Center for Drug Evaluation and Research (CDER)
Small Business Assistance Program

The Information Source for Regulated Domestic and International Small Pharmaceutical Business
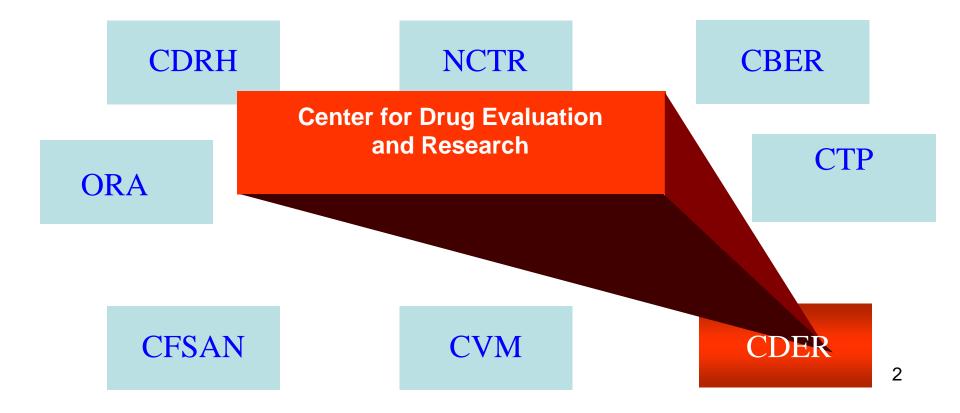
CAPT Brenda Stodart, USPHS
Program Director
CDER Small Business Assistance
Division of Drug Information
Office of Communications
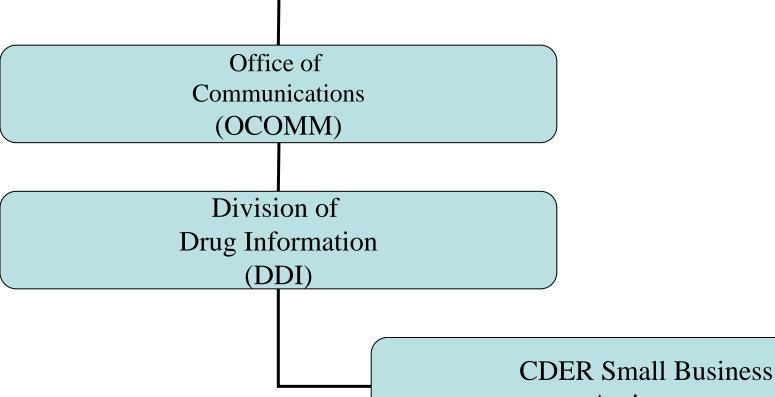**Center for Drug Evaluation and Research**
Food and Drug Administration

Organizational Structure

CDER

Office of
Communications
(OCOMM)

Division of
Drug Information
(DDI)

CDER Small Business
Assistance

Mission

- **Food and Drug Administration (FDA)**

  Protect and advance the public health of the Nation

- **Center for Drug Evaluation and Research (CDER)**

  Promote and protect the health of Americans by assuring that prescription and over-the-counter drugs are safe and effective

- **CDER Small Business Assistance Mission**

  Promote productive interaction with regulated industry by assisting regulated domestic and international small pharmaceutical business who are seeking timely and accurate information relating to development and regulation of human drug products

Definition of Small Business

- The term small business is defined as a business that has no more than 500 employees, including affiliates.

- An affiliate is a business entity that has a relationship with a second business entity if one business entity controls, or has the power to control, the other business entity, or a third party controls, or has the power to control, both entities. (Section 735(9) of the Food, Drug &Cosmetic Act (FD&C Act)).

Resources

- Website

- Widget and Online Survey

- ListServ and Twitter

- FDA Basics for Industry

- Educational Outreach

- Inquiries

Widget and Online Survey

- Widget

- Online survey

Small Business Assistance

Search Small Business Assistance

[   ] go

The Information Source for Regulated Domestic and International Small Pharmaceutical Business

For easier access to CDER Small Business Assistance download our widget

Small pharmaceutical business is integral in bringing innovative medical products to the U.S. marketplace. The purpose of this website is to support the CDER Small Business Assistance Program's mission of promoting productive interaction with regulated industry by assisting regulated domestic and international small pharmaceutical business seeking timely and accurate information relating to development and regulation of human drug products.

In order to collect valuable information and better improve our services, we ask that you PLEASE TAKE OUR SHORT SURVEY ⌕. Please complete the survey only once.

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Twitter, FDA Basics for Industry and ListServ

Spotlight

- Follow FDA Drug Info on Twitter
- FDA Basics for Industry
- CDER Small Business E-mail Updates
- Workshops and Webinars
- CDERLearn

FDA Basics for Industry

➢ Contact portal

➢ Navigation guide

➢ A – Z index

➢ Frequently Asked Questions

➢ Educational Resources

Educational Outreach

- Webinars

- Workshops

- CDERLearn

- Industry meetings

- Exhibits

- Presentations

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Educational Outreach- CDERLearn

+ The Past, Present, and Future of FDA Human Drug Regulation

+ Bringing an Unapproved Drug Into Compliance

+ The FDA Process for Approving Generic Drugs

+ An Introduction to the Improved FDA Prescription Drug Labeling

Inquiries

- Determination of regulatory status (is it a drug, device, food)
- Financial Incentives
- Pre-IND meetings
- Identify appropriate review division and facilitate interaction with SB entity and division
- GMP issues

- Imports
- Labeling
- OTC Monographs
- Medical gases
- Pediatric exclusivity
- Repackaging
- Orphan drug designation
- Unapproved drugs
- Registration and listing queries
- Clinical studies

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Financial Incentives

- Prescription Drug User Fee Act (PDUFA) user fee waiver: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm

- Guidance for Industry User Fee Waivers, Reductions, and Refunds for Drug and Biological products (03/11/11) http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079298.pdf

  - Public Health
  - Barrier to Innovation
  - Small Business

Financial Incentives - continued

➤ Under section 736(d)(1)(D) of the Act, an applicant is eligible for a waiver of the *application fee*

if the applicant is a small business submitting its first human drug application to the Agency for review and does not have another product approved under a human drug application and introduced or delivered for introduction into interstate commerce.

An applicant is eligible for a small business waiver when:

Financial Incentives continued

- The applicant employs fewer than 500 employees, including employees of affiliates;

- The applicant does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce; and

- The applicant, including its affiliates, is submitting its first human drug application.

To qualify for a small business waiver, an applicant must meet all of these criteria.

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069943.htm

http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093376.htm

Financial Incentives <small>continued</small>

- **Applications**
  - ➢ Requiring clinical data

  $1,542,000

  - ➢ Not requiring clinical data

  $771,000

- Establishments

  $497,200

- Product

  $86,520

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Pre-IND Meeting

➢ Identifying and avoiding unnecessary studies
➢ Ensuring that necessary studies are designed to provide useful information
➢ Gaining FDA support for a proposed strategy
➢ Minimizing potential for clinical hold
➢ Providing opportunity for creative exchange of ideas
➢ Obtaining regulatory insight
➢ Minimizing costs
➢ Clearly defining endpoints and goals of the development program
➢ Allowing early interactions/negotiations with FDA

Pre-IND Meeting Request

➤ Listing of specific questions categorized and grouped by discipline, for example, chemistry, manufacturing, and controls (CMC), pharmacology/toxicology, clinical pharmacology and biopharmaceutics, and clinical investigations

➤ Quantitative composition (all ingredients by percent composition) of the drug proposed for use in the study to be discussed

➤ Dosing regimen, including concentration, amount dosed, and frequency and duration of dosing if known

Pre-IND Meeting Packet

- Provides the historical background information on the chemical development concept
- Provides information on the active ingredient
- Provides an initial clinical and preclinical development strategy
- Provides future development strategy including product scale-up and final formulation, and animal and clinical studies proposed in support of an NDA
- Provides FDA with a clear and concise overview of the planned development program
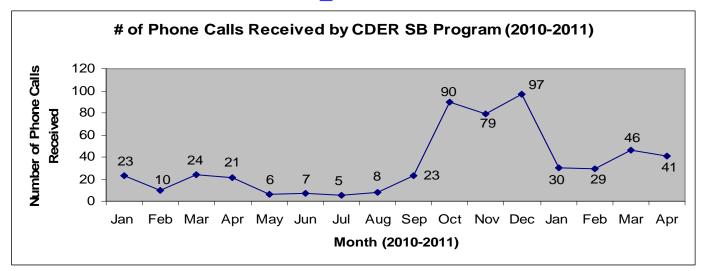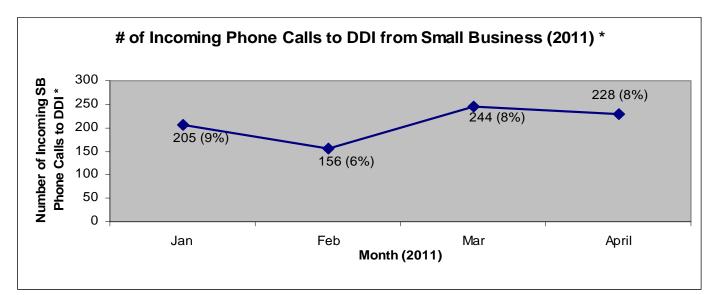- Allows FDA the opportunity to comment on a proposed program of development

Audience*

+ Demographics
  - 95% Small Business
    (other: consultants, large pharma, etc.)
  - 56% of the companies employ <10 people

+ Location
  - Most of clientele is in the U.S.
  - Global reach: India, China, Mexico, Switzerland, Spain, Sri Lanka, Canada, Jordan, Chile.

+ Industry experience
  - 39% have submitted or are in the process of submitting a drug application to FDA
  - 87% do not have an FDA approved drug application

* This information was extracted 3/2011 from a survey posted on our SB website, and may not be reflective of our entire audience
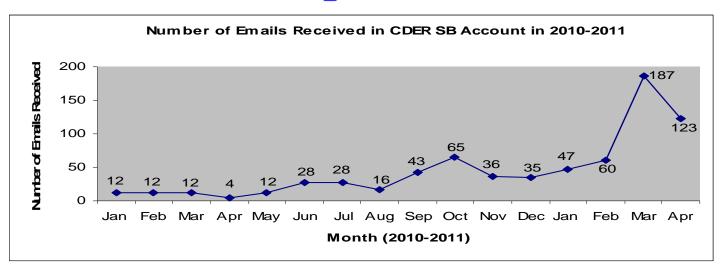
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Accomplishments

# of Phone Calls Received by CDER SB Program (2010-2011)

# of Incoming Phone Calls to DDI from Small Business (2011) *

22

Accomplishments

Number of Emails Received in CDER SB Account in 2010-2011

# of Emails Received in DDI account from Small Business (2011)

* % indicates percentage of total emails received by DDI

Goals

- Increase inquiries to SB account by 50% in 2011

- Increase global audience and presence

- Webinars – one per month

- Workshops – at least 2 per year

- Develop CDERLearn courses (2 per year)

- Increase visibility

  – Speaking at Industry conferences

  – Networking within and outside of FDA

  – Holding workshops at the 5 Regional Offices

CDER Small Business Contact

Telephone – 1.866.405.5367 or
          301.796.6707

Web-Site - http://www.fda.gov/smallbusinessdrugs

Email – CDERSmallBusiness@fda.hhs.gov

Mail - 10001 New Hampshire Ave.
      Hillandale Building, 4th Floor
      Silver Spring, MD 20993 -0002

- **Sign up for the CDER Small Business Listserv on our website**

- **Download our Widget from website**