

**Section 1128 of the Food and Drug  
Administration Safety and Innovation Act  
(FDASIA)  
Small Business Report to Congress**

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## Overview

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The U.S. biomedical industry plays an essential role not only in the health of individuals and communities, but also in the health of the overall economy. Drug and biologic companies employ more than 650,000 workers, support a total of 4 million jobs across the country, and contribute more than \$917 billion in economic output on an annual basis, according to a study by the Pharmaceutical Research Manufacturers of America (PhRMA).<sup>1</sup> The United States also enjoys a robust medical device industry, which employs over 400,000 workers nationwide with sales of \$147.6 billion.<sup>2</sup> Taken together, the hundreds of thousands of medical products in use every day serve a vital role in the health care system, providing technologies that protect, sustain, and enhance the quality of life for patients and consumers.

Small businesses account for much of this activity. It is widely known that the medical device industry is largely made up of small companies—the U.S. Department of Commerce estimates that 62 percent of medical technology firms have fewer than 20 employees and only 2 percent have more than 500 employees.<sup>3</sup> But small companies are an increasingly important factor in the pharmaceutical sector as well. The new drug research and development paradigm is shifting rapidly from traditional big pharmaceutical companies to venture capital-backed small companies.<sup>4</sup> According to a Food and Drug Administration (FDA or the Agency) analysis, in calendar year 2012, 42 percent of the new drug approvals were from emerging sponsors, primarily small companies, compared to 37 percent in 2011.<sup>5</sup>

Small venture-backed companies are developing innovative, even transformative, drugs, biologics, and devices that spawn new product sectors that contribute to the growth of the biomedical industry. For example, three new drugs approved by FDA in 2012 for diseases with no prior approved therapies were developed by small businesses. The importance of small companies is likely to grow in the age of personalized medicine because of their potential interest in developing products targeted to individual patients or small groups of patients.

Given the important role of small businesses in medical product development and in the future of the biomedical industry, FDA recognizes how important it is that small firms can successfully navigate the regulatory landscape.

On July 9, 2012, the President signed into law the [Food and Drug Administration Safety and Innovation Act](#) (FDASIA) (Public Law 112-144). Section 1128 of Subtitle C of Title XI of

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<sup>1</sup> PhRMA. *2013 Profile: Biopharmaceutical Research Industry*. p. 20.

<http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf>. April 2013. Accessed June 12, 2013.

<sup>2</sup> AdvaMed Advanced Medical Technology Association. *The American Medical Technology Industry and International Competitiveness*. <http://advamed.org/res/32/background-the-american-medical-technology-industry-and-international-competitiveness>. August 15, 2011. Accessed June 12, 2013.

<sup>3</sup> U.S. Department of Commerce, unpublished data, 2002.

<sup>4</sup> Jenkins, John K. FDA. Presentation. FDA/CMS Summit. *CDER New Drug Review: 2012 Update*. Page 29. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM331454.pdf>. December 10, 2012. Accessed June 12, 2013.

<sup>5</sup> Jenkins, John K. FDA. Presentation. FDA/CMS Summit. *CDER New Drug Review: 2012 Update*. Page 31. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM331454.pdf>. December 10, 2012. Accessed June 12, 2013.

FDASIA<sup>6</sup> requires the Commissioner of Food and Drugs to submit a report to Congress on FDA programs to assist small businesses, specifically:

- FDA's small business offices;
- Partnership efforts between the FDA and the Small Business Administration;
- Outreach efforts to small businesses;
- Assistance to small business through the Orphan Drug program;
- FDA's unsolicited and solicited grant programs; and
- Barriers small businesses encounter in the drug and medical device approval process.

This report responds to this mandate and will focus on activities for FDA's three human medical product Centers: the [Center for Biologics Evaluation and Research](#) (CBER), the [Center for Drug Evaluation and Research](#) (CDER), and the [Center for Devices and Radiological Health](#) (CDRH).

## **Identifying Barriers for Small Business**

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Small biomedical companies have a unique set of needs compared to their larger counterparts. By nature of their size, small businesses face challenges ranging from the science of medical product development to meeting the necessary requirements of getting that product to market. Small companies are also less likely to have extensive capacity in these areas internally.

As FDA engages with small businesses, both proactively and in response to questions, a fairly consistent cadre of issues persists. These challenges for small business can include:

- limited financial resources;
- not understanding how to effectively engage with FDA staff or utilize available resources;
- lack of experience in product development (e.g., clinical trial design, scientific standards); and
- lack of experience with the marketing application process.

One of FDA's priorities is better identification and understanding of the issues that small businesses must surmount. The Agency continues to take dedicated steps to assist small businesses in overcoming identified barriers: building in fee reductions or financial incentives for firms to utilize; focusing efforts to enhance access and information to make the regulatory process easier and more transparent; targeting education and training for small business needs; developing innovative approval pathways for products; and engaging with external groups to facilitate partnerships and greater outreach to small companies.

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<sup>6</sup> See Appendix A for full text of Section 1128.

## **FDA Takes an Active Role in Problem-Solving for Small Business**

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Over the past several years, FDA has continued to build upon its existing resources to help small businesses succeed, most of which are focused on helping these companies understand regulatory review requirements, assisting them with finding information regarding FDA law, and pointing them to helpful resources such as guidance documents and online training.

### **I. Financial Assistance and Incentives**

One of the biggest barriers for small businesses relates to having the capital and resources to develop and bring products to market. FDA takes into account the financial burden of fees and offers several opportunities for fee reductions. The Agency also provides incentive and grant programs to help firms, particularly small businesses, get their products developed, to market, and into the hands of those who need them.

#### **A. Small Business User Fee Discounts**

##### *1. Drugs and Biologics*

The [Prescription Drug User Fee Amendments](#) (PDUFA) to the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act or the Act) provides a waiver specifically for a small business. Under [section 736\(d\)\(1\)\(D\) of the Act](#), an applicant is eligible for a waiver of the application fee (for fiscal year (FY) 2013, the application fee is \$1,958,800), if the applicant meets certain criteria.

An applicant is eligible for a small business waiver when:

- 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.

After an applicant or its affiliate is granted a small business waiver and submits its first human drug application, the applicant cannot receive another small business waiver. That means that the applicant or its affiliate is not eligible to receive a small business waiver for any subsequent human drug application or a supplement to an application (see [section 736\(d\)\(4\)\(B\) of the Act](#)).

Unlike the application fee, there is no specific provision in the Act for a waiver or reduction of product and establishment fees for small businesses (for FY 2013 the product fee is \$98,380 and the full establishment fee is \$526,500). However, small businesses may apply for a waiver or reduction of product and establishment fees through the public health or barrier-to-innovation waiver provisions. For a full discussion on public health and barrier-to-innovation waivers, see FDA's guidance for industry titled [User Fee Waivers, Reductions, and Refunds for Drug and Biologic Products](#).

Further, although not specifically designated for a small business, there is an orphan exemption for product and establishment fees for certain entities that meet a financial test. Under [section 736\(k\) of the Act](#), a drug product designated under [section 526 of the Act](#) for a rare disease or

condition, and approved under [section 505 of the Act](#) or [section 351](#) of the [Public Health Service Act](#), is exempt from the product and establishment fees if it meets the public health requirements contained in the Act, as such requirements are applied to requests for waivers of product and establishment fees. In addition, the applicant must have less than \$50 million in gross worldwide revenue during the year preceding the request for exemption.

Pursuant to the new [Biosimilar User Fee Act](#) (BsUFA), FDA will waive the application fee for the first biosimilar biological product application submitted by a small business or its affiliate. To be eligible for the waiver, the small business or affiliate must meet all of the following criteria:

- Fewer than 500 employees, including employees of affiliates;
- Does not have a product that has been:
  - approved under a [PDUFA](#) human drug application or a biosimilar biological product application, and
  - introduced or delivered for introduction into interstate commerce;
- The applicant, including its affiliates, is submitting its first biosimilar biological product application.<sup>7</sup>

The FY 2013 fee for a biosimilar biological product application requiring clinical data is \$1,958,800 minus the cumulative amount of previously paid biosimilar biological product development (BPD) fees for the product that is the subject of the application. Please refer to the [BsUFA website](#) for more information.

No small business reduction or waiver exists in the new [Generic Drug User Fee Amendments \(GDUFA\) program](#). Unlike brand manufacturers, the majority of generic companies are small businesses. A fee waiver was considered during negotiations and rejected because it would have diminished the number of companies required to pay the fees, which in turn would have raised the fees for the fee-paying companies. The FY 2013 fee for an abbreviated new drug application (ANDA) is \$51,520. Please refer to the [GDUFA website](#) for more information.

## 2. *Medical Devices*

Regarding medical devices, small businesses receive financial benefits in the form of substantially reduced user fees for medical device submissions, under statutorily defined conditions ([Section 738\(d\) and\(e\) of the FD&C Act](#) and FDA guidance, "[FY 2013 Medical Device User Fee Small Business Qualification and Certification](#)"). Specifically, qualified small businesses may pay a reduced fee for the following medical device submission types: premarket approval (PMA) application, biologics license application (BLA), product development protocol (PDP), premarket report (PMR), panel-track PMA supplement, BLA efficacy supplement, 180-day PMA supplement, real-time PMA supplement, 510(k) premarket notification, 30-day notice, 513(g) request for classification information, and annual fee for periodic report on a class III device.

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<sup>7</sup> These additional requirements are in section 744H(c)(3).

Of note, the standard fee for a PMA, PDP, PMR, or BLA is \$248,000 (for FY 2013). The small business fee for FY 2013 is reduced to \$62,000.<sup>8</sup> The standard fee for a 510(k) premarket notification for FY 2013 is \$4,960, and the small business fee is reduced to \$2,480.<sup>9</sup> In addition, small businesses with gross receipts or sales of \$30 million or less may qualify for a one-time waiver of the fee for their first PMA, PDP, PMR or BLA.

## **B. Grant Programs**

FDA offers grants for development of products aimed at small populations, both human and animal, and applicants to these classes of grants are often small businesses. Additional information about FDA grant programs, including a breakdown of award amounts by year, is located in Appendix E.

### *1. Unsolicited Grant Program*

Unsolicited grants are awarded to organizations that applied for funding from the Agency but did not apply in response to a Funding Opportunity Announcement. FDA does not generally award unsolicited grants as a matter of practice, but businesses may apply by contacting the [Office of Acquisition & Grants Services](#).<sup>10</sup>

### *2. Solicited Grant Program*

Nearly all grants awarded by FDA are considered to be solicited as they are awarded to applicants who have responded to a [Funding Opportunity Announcement](#). FDA welcomes applications by small businesses to its solicited grants program. As of May 31, in FY 2013, FDA solicited applications for 14 grants that do not specify business size as a criterion for eligibility.<sup>11</sup> FDA does not track or collect data on the number of small businesses that apply for these grants because the solicited grants are open to all organizations.

While small businesses are welcome to apply for grants that can be sought by a broader variety of organizations, FDA has also participated in the [Small Business Innovation Research \(SBIR\) Program](#) since FY 2008, which solicits grant applications specifically from small businesses. As a way to strengthen scientific research in U.S. small businesses, Congress passed the [Small Business Innovation Development Act](#) in 1982.<sup>12</sup> The Act requires federal agencies with extramural research and development budgets over \$100 million to administer SBIR programs. These programs are funded by annual set aside funds for small companies to conduct innovative research or research and development that have potential for commercialization and public benefit.

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<sup>8</sup> FDA. *PMA Review Fees*. FDA website.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm>. Last updated September 28, 2012. Accessed June 12, 2013.

<sup>9</sup> FDA 510(k) website:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm>

<sup>10</sup> See Appendix E for Office of Acquisition & Grants Services contact information.

<sup>11</sup> Grants.gov Database. <http://www.grants.gov/>. Accessed May 31, 2013.

<sup>12</sup> Public Law 97-219

From FY 2008 to May 31, 2013, FDA received 167 SBIR grant applications.<sup>13</sup> Since FY 2008, FDA has awarded 36 SBIR grants.<sup>14</sup>

### **C. Waivers and/or Exclusivity**

Although the majority of incentives offered for medical product development are not exclusive to small businesses, many small firms develop innovative products for niche areas that fall under broader categories discussed below. Therefore, many small businesses have opportunities to benefit from these incentives.

#### *1. Orphan Medical Products*

The mission of FDA's [Office of Orphan Products Development](#) (OOPD) is to assist and encourage the identification, development, and availability of safe and effective products for people with rare diseases/disorders. OOPD administers the major provisions of the [Orphan Drug Act](#), which provide incentives for sponsors to develop products for rare diseases, generally defined as affecting fewer than 200,000 people in the United States.

The [Orphan Products Grants Program](#) in OOPD, with an annual budget of approximately \$14 million, supports clinical development of products, including drugs, biologics, medical devices, and medical foods, for use in rare diseases and conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. This program provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. In addition, OOPD administers the [Pediatric Device Consortia Grant Program](#), which provides funding to develop nonprofit consortia to facilitate pediatric medical device development.

Present data recorded by FDA cannot expeditiously be sorted by the size of the business to produce a figure of the number of small businesses that submit grant applications. FDA is able to assess retroactively the number of OOPD grants awarded to small businesses. Since 2008, OOPD awarded 30 of the 92 OOPD grants to small businesses<sup>15,16</sup>. As of May 31, 2013, OOPD reports that 15 of these grants made to small businesses are presently active.<sup>17</sup>

#### *2. Pediatric Products*

Under the [Best Pharmaceuticals for Children Act](#) (BPCA), FDA may issue a Written Request for studies that may produce health benefits in the pediatric population. If the holder of the Written Request agrees to the request, completes the studies using appropriate formulations for each pediatric age group, and submits the studies within a requested timeframe, FDA may grant additional marketing exclusivity. Under FDASIA, BPCA was permanently reauthorized.

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<sup>13</sup> See Appendix E for more information on SBIR grants.

<sup>14</sup> See Appendix E for more information on SBIR grants.

<sup>15</sup> Orphan Products Grant Program Database. <http://www.accessdata.fda.gov/scripts/opdlisting/oopdgrants/>. Accessed May 31, 2013.

<sup>16</sup> Small businesses status determined using data from the U.S. Small Business Administration

<sup>17</sup> Orphan Products Grant Program Database. <http://www.accessdata.fda.gov/scripts/opdlisting/oopdgrants/>. Accessed May 31, 2013.



The Agency also offers additional training for firms, no matter the size, that are interested in developing pediatric products. For example, CBER has a webinar regarding Pediatric Clinical Trials for cellular, tissue, and gene therapies to assist industry with the clinical testing of these products.<sup>18</sup>

For assistance in navigating CDRH's pediatrics device programs, the Chief Pediatric Medical Officer in CDRH serves as a resource to all device developers who require guidance in their quest for pediatric device approval or clearance. Any PMA, premarket report, or 510(k) premarket notification submission that is intended solely for a pediatric population is exempt from user fees.

### *3. Neglected Tropical Disease Priority Review Vouchers*

The [Neglected Tropical Disease \(NTD\) Priority Review Program](#) provides for a voucher that is awarded at the time of approval of certain products that treat a designated NTD. These can subsequently be redeemed for a priority review of a drug submitted at a later time, for any indication.<sup>19</sup>

### *4. Pediatric Rare Disease Priority Review Vouchers*

The [Rare Pediatric Disease Priority Review Voucher Incentive Program](#) provides for a voucher that is awarded at the time of approval of certain products that are intended to prevent or treat rare pediatric diseases. The voucher may subsequently be redeemed for a priority review of a drug submitted at a later time, for any indication. In addition, the holder of a priority review voucher under this program may transfer (including by sale) the entitlement to such voucher. Furthermore, there is no limit on the number of times a voucher under this program may be transferred before such voucher is used.

### *5. Generating Antibiotic Incentives Now (GAIN)*

Research and development for new antibacterial drugs has been in decline in recent decades, and the number of new FDA-approved antibacterial drugs has been falling steadily since the 1980s. During this time, the persistent and sometimes indiscriminate use of existing antibacterial drugs worldwide has resulted in a decrease in the effectiveness of these drugs. This phenomenon, known as antibacterial drug resistance or antibiotic resistance, has become a serious issue of global concern.

[Title VIII of FDASIA](#), titled, "Generating Antibiotic Incentives Now (GAIN)," was enacted to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. Among other things, GAIN added a new section to the FD&C Act that provides that a sponsor, including small firms, submitting an application for a drug that is designated a "qualified infectious disease product" may receive an additional 5 years of exclusivity to be

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<sup>18</sup> For a complete list of webinars and other events, see the links provided in Appendix D.

<sup>19</sup> See draft guidance *Tropical Disease Priority Review Vouchers*, which can be found at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf>

added to certain exclusivity periods already provided by the FD&C Act. In addition, applications for qualified infectious disease products are also eligible for priority review and fast track status.

## *6. Humanitarian Device Exemption*

An important niche area for small device firms is the development of a [Humanitarian Use Device](#) (HUD), a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year."<sup>20</sup> A [Humanitarian Device Exemption](#) (HDE) is an application that is similar to a PMA application, but is exempt from the effectiveness requirements of [sections 514 and 515](#) of the FD&C Act. FDA approval of an HDE authorizes an applicant to make a HUD. HDEs are also exempt from user fees.

## **II. Enhanced Access and Information**

In order for small businesses to understand the regulatory requirements for specific products they develop, they need to have ready access to accurate and relevant information and/or access to FDA experts who can respond to their questions and help them navigate those requirements and the Agency. Toward this end, FDA has several programs in place to assist small businesses.

### **A. Dedicated Small Business Assistance Programs**

Each of the medical product Centers has a small business arm, designed to provide technical assistance and education to small companies by holding meetings to hear the views and perspectives of small businesses, conducting educational workshops, developing educational materials, and providing an accessible, efficient channel through which small businesses can acquire information from FDA. In addition to expertise at FDA headquarters, there is a small business representative who covers the Northeast Region to provide additional assistance. Outside the Northeast Region, small businesses may contact the small business points of contact in each FDA Center. Contact information for each of the small business offices and the Northeast Regional office is in Appendix B.

While the majority of these offices focus on small businesses, their resources and outreach activities are not restricted to small businesses alone. FDA staff are constantly searching for methods to improve the information provided externally for the industry, while also serving as a "small business voice" within the Agency. Activities from these small business offices include sharing new and relevant information via industry listservs, publishing newsletters, hosting webinars and workshops, and responding to telephone and email inquiries.

For example, CDRH created the [Division of Small Manufacturers, International and Consumer Assistance](#) (DSMICA), as mandated by the Medical Device Amendments of 1976, to provide technical and regulatory assistance to small manufacturers to help them comply with the

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<sup>20</sup> [21 CFR §814.3\(n\)](#)

regulatory requirements for medical devices.<sup>21</sup> CDRH has seen continuous growth in the number of business inquiries and responds to over 1,000 emails and 2,000 phone calls each month, a majority of them from small firms.

CDER's [Small Business Assistance Program](#) was restructured in 2009. For 2012, the office fielded over 1,500 emails and 4,100 phone calls, and managed an active listserv with over 61,000 subscribers.

CBER's [Manufacturing Assistance Program](#) fielded a total of over 2,000 calls, almost 1,200 e-mails and letters, and managed a listserv with approximately 41,000 subscribers during 2012, primarily from small or start-up firms.

## **B. Access to Online Resources**

While FDA has a robust website overflowing with resources for industry, wading through the multitude of documents can be overwhelming for a company new to the Agency. To make it simpler, FDA launched "[FDA Basics for Industry](#)" in January 2011, a program designed to improve communication between FDA and industry by making basic information about the regulatory process more accessible to companies in a user-friendly format. Information on the website includes:

- How to determine if a product is regulated by FDA;
- Information about the product application and petition review process;
- How to register facilities and products with the Agency;
- How to submit comments to open dockets; and
- Information about FDA's Office of the Ombudsman and the dispute resolution process.

"FDA Basics for Industry" also includes a Training and Education Portal where industry stakeholders are able to participate in educational tutorials offered by FDA Centers. To date, "FDA Basics for Industry" has been viewed over 1.1 million times.

In addition, each of the small business offices within the Centers have organized a website to provide access to the most frequently used and requested content for small businesses, including information on approval pathways, Good Clinical Practices, current Good Manufacturing Practices, information on importing and exporting products, and Frequently Asked Questions and Common Complaints.

Specifically, CDRH maintains a popular "[Device Advice](#)" site, a comprehensive web-based regulatory assistance program, which features hundreds of pages of resources, references, and information that is designed to assist the regulated industry, including small businesses, with learning about the various medical device programs. CBER will soon introduce a web application to submit Investigational New Drug (IND) applications specifically designed for sponsors with limited regulatory experience or IT resources. On CDER's [site](#), the IND and NDA

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<sup>21</sup> FDA. *Answering Questions*. FDA website. <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm142674.htm>. Last updated June 18, 2009. Accessed June 12, 2013.

or BLA review processes, timelines, and types of regulatory communications provided as, useful resources for small firms needing to navigate the drug or biologic approval process.

FDA also developed a [Small Business Guide](#), which is posted to the Agency's website, [www.fda.gov](http://www.fda.gov), and serves as a helpful starting point for small firms seeking to produce commodities potentially regulated by the FDA.

### **C. Early Communications with FDA Experts**

For the medical product industry, one of the central components of success in bringing a product to market is early interaction with FDA.

An independent analysis of FDA's first cycle review performance for new drug and biological products commissioned by FDA showed that [End-of-Phase 2](#) meetings have a positive impact on first-cycle approval rates.<sup>22</sup> A different preliminary analysis performed by CDER demonstrated that the average clinical development time of new drugs that were approved with the benefit of pre-IND meetings was shorter compared to approved drugs for which no pre-IND meeting was held.<sup>23</sup> This time and resource savings is especially critical to small businesses.

For medical devices, CDRH encourages early communications between the Center and sponsors, especially for sponsors who intend to file a PMA application for a high-risk device and who have little to no experience with FDA or who are proposing to study new technologies or new uses for existing technologies. Early interaction with FDA helps to increase an applicant's understanding of FDA requirements, regulations, and guidance documents, and allows FDA personnel to familiarize themselves with the new technologies. Increased interaction between FDA and applicants helps to speed up the regulatory process and minimize delays in the development of useful devices intended for human use.

FDA's [Rare Disease Program](#) engages with small businesses, even individual researchers, early in the drug development and application process. For original commercial IND applications submitted to CDER, around 5-10 percent of such applications are for rare diseases, and most of these are filed by small firms. Much of the time spent by FDA with these firms focuses on what science is needed for an application, such as the basic toxicology data needed to start any drug trial. Although both a benefit to the rare disease community, as well as small firms developing products in this field, this type of engagement by FDA is labor-intensive because it requires experienced staff to hold multiple conversations or meetings with a particular company. Since drug development progresses is a multi-step process, these interactions occur over many years at different stages of development.

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<sup>22</sup> Booz Allen Hamilton. *Independent evaluation of FDA's first cycle review performance – retrospective analysis final report text*. FDA website. <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119469.htm#execsum>. January 2006. Accessed May 30, 2013.

<sup>23</sup> Pariser A. *Early communication: A key to reduced drug development and approval times*. FDA website. <http://blogs.fda.gov/fdavoices/index.php/2013/02/early-communication-a-key-to-reduced-drug-development-and-approval-times/>. February 6, 2013. Accessed May 30, 2013.

The broader biomedical industry also recognizes the importance of early meetings. As part of the reauthorization of PDUFA for FYs 2013-2017 included in FDASIA, a new [Enhanced Communication Program](#) was initiated. This program promotes innovation and transparency between the industry and FDA for drug and biologic applications, and is a complement to both CBER and CDER's Small Business Assistance Programs. Enhanced Communication Liaison staff from FDA do not serve as consultants to the industry, but rather serve as facilitators, steering them to the right Agency resources. When a breakdown in communication occurs, liaison staff assists in evaluating the issues, determining next steps, and facilitating a resolution.

Also as part of this program, FDA is identifying Agency staff to train on best practices for enhanced communication.

#### **D. Access to Ombudsmen**

All of the medical product Centers have a designated ombudsman who is an excellent resource for small businesses. These individuals work to resolve problems and issues occurring within their own Center. If that effort is unsuccessful, or if intercenter issues are involved, the matter will go to the [FDA Ombudsman's Office](#). The offices are in close communication with common goals of efficient dispute resolution. Contact information for each ombudsman is in Appendix C.

### **III. Targeted Education and Training**

As FDA continues to engage with small businesses and gather feedback, the Agency recognizes the importance of education and training, specifically targeted to the needs of small companies. The small business offices in the Centers assess the types of questions coming into their phone lines and emails to identify knowledge gaps and develop relevant, up-to-date content. As a result, the Agency has prioritized both live and online training based on some of the most common issues small businesses face, as well as on new guidances or regulations that impact these firms. Not only is this content relevant to the needs of small firms, it is also free and readily accessible—two important components for companies without significant resources.

#### **A. Regional Face-to-Face Training**

In 2012, CDER and CDRH collaborated to launch the [FDA Small Business Regulatory Education for Industry Conference](#). This two-day, dual-track workshop had over 350 attendees at both its Chicago, IL, and Washington, D.C., events. The Chicago site selection was based upon a review of the geographic concentration of FDA-registered small facilities and the need to get out and engage face-to-face with small businesses. Feedback from the attendees was extremely positive, and with the 2013 conference slated for Dallas, TX, the Agency hopes to turn this into an annual training for small medical product companies.

#### **B. Seminars and Webinars**

To maximize resources, many key questions and issues are developed as webinars to allow for free, 24-hour access for both domestic and international small businesses.

In 2008, CDRH launched [CDRHLearn](#), a video-based training program that addresses a variety of long-standing and timely topics regarding medical device regulations, premarket, and postmarket issues. Since its foundation, over 65 online videos and training modules have been developed. For instance, the Center developed a module on the implementation of the Medical Device User Fee Act (MDUFA) III. CDRH is currently working with device trade associations to identify other topics that would be useful to include in CDRHLearn.

CDER has also launched a [CDERLearn](#) webinar program, with a series dedicated exclusively to small businesses. This content will also continue to grow over time as new topics are identified and as resources allow.

CBER launched a webinar program, titled [OCTGT-Learn](#), which first became publicly- available in 2011. Targeted toward cellular, tissue, and gene therapies, the program has 16 webinar courses available.

A list of current meetings, workshops, and/or webinars is in Appendix D.

### **C. Internal Training**

In addition to educating small businesses about the FDA regulatory process, the Agency understands the importance of educating its own staff about small business needs.

For example, the [CDRH Vendor Day Program](#) is an educational activity that allows device manufacturers to display and provide to FDA reviewers a product demonstration highlighting the scientific basis for their product. The Vendor Day is held at FDA headquarters where scientific reviewers visit industry displays that include devices and other appropriate items such as videotapes and simulators. Reviewers also have the opportunity to query manufacturers, scientists, and engineers about product design, operation, and application, providing them with useful information about the device.

CDRH has also hosted three Industry Forum events (industry presentations to CDRH staff involved in premarket review) to educate FDA staff on the “real world” challenges industry faces to design/develop, manufacture, test, work through FDA clearance/approval, and market medical devices. These events have been molded to meet the needs of FDA staff to provide better understanding of the challenges faced by companies, particularly smaller companies that may be interacting with FDA for the first time.

In 2012, CDRH launched a pilot [Experiential Learning Program](#) (ELP). ELP provides a formal training mechanism for regulatory review staff to visit research, clinical, manufacturing, and health care facilities to observe firsthand how medical devices are designed, developed, and utilized. This training is intended to provide CDRH premarket review staff with an opportunity to observe the device development life cycle and provide a better understanding of the medical devices they review, and the challenges faced throughout development, testing, manufacturing, and clinical use.

Aside from the educational benefits afforded FDA reviewers, the Vendor Day, Industry Forum, and ELP also provide for improved communications between industry and FDA and provides

both groups with a better understanding of the public health issues involved with medical device technology.

#### **IV. Innovative Development Programs and Approval Pathways**

Expediting the availability of promising medical products to patients has always been a priority for FDA, and with the passage of FDASIA, FDA is expanding its efforts to expedite development and review of therapies intended to treat patients with serious conditions.

While these pathways are open to all businesses, they hold particular promise for small businesses because once a product has been designated for a particular path, FDA works to provide sponsors with more intensive guidance on an efficient drug or device development program. By engaging with innovators much earlier, more collaboratively, and in new ways, the Agency believes it can reduce the time and cost of the entire process of bringing safe and effective technologies to patients more quickly, which translates into a big impact for small businesses.

For instance, more than half (56 percent<sup>24,25,26</sup>) of the 39 drug approvals for FY 2012 were designated in one or more categories of [Fast Track, Priority Review, and/or Accelerated Approval](#). It is important to note that while these programs can expedite the approval of a drug or biologic for a serious condition, they do not compromise the standards for safety and effectiveness.

##### **A. Breakthrough Designation**

FDASIA created the [Breakthrough Therapy](#) designation, which is intended to expedite the development of new drugs or biologics when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies for patients with serious or life-threatening conditions. Breakthrough Therapy brings an “all hands on deck” mentality to FDA when a firm has a good scientific idea backed by promising early clinical data. A sponsor that receives a breakthrough designation will usually receive more intensive guidance, beginning as early as Phase 1, as well as the involvement of senior FDA management. As of May 30, 2013, CDER received 52 breakthrough therapy designation requests, of which 20 have been granted, four have been denied, and the rest are either pending or have been withdrawn by the sponsor. CBER received six requests for breakthrough therapy designation. Five have been denied and one is pending final review/decision.

FDA recently released a draft guidance titled, “Draft Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics.” This draft guidance provides a single resource for information on FDA’s policies and procedures related to expedited programs for

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<sup>24</sup> Pariser AR, Robb M, Sherman RE. *Expedited programs for drug development and approval*. Expert Opinion on Orphan Drugs. In press, May 2013.

<sup>25</sup> Jenkins, John K. FDA. Presentation. FDA/CMS Summit. *CDER New Drug Review: 2012 Update*. Page 31. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM331454.pdf>. December 10, 2012. Accessed June 12, 2013.

<sup>26</sup> FDA. *FY 2012 innovative drug approvals*. FDA website. <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm276385.htm>. Updated December 10, 2012. Accessed may 30, 2013.

serious conditions, including fast track development, breakthrough therapy development, accelerated approval, and priority review.

## **B. Device Innovation Pathway**

The [Innovation Pathway](#) is an evolving system designed to help safe and effective breakthrough medical devices reach patients in a timely manner. The Innovation Pathway ultimately aims to shorten the overall time and cost it takes for the development, assessment, and review of medical devices, and to improve the way FDA staff and innovators work together.

Innovation Pathway 2.0 offers new and modified tools and methods to deepen collaboration between the FDA and innovators early in the process, prior to pre-market submission, with the goal of making the regulatory process more efficient and timely. For example, Innovation Pathway 2.0 focused on breakthrough devices for end-stage renal disease, and CDRH worked with three companies on the project, two of which were small firms. This is a resource-intensive undertaking for CDRH, but to date, the anecdotal evidence from these firms has been overwhelmingly positive.

The Innovation Pathway also serves as a living laboratory to test new tools and methods for breakthrough devices that may also apply to other technologies to enhance all device pre-market programs.

## **V. Engagement with External Groups**

As FDA continues to try and anticipate the needs of small businesses, it is obvious that external partnerships are a vital component, not only for the identification of barriers, but also for maximizing outreach and leveraging resources.

### **A. Small Business Administration**

FDA continues to explore a potential partnership with the [Small Business Administration](#) (SBA) to find innovative, strategic ways to strengthen and support the diverse needs of small businesses. This partnership could assist small companies to grow and compete in global markets by providing training, expert advice, and access to both FDA and SBA resources.

It could also serve as an opportunity for FDA and SBA staff to gain a greater understanding of programs that each Agency offers, and allow for cross-promotion of training and resources to small businesses, including those in the biomedical industry.

FDA and SBA are exploring how to formalize this collaboration through a Memorandum of Understanding.

### **B. The Medical Device Innovation Consortium**

The new [Medical Device Innovation Consortium](#) (MDIC) is an independent, nonprofit corporation, created by LifeScience Alley, Inc., a biomedical science trade association. The MDIC will receive input from industry, government, and other nonprofit organizations, and FDA staff may collaborate with the MDIC on MDIC-supported research and other projects.



MDIC will prioritize the regulatory science needs of the medical device community and fund projects to help simplify the process of medical device design and pathway to market. Regulatory science—the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products—is critical to the medical device industry and to public health. Advancements in regulatory science not only aim to improve how products are developed and evaluated, but also to potentially reduce the cost and time it takes for a promising device to come to market. For example, a computer model might be developed to test an implant on a virtual patient before a manufacturer spends the time and budget to study that product in a clinical trial.

MDIC will bolster the country’s investment in regulatory science research by pooling people, funding, resources, and ideas to develop new tools, models, and methods that may be utilized to better and more efficiently evaluate new devices.

### **C. FDA-NIH Engagement**

#### *1. FDA-NIH Task Force*

FDA works closely with other federal partners to engage small businesses. For example, CDER started a task force with the National Institutes of Health (NIH) to help researcher-investigators or small businesses navigate drug development. This training is in the process of being developed, and some portions are currently available on FDA’s website.<sup>27</sup> The training focuses on [emergency INDs](#) and developing regulatory training materials. The goal of this training is to familiarize research-investigators and small businesses with regulatory requirements for submitting and maintaining IND applications, and to assist these investigators with accessing available tools and information regarding INDs.

#### *2. NIH- Small Business Innovation Research Program and the Small Business Technology Transfer*

CDER also participates in the [NIH Commercialization Assistance Program](#), offered annually since 2004. This program is designed to help some of the most promising small life science and healthcare Phase II grantees develop their commercial businesses and transition their SBIR/STTR-funded technologies into the marketplace. Applicants are selected via a competitive process for a limited number of slots in the program. Feedback Sessions are face-to-face working meetings for the participant to present its Commercialization Roadmap (18-month Strategic Action Plan) to a group of mentors and life science industry experts for critique and constructive feedback.

### **D. Trade Organizations**

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<sup>27</sup> FDA. *Investigational new drug applications for clinical treatment with investigational drugs in emergency situations*. FDA website. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343022.htm>. Last updated April 3, 2013. Accessed May 30, 2013.

Some trade organizations have small business components or largely represent small businesses, for example, AdvaMed, the largest medical device trade organization, maintains the AdvaMed Emerging Growth Company Council. FDA participates in liaison meetings with trade organizations whose memberships include small businesses. These meetings help manufacturers inform the Agency of areas where they need additional FDA assistance (such as a guidance document, etc.) and allow for an open communication between the representative of small businesses and FDA.

## **Conclusion**

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Small businesses will continue to play an invaluable role in the health of the biomedical industry. FDA will maintain its focus to help small companies navigate the regulatory requirements and become a strong part of the ecosystem needed to bring important medical products to U.S. patients. The Agency continues to prioritize efforts to enhance access and information to make the regulatory process easier and more transparent, to target education and training to small business needs, to develop innovative approval pathways for medical products, and to engage external groups to facilitate partnerships and greater outreach to small companies.

## **Appendix A: FDASIA Section 1128**

### SEC. 1128. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

- (1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;
- (2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;
- (3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;
- (4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;
- (5) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;
- (6) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration; and
- (7) barriers small businesses encounter in the drug and medical device approval process.

## **Appendix B: FDA Small Business Contacts**

### **Center for Biologics Evaluation and Research (CBER)**

Faye Vigue, Branch Chief

Manufacturers Assistance and Technical Training (MATT)

1401 Rockville Pike

Suite 200N/HFM-41

Rockville, MD 20852-1448

Phone: 301-827-1800

800-835-4709

Fax: 301-827-3843

E-mail: [Industry.Biologics@fda.gov](mailto:Industry.Biologics@fda.gov)

Website:

<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ManufacturingQuestions/default.htm>

The Center for Biologics Evaluation and Research has four staff in its Manufacturer's Assistance and Technical Training Branch who handle inquiries from both large and small business biologics manufacturers.

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

Brenda Stodart, PharmD

Small Business Assistance

10903 New Hampshire Avenue

WO-51- 2201

Silver Spring, MD 20990-0002

Phone:

Toll-free and International: 866-405-5367

Local: 301-796-6707

Fax: 301-847-8715

E-mail: [CDERSmallBusiness@fda.hhs.gov](mailto:CDERSmallBusiness@fda.hhs.gov)

Website:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm>

The CDER Small Business Assistance Office has two staff dedicated to small business. CDER Small Business Assistance operates within the Division of Drug Information which has 22 staff who respond to inquiries from industry as well as consumers and health professionals.

### **Center for Devices and Radiological Health (CDRH)**

Elias Mallis, Director

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

10903 New Hampshire Ave.

WO66-4613

Silver Spring, MD 20993

Phone: 301-796-7100 or 800-638-2041

Fax: 301-847-8149

E-mail: [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)

Website: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm>

The Center for Devices and Radiological Health (CDRH) has 19 staff devoted to small business. There are 21 people employed in CDRH's DSMICA, which provides regulatory assistance to manufacturers, consumers, healthcare professionals, and patients on FDA's regulations, policy, and guidance about medical devices and radiation-emitting products, through educational programs and by responding to inquiries. A majority of the industry calls are from small businesses.

### **Center for Food Safety and Applied Nutrition (CFSAN)**

Division of Education and Communication

Communication and Coordination Branch, HFS-9

5100 Paint Branch Parkway

College Park, MD 20740-3835

Phone: 1-888-SAFE-FOOD

E-mail: [Industry@fda.gov](mailto:Industry@fda.gov)

Website: <http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/default.htm>

### **Center for Tobacco Products (CTP)**

Joanna Weitershausen

9200 Corporate Boulevard

Rockville, MD 20850-3229

Phone: 1-877-CTP-1373 (1-877-287-1373)

E-mail: [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov)

Website: <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm189635.htm>

The Center for Tobacco Products has an Office of Small Business Assistance with 4 staff who spend a majority of their time on the receipt and managing of correspondences from businesses, retailers, manufacturers, consumers, and health professionals, some of whom are small businesses. Additionally, appropriate subject matter experts from the Center are involved in the review of small business issues. Interactions can be handled through phone calls, emails, and webinars.

### **Center for Veterinary Medicine (CVM)**

Joanne Kla

7519 Standish Place

HFV-12

Rockville, MD 20855

Phone: 240-276-9300

Direct Line: 240-276-9129

E-mail: [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov)

Website: <http://www.fda.gov/AnimalVeterinary/default.htm>

CVM has two staff members who spend a portion of their time working with small businesses, as well as one additional staff member who assists in correspondence with small businesses. Because the majority of business the Center deals with are small businesses, there are no separate programs designed specifically to address small business issues. A majority of the industry inquiries received at [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov) are from small businesses.

### **Office of Regulatory Affairs (Headquarters)**

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: (301) 796-8800

Fax: (301) 595-7943

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm>

**Office of Regulatory Affairs Small Business Representative for the Northeast Region (CT, MA, NH, NY, RI, VT)**

Marilyn Rodriguez-Bohorquez

158-15 Liberty Avenue

HFR-NE17

Jamaica, NY 11433-1034

Phone: 718-662-5618

Fax: 718-662-5434

E-mail: [oranersbr@fda.hhs.gov](mailto:oranersbr@fda.hhs.gov)

ORA has one staff member who serves as the Small Business Representative for the Northeast Region.

**Office of Small Disadvantaged Business Utilization**

Teresa Lewis, Director

535-H

200 Independence Avenue SW

Washington, DC, 20201

Phone: (202) 690-7235

E-mail: [teresa.lewis@hhs.gov](mailto:teresa.lewis@hhs.gov)

Web site: <http://www.fda.gov/AboutFDA/business/ucm134069.htm>

**Appendix C: FDA Ombudsmen**

**FDA Office of the Ombudsman**

Laurie Lenkel, Director

Andrew Moss, Deputy Ombudsman

Talisha Williams, Paralegal Support Specialist

10903 New Hampshire Avenue

WO 32, Room 4231

Silver Spring, MD 20993

Phone: (301) 796-8530

Fax: (301) 847-8628

E-mail: [ombuds@oc.fda.gov](mailto:ombuds@oc.fda.gov)

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/ucm197508.htm>

**CBER Ombudsman**

Sheryl Lard-Whiteford, Ph.D.

HFM-4

Center for Biologics Evaluation and Research

Food and Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Phone: 301-827-0379

Fax: 301-827-2920

E-mail: [cberombudsman@fda.hhs.gov](mailto:cberombudsman@fda.hhs.gov)

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122881.htm>

### **CDER Ombudsman**

Virginia Behr

Center for Drug Evaluation and Research

Food and Drug Administration

WO 51, Room 6158

Silver Spring, MD 20993

Phone: 301-796-3436

Fax: 301-847-8752

E-mail: [cderombudsman@fda.hhs.gov](mailto:cderombudsman@fda.hhs.gov)

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm>

### **CDRH Ombudsman**

David Buckles, Ph.D.

Center for Devices and Radiological Health

Food and Drug Administration

WO66 Room 5428

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 301-796-5447

Fax: 301-847-8516

E-mail: [CDRHombudsman@fda.hhs.gov](mailto:CDRHombudsman@fda.hhs.gov)

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm>

## **Appendix D: Seminars and Webinars**

Lists of seminars, conferences, workshops, and online learning targeted to or open to small businesses can be found on the following web pages.

CBER workshops, meetings, and conferences open to small businesses:

- Previous:

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm280537.htm>

- Upcoming:  
<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm280422.htm>
- CBER OCTGT-Learn:  
<http://www.fda.gov/biologicsbloodvaccines/newsevents/ucm232821.htm>

CDER workshops and webinars, previous and upcoming:

- Targeted to small businesses:  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm070334.htm>
- Open to small business: <http://www.fda.gov/Drugs/ucm273272.htm>
- CDERLearn: <http://www.fda.gov/training/forhealthprofessionals/default.htm>

CDRH workshops and conferences open to small businesses:

- Previous:  
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm111051.htm>
- Upcoming:  
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>
- CDRHLearn:  
<http://www.fda.gov/training/cdrhlearn/default.htm>

### **Appendix E: FDA Grant Awards**

This includes grants awarded beginning January 1, 2008, to the present.

#### Unsolicited Grants

##### Grants Solicited under Small Business Innovation Research (SBIR) Program

Year	Number of Grant Applications Received	Number of Grants Awarded	Total Annual Award	Average Award Amount
FY 2008	18	6	\$582,000	\$116,400
FY 2009	33	8	\$1,606,070	\$200,759
FY 2010	26	7	\$1,464,078	\$209,154
FY 2011	34	10	\$1,464,348	\$145,435
FY 2012	26	5	\$1,111,000	\$150,000
FY 2013 <sup>28</sup>	30	N/A	N/A	N/A

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<sup>28</sup> As of May 31, 2013



Contact:

FDA Office of Acquisition & Grants Services

Glenda Barfell, Director

FHSL RM2109 HFA-500

5630 Fishers Lane

Rockville, MD 20857

Phone: 301-827-7042

E-mail: [Glenda.Barfell@fda.hhs.gov](mailto:Glenda.Barfell@fda.hhs.gov)

Website: <http://www.fda.gov/AboutFDA/business/default.htm>

Solicited Grants

FDA welcomes applications to its solicited grants by small businesses. As of May 31, 2013, FDA has solicited applications for 14 grants eligible to small businesses in FY 2013.<sup>29</sup>

Contact:

FDA Office of Acquisition & Grants Services

Glenda Barfell, Director

FHSL RM2109 HFA-500

5630 Fishers Lane

Rockville, MD 20857

Phone: 301-827-7042

E-mail: [Glenda.Barfell@fda.hhs.gov](mailto:Glenda.Barfell@fda.hhs.gov)

Website: <http://www.fda.gov/AboutFDA/business/default.htm>

Research Grants Approved Under Orphan Drug Act

- 1) Since 2008, the FDA Office of Orphan Products Development (OOPD) awarded 30 grants to small businesses.<sup>30, 31</sup>

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<sup>29</sup> Grants.gov Database. <http://www.grants.gov/>. Accessed May 31, 2013.

<sup>30</sup> Orphan Products Grant Program Database. <http://www.accessdata.fda.gov/scripts/opdlisting/oopdgrants/>. Accessed May 31, 2013.

<sup>31</sup> Small businesses status determined using data from the U.S. Small Business Administration

- 2) As of May 31, 2013, OOPD reports that 15 of these grants made to small businesses are presently active.<sup>32</sup>

Contact:

FDA Office of Orphan Products Development

Katherine Needleman, Director, Office of Orphan Products Grants Program

WO32 RM5282

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 301-796-8664

E-mail: [Katherine.Needleman@fda.hhs.gov](mailto:Katherine.Needleman@fda.hhs.gov)

Website:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018190.htm>

### **Appendix F: FDA Small Business Liaison Program**

In 2011, the Agency considered development of a centralized Small Business Liaison Program to bring in business experts from the community to consult with small businesses and FDA staff. However, there is little commonality in the regulatory requirements across FDA's medical product Centers. Even the definition of "small business" varies across the programs, reflecting the different attributes and needs of the different industry sectors. For these reasons, we decided that it would be more effective if each Center continues to design its small business program to reflect the specific regulatory requirements and industries it serves. For now, we believe that a central program would be an added-layer, rather than value-added.

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<sup>32</sup> Orphan Products Grant Program Database. <http://www.accessdata.fda.gov/scripts/opdlisting/oopdgrants/>. Accessed May 31, 2013.