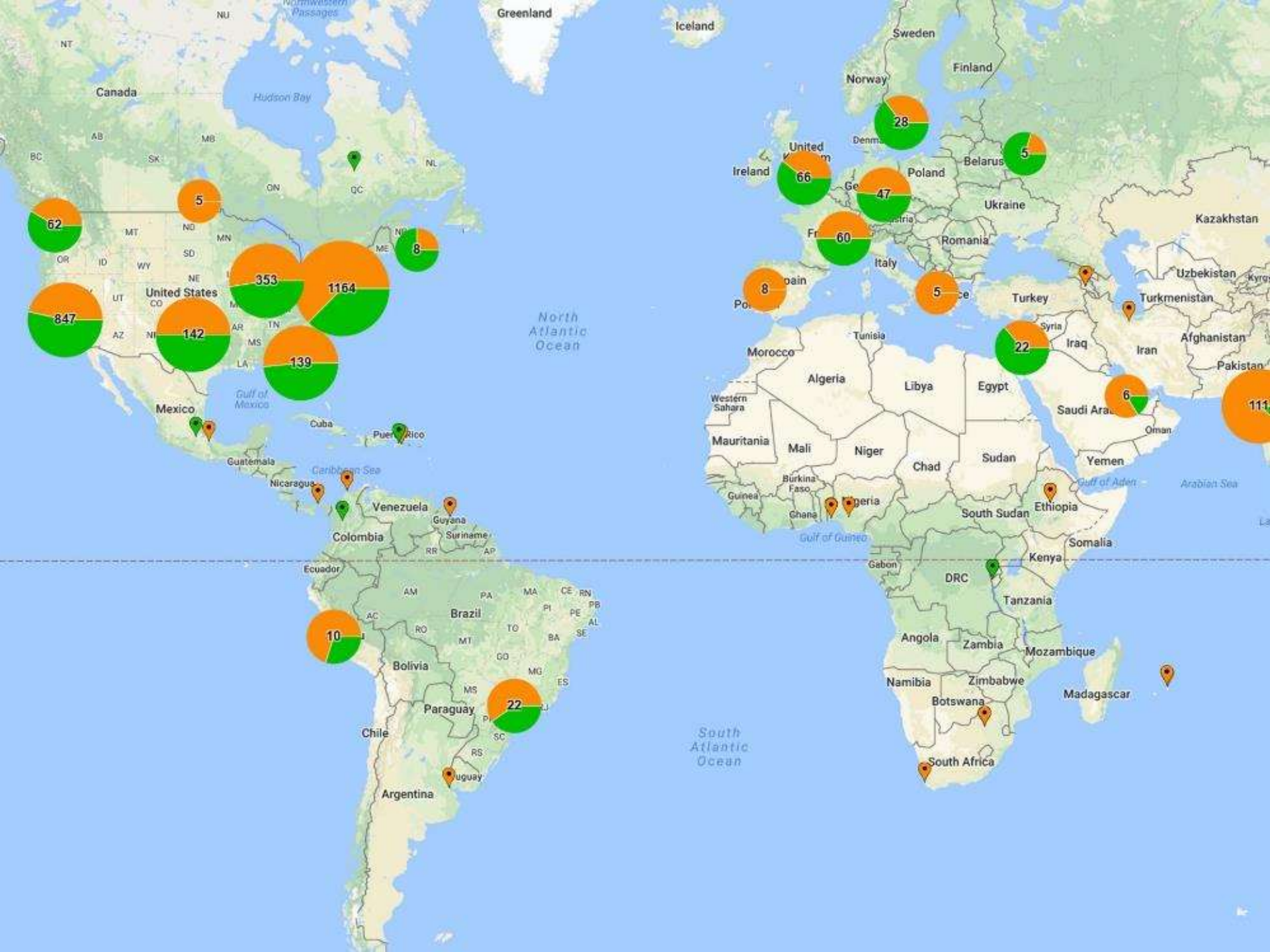
SBIA Audience

Company size (# of employees)



SBIA resources and outreach activities extend to all of the regulated pharmaceutical industry, and are not restricted to small business.

~ 48% of our audience has never submitted an IND, NDA, ANDA, or BLA to CDER

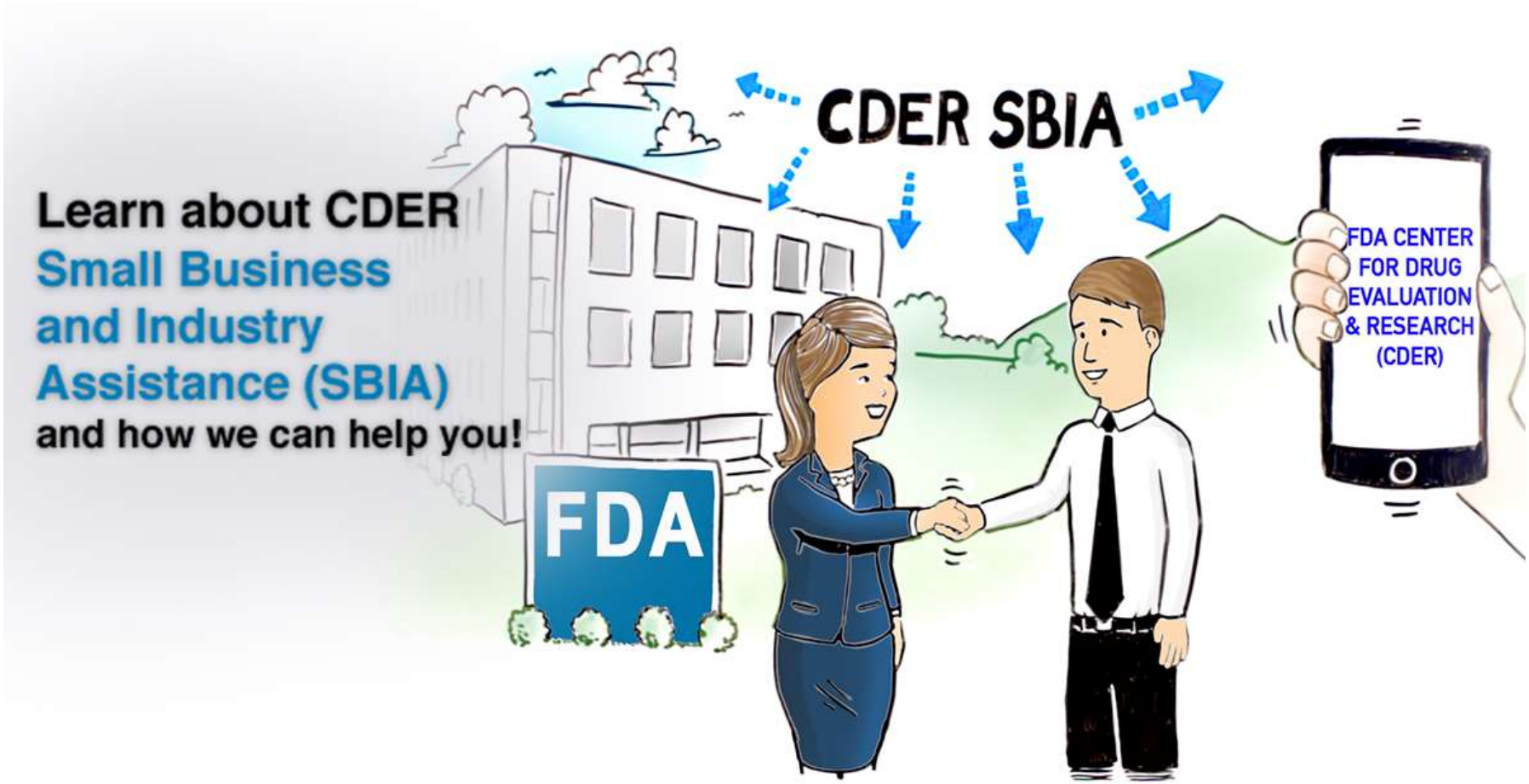

Greenland
Iceland
Canada
Hudson Bay
Sweden
Finland
Norway
Ireland
Poland
Belarus
Ukraine
Romania
Italy
Kazakhstan
Uzbekistan
Turkmenistan
Turkey
Syria
Iraq
Iran
Afghanistan
Pakistan
Morocco
Tunisia
Algeria
Libya
Egypt
Western Sahara
Mauritania
Mali
Niger
Chad
Sudan
Yemen
Oman
Saudi Arabia
Ethiopia
South Sudan
Somalia
Kenya
DRC
Tanzania
Angola
Zambia
Mozambique
Namibia
Zimbabwe
Botswana
Madagascar
South Africa
United States
Mexico
Cuba
Puerto Rico
Guatemala
Nicaragua
Venezuela
Guyana
Suriname
Colombia
Ecuador
Brazil
Bolivia
Paraguay
Chile
Uruguay
Argentina
North Atlantic Ocean
South Atlantic Ocean
Gulf of Mexico
Caribbean Sea
Gulf of Guinea
Gulf of Aden
Arabian Sea
Northwestern Passages
28
5
66
47
60
8
5
22
6
111
62
5
847
353
1164
142
139
8
10
22

SBIA Outreach

CDER SBIA provides the global pharmaceutical industry with information relating to the development and regulation of human drug products. Services include:

- Conferences
- Direct Communication Services
- CDER SBIA Chronicles & Podcasts
- Webinars
- Presentations & Exhibits
- Webpages
- CDERLearn
- Publications
- Listserv
- Interactions with Foreign Regulators
- LinkedIn

FDA


Learn about CDER
Small Business
and Industry
Assistance (SBIA)
and how we can help you!
CDER SBIA
FDA
FDA CENTER
FOR DRUG
EVALUATION
& RESEARCH
(CDER)

Direct Communication Services

DDI/SBIA staff respond to inquiries from the public

No ‘small business qualifications’
Anyone can contact SBIA

In 2018, SBIA responded to:

3,686 Emails
5,994 Phone Calls
10 Correspondence/Letters
20 Social Media Messages
Total: 9,710

Workshops and Conferences

Webinars

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)

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

Accompanied by audio podcast downloads

www.fda.gov/cdersbiachronicles

PRESENTATIONS

Annual Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Conferences

National Institutes of Health Commercial Accelerator Program (NIH CAP)

EXHIBITS

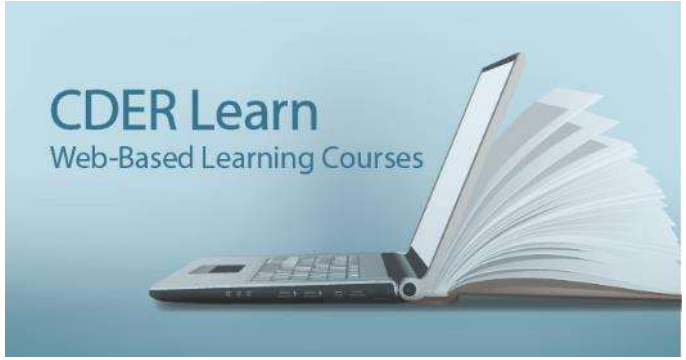
The Association of Clinical Research Professionals

Drug Information Association

Society of Clinical Research Associates

CDERLearn

Web-based learning tutorials 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 – Part 1

GDUFA Self-Identification (SPL) Submission – Part 2

The Small Biz Buzz

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

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Get Email Updates: Drugs Small Business and Industry Assistance

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- CDER Small Business & Industry Assistance (SBIA)
- About CDER Small Business and Industry Assistance (SBIA)
- CDER SBIA Learn: Webinars, Conferences, Trainings & Upcoming Events

2019 Regulatory Education for Industry (REdI) Event Calendar

May 9	May 29-30	Sept 25-26
Webinar: Introduction to FDA MyStudies Platform 10 AM – 3 PM EDT	REdI Annual Conference Boston, MA	Complex Generic Drug Product Development Workshop College Park, MD

- **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**
- **Post Marketing Activities**

www.fda.gov/cdersbia

CDER SBIA Learn: Webinars, Conferences, Trainings & Upcoming Events

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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**

www.fda.gov/cdersbialearn

Challenge Question

How can one stay in the know about upcoming SBIA conferences, webinars, and news?

A. Sign up for the Small Biz Buzz email updates via www.fda.gov/cdersbia.
B. Bookmark www.fda.gov/cdersbia and continually check the Event Calendar.
C. Follow the Small Business and Industry Assistance LinkedIn page via the link at www.fda.gov/cdersbia.
D. All of the above

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