



Center for Biologic Evaluation and Research(CBER)

Overview

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Role of a Regulatory Agency

Definition: A regulatory agency, such as the FDA, is responsible for exercising complete authority over some area of human activity in a regulatory capacity (restricting according to rules or principles).

- FDA regulates \$1 trillion worth of products a year, approximately \$0.24 of every dollar spent in the U.S.



CBER Strategic Plan

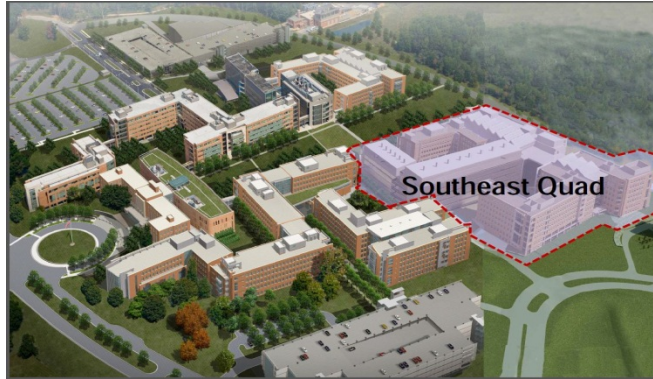
- Goal 1: Increase nation's preparedness to address threats
- Goal 2: Improve global public health through international collaboration
- Goal 3: Enhance advances in science & technology to facilitate development of biologics
- Goal 4: Ensure Safety of biological products
- Goal 5: Advance regulatory science & research
- Goal 6: Manage for organizational excellence and accountability

What products does **CBER** regulate?

A diverse array, both investigational and licensed, including:

- Allergens
- Blood and Blood Products
- Cellular and Gene Therapy
- Human Tissues and Tissue Products
- Vaccines
- Xenotransplantation Products

Where are we located



Buildings 52, 71, 72 and 75



DCC • OBE • OBRR • OCBQ • OCOD • OCTGT • OD • OM • OVRR



OBRR • OCBQ • OCTGT • OVRR



OCBQ • OVRR • OD-HIVE Group

CBER Acquisition Support Team

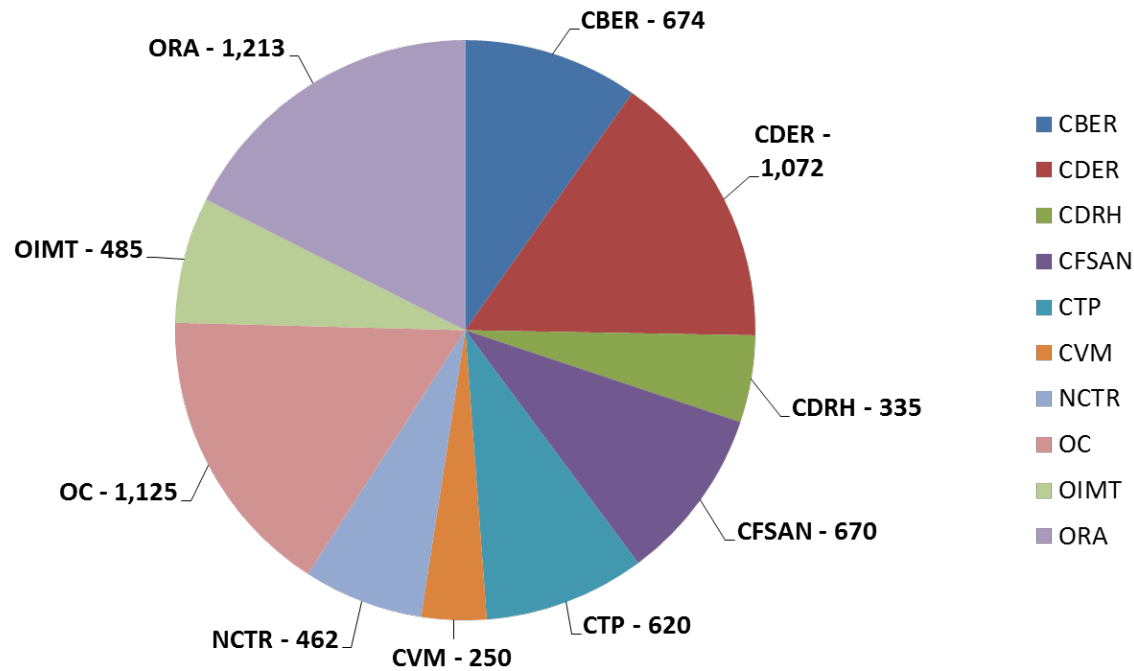
- The Acquisition Team provides an internal control structure to provide efficient and effective services related to acquisitions and assistance.
 - All activities regarding acquisition/assistance services must flow through the OM/Acquisition Team.
 - The Acquisition Team is responsible for developing and maintaining a mutually respectable working relationship with (OAGS), CBER staff, contracted vendors, grantees, and other Federal Agencies.
 - The team is focused on providing outstanding services to both internal and external customers by maintaining responsiveness and the expeditious handling of requests.
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What We Buy

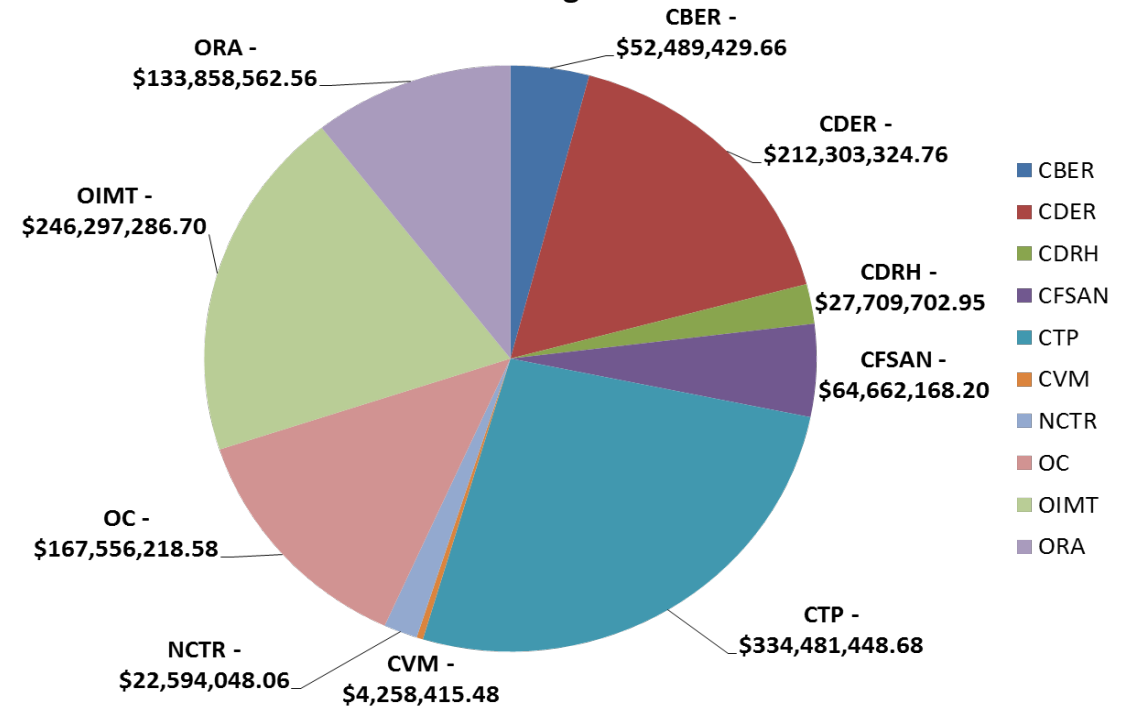
<p>General/Science Support Services</p>	<ul style="list-style-type: none"> • Scientific Support Services (i.e. Lab Technician, Animal Care Technicians, etc.) • Sequencing Services • Consultation Services • Executive Coaching
<p>Scientific Equipment</p>	<ul style="list-style-type: none"> • Mass Spectrometers • Cytometers • Advanced Microscopes • Sample Storage Ultra Low Freezers
<p>Information Technology (IT)</p>	<ul style="list-style-type: none"> • Small System Development • Support Services and Consultation
<p>Scientific Samples</p>	<ul style="list-style-type: none"> • DNA/RNA Protein Samples • Virus/Bacteria Specimen Samples • Derivation Samples
<p>General Laboratory Supplies</p>	<ul style="list-style-type: none"> • Laboratory Glass Ware (Pipettes, Beakers, Petri dishes, etc.) • Safety Products (Latex Gloves, Disposable Lab Coats, etc.) • Cleaning Products and Solutions

CBER Fiscal Year 2017 Overview

FY17 Awarded Contract Count



FY17 Dollars Obligated



ACQUISITION STRATEGIES

- Strategic Sourcing/Category Management
- GSA Federal Supply Schedules (FSS)
- Government Wide Acquisition Contracts (8(a) STARS II, CIOSP3 (SB), Alliant SB, NASA SEWP)
- Open Market
 - Indefinite delivery/indefinite quantity vehicles
 - Contracts
 - Purchase orders

DOING BUSINESS WITH CBER

- CBER in coordination with OAGS, provides opportunities for small business including: small disadvantaged business, woman-owned small business, veteran-owned small business, service-disabled veteran-owned small business and HUBZone small business.
- Small businesses should first contact the OSDBU Small Business Specialist supporting the FDA (Allyson Brown). Additional contacts can be found at:
<https://www.hhs.gov/grants/grants-business-contacts/small-business-staff/specialists/index.html>
- For more information on how to do business with the FDA, please visit the Office of Finance, Budget, and Acquisitions web page at:
<https://www.fda.gov/aboutfda/centersoffices/officeofoperations/officeoffinancebudgetandacquisitions/default.htm>

GUIDELINES FOR SUCCESS

- **Understand the customer's needs.** Submits a response to the RFI or sources sought announcement that provides specific information the Government requested, and not standard marketing information.
- **Carefully review posted information.** Submits detailed, well thought-out questions to any draft solicitation materials detailing requirements that will impact delivery post-award
 - During any face-to-face discussion, bring ideas, suggestions, and potential solutions for consideration.
 - Questions are specific and represent an understanding of the current challenges.
- **Determine the likelihood of submitting a successful and responsive proposal.** Proposals are well organized to Section L instructions and address every portion of Section M evaluation criteria with substantiation and proof points to demonstrate they (1) understand the requirement, (2) have a viable solution, and (3) are a low-risk contractor
- **Analyze if the risk is manageable.** During contract award and negotiation, contractors are easy to work with and do not try to alter terms, pricing, or requirements of contract during discussions and negotiations

QUESTIONS

