

# FDA/CDER SMALL BUSINESS CHRONICLES

APRIL 12<sup>TH</sup>, 2012



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industry with useful  
information to assist  
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regulation*

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## Welcome

Everyone, even the President of the United States, is talking about small business. And we at the Center for Drug Evaluation and Research (CDER) truly believe that small business is integral to the development of innovative drug products.

Imagine landing on this very computer screen 50 years from now to peek in on the progress of medicine. If medicine continues to advance at the current pace, illnesses like cancer, heart disease, and diabetes will hopefully be ancient history to future generations. In the past fifty years, amazing new life-saving drugs have become available, such as insulin to manage diabetes; antivirals to dramatically increase the life expectancy of those living with HIV and AIDS; drugs to dissolve clots and save the lives of those suffering heart attacks; and the list goes on and on.

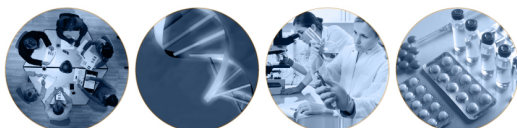
Last year, we attended the 13<sup>th</sup> Annual Small Business Innovation Research & Small Business Technology Transfer conference where we had the opportunity to meet with many inspirational and brilliant small business entrepreneurs and scientists, and speak with them about how to advance their ideas and products through the FDA review process.

You may have a great idea for a drug that can cure cancer, but the development process from idea to marketed product in the U.S. may take many years [see [From Fish to Pharmacies: A Story of Drug Development](#).] In the end, not all will succeed, but those that do possess the key to the future of public health.

This monthly newsletter provides industry with useful information to assist in all aspects of drug marketing and regulation. Issues are delivered via listserv every month. If you have topics of interest, please email us at [CDERSmallBusiness@fda.hhs.gov](mailto:CDERSmallBusiness@fda.hhs.gov).

## Inside This Issue

- 1 Welcome to CDER Small Business Chronicles
  - a. Small Business Innovation
  - b. CDER Small Business Assistance Program
- 2 Upcoming Events
  - a. **4/16:** Small Business Webinar on Time and Extent Applications for Nonprescription Drug Products
  - b. **5/11:** [Public Hearing on Draft Guidances Relating to the Development of Biosimilar Products](#)



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

## How Can We Help You?

As stated in FDA's '[Driving BioMedical Innovation](#)' report, FDA is strengthening its outreach to small business. The CDER [Small Business Assistance Program](#) in the Office of Communication's [Division of Drug Information](#) is a thriving program geared towards helping regulated small pharmaceutical companies.

The Small Business Assistance Program's mission promotes 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 other words, we are here to help **you**, small pharmaceutical business, be successful.

The small business webpage [<http://www.fda.gov/smallbusinessdrugs>] provides links to most of the information you are seeking from FDA.

If you are unable find the information you seek, contact us via email or phone (see footer for details) for assistance.

In addition to answering inquiries from industry, we offer free [webinars](#), [online courses](#), and [workshops](#). We also maintain a listserv through which we send this monthly newsletter, along with information of interest to small business such as new guidances, meetings, and webinars, at least twice a month. Information about these offerings is posted in the Spotlight box on our website.



Consider copying our widget (shown to the left) from the CDER Small Business Assistance webpage to yours for quick links to small business resources.

If you are developing a non-drug product such as a device, vaccine, non-therapeutic biologic, animal product, food, or cosmetic, note that each of FDA's Centers has its own [Small Business Assistance Contacts](#). Please utilize these contacts.

As always, we are open to ideas on how we can better meet your needs.

Until next time...

The CDER Small Business Assistance Team

*Coming soon:*

*Issues of FDA/CDER Small Business Chronicles will soon be posted on our webpage*

