



FDA Broad Agency Announcement Industry Day

Leonard Grant, Director
Office of Acquisitions and Grants Services



- ❑ **The Food and Drug Administration (FDA) launched the Broad Agency Announcement (BAA) to spur regulatory science innovation in the scientific community and leverage its knowledge and infrastructure (regulatory science three charges)**
 - Modernize development and evaluation of FDA-regulated products
 - Strengthen post-market surveillance and labeling of FDA-regulated products
 - Invigorate public health preparedness and response of the FDA, patients, and consumers.
- ❑ **FDA is encouraging science and technology-based firms as well as academia to participate with us in developing innovative ideas and approaches to regulatory science.**
 - BAA is issued under the Federal Acquisition Regulation (FAR) part 35.016(c)
 - Opportunity to present ideas and proposals directly to FDA's scientific thought leaders for consideration
- ❑ **OAGS posted the FY23 FDA BAA for Advanced Research and Development of Regulatory Science on www.Sam.gov on November 14, 2022 (FDABAA-23-00123).**
 - Utilize industry and academia's capabilities to advance the state of the art and achieve improvements in science and technology
 - Open to all responsible sources and Small Businesses are strongly encouraged to respond
 - Contracts will be the instrument used to make awards (not Grants) and based on the funding available
 - In FY22, there were 46 awards with an approximate value of \$220M. Anticipate a similar number of awards and value this FY
- ❑ **Take advantage of this virtual event and the opportunities provided to understand our mission, meet, and network with the attending FDA staff (to include Contracting, Program)**



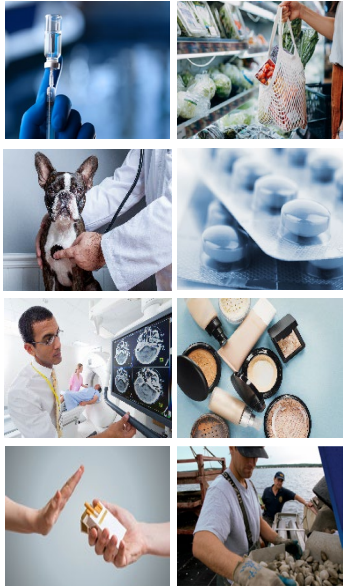
“The Contracts/Grants/IAAs/Purchase Card actions we handle helps...”



- The Food and Drug Administration is responsible for **protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to **protect the public health and to reduce tobacco use by minors**.
- FDA is responsible for advancing the public health by **helping to speed innovations** that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.
- FDA also plays a significant role in the Nation's **counterterrorism capability**. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

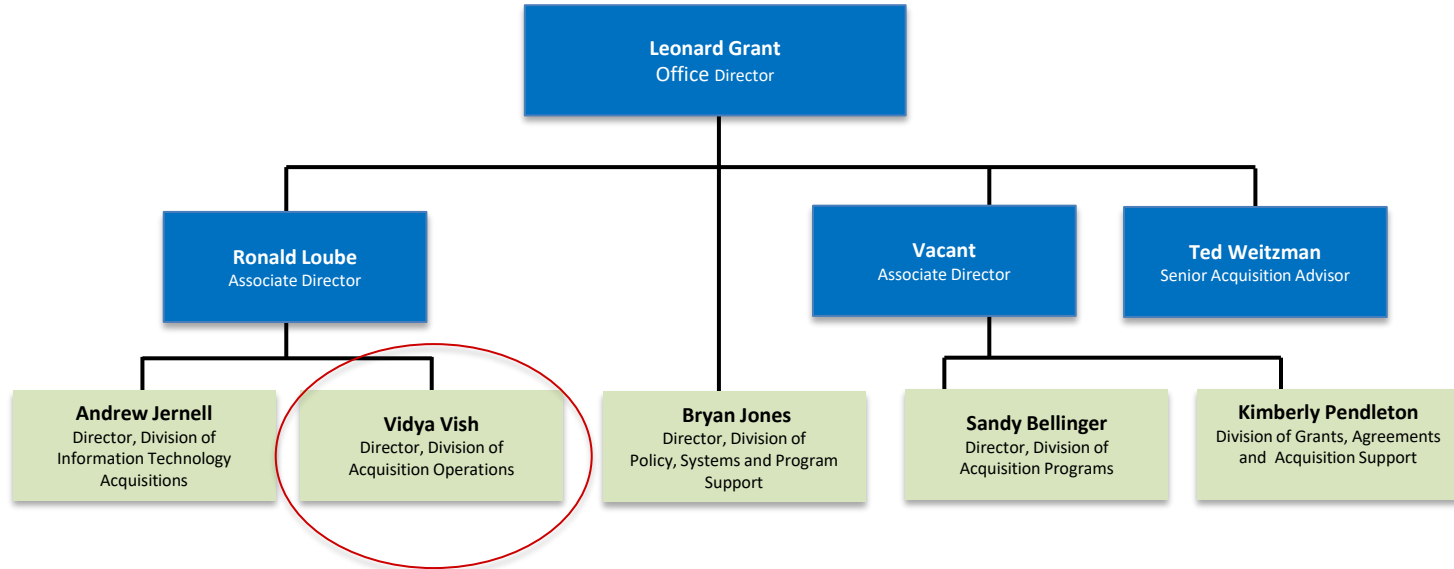


FDA Centers and Offices (Our Stakeholders)



- **Center for Biologics Evaluation and Research (CBER)**
- **Center for Drug Evaluation and Research (CDER)**
- **Center for Devices and Radiological Health (CDRH)**
- **Center for Food Safety and Applied Nutrition (CFSAN)**
- **Center for Tobacco Products (CTP)**
- **Center for Veterinary Medicine (CVM)**
- **National Center for Toxicological Research (NCTR)**
- **Office of Digital Transformation (ODT)**
- **Office of Regulatory Affairs (ORA)**
- **Office of the Commissioner/Office of Operations (OC/OO)**

For more information on each Center/Office and its mission please visit www.fda.gov .



Our staff provides the required depth of knowledge, experience, and workflow support to deliver value across the FDA



How We are Organized



Innovation, Systems & Data Quality Branch

Provides system support and serves as the PRISM, UFMS, FPDS, WorkSmarter and AAP focal point for OAGS. Tracks and analyze acquisition data, performs audits of acquisition actions, and supports program acquisition needs, i.e. IGCEs, SOWs, Evaluation Criteria, etc. Looks for innovative ways to promote office efficiency and effectiveness

Grants and Assistance

Agreements Branch

Negotiate, award and monitor federal funds awarded through various grant mechanisms. Award and administer Inter-Agency Agreements (IAGs)

CTP Contracts Branch

Contracts to support the compliance and enforcement of The Family Smoking Prevention and Tobacco Control Act (TCA). Contracts with states, territories, private contractors and tribal governments, to conduct compliance check inspections of tobacco product retailers

ORA State Contracts Branch

Contracts to support the Mammography Standards Quality Act, Food, Tissue and Feed Programs. These contracts commission the states to conduct inspections to ensure the quality and safety of the nations' food, animal feed and medical devices

Facilities Support Branch

Provides facility support, furniture, construction and renovation, architect/engineering services contracts and simplified acquisitions for all headquarter locations, Irvine, San Juan, and Dauphin Island

Field Operations Branch

Provides support for National Center for Toxicological Research (NCTR) (Jefferson, AR) related work as well as lab supplies and lab equipment as designated

Scientific Support Branch

Mission specific contracts and simplified acquisitions, including research and development requirements and lab supply and equipment requirements

Information Technology Branches (IT Acquisitions, Strategic Support & Systems Technology)

All information technology related contracts and simplified acquisitions

Service Contracts Branch

Service contracts and simplified acquisitions, including but not limited to, document control/records management, events management, management support services, guard services, moving, library support, custodial, etc.

Contract Operations Branch

Service contracts and simplified acquisitions, including but not limited to, studies, chemicals/drugs/reagents, animals, lab equipment, etc.

Contract Admin Branch

Serves as a central support function for contract administration of all transactions from the time the contract is awarded through closeout. Has the responsibility of tracking and processing invoices. Serves as the conduit for the preparation, processing, coordination, execution, administration, and close-out of Interagency Agreements (IAAs)

Training & Development Branch

Provides training and developmental courses to promote staff growth and development. Conducts specialized training for entry level Contracts Specialists. Provides Acquisition Career Management overseeing the certification programs, FAC-C, FAC-COR, FAC-P/PM





FDA Socioeconomic Goals



Small Business Award Categories	FY Goal (FY15-21)	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY 22 Goal (new)	FY22
Small Businesses	38%	50.10%	48.5%	39.64%	36.8%	39.06%	40.09%	34.33%	37.09%	33.49%
Small Disadvantaged Businesses	5.0%	29.50%	27.9%	24.31%	25.0%	27.14%	26.96%	23.84%	25.20%	23.96%
Women-Owned Small Businesses	5.0%	15.90%	17.8%	14.22%	14.1%	14.13%	12.68%	10.33%	11.99%	11.01%
HubZone Businesses	3.0%	2.20%	2.0%	1.40%	1.8%	2.75%	4.09%	3.81%	4.94%	4.48%
Service-Disabled Veteran Owned	3.0%	3.17%	4.9%	3.42%	3.4%	2.81%	3.91%	2.29%	3.80%	3.22%



- The BAA program allows for the **development and innovation of scientific research** pertinent for public health that the government may not otherwise have visibility on.
- The BAA mechanism allows academic institutions and industry to **present their ideas and proposals directly to the governments scientific thought leaders** for consideration.
- The open BAA process allows these academic institutions, as well as small and large businesses, **to help shape the path of the FDA's efforts for years to come** using an innovative contracting process.
- Mr. Ian Weiss, Branch Chief, Scientific Support Branch will elaborate on this further the **contracting process** later today.
- Take advantage of this **virtual event and the opportunities** provided to understand our mission, meet and learn from FDA staff that are participating.



THANK YOU FOR ATTENDING FDA BAA Day



U.S. FOOD & DRUG
ADMINISTRATION