Center for Drug Evaluation and Research (CDER)

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Acquisitions Support Branch

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CDER's Mission

is to protect and promote public health by helping to ensure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients.

What does CDER Regulate

- **Prescription Drugs -** Prescription medicines include any drug product that requires a doctor's authorization to purchase.
- **Generic Drugs** - A generic drug is a drug product that is equivalent to brand name products in terms of quality and performance.
- **Over-the-Counter Drugs** - OTC drug products are available to consumers without a doctor's prescription. Includes fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens.

CDER Offices

- **Office of the Center Director (OCD)** - provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished.
- **Office of Communications (OCOMM)** - is the primary resource for communicating human drug information.
- **Office of Compliance (OC) -** shields patients from poor quality, unsafe, and ineffective drugs through compliance strategies and risk-based enforcement actions.
- **Office of Executive Programs (OEP) -** oversees a variety of Center-wide programs, including executive project management, the Center's executive secretariat function, scientific advisory committees, training and development, CDER's ombudsman, and program and administrative management.
- **Office of Generic Drugs (OGD) -** ensures, through a scientific and regulatory process, that Americans receive safe, effective, and high-quality generic drugs. FDA-approved generic drugs account for more than 88 percent of prescriptions filled in the United States.

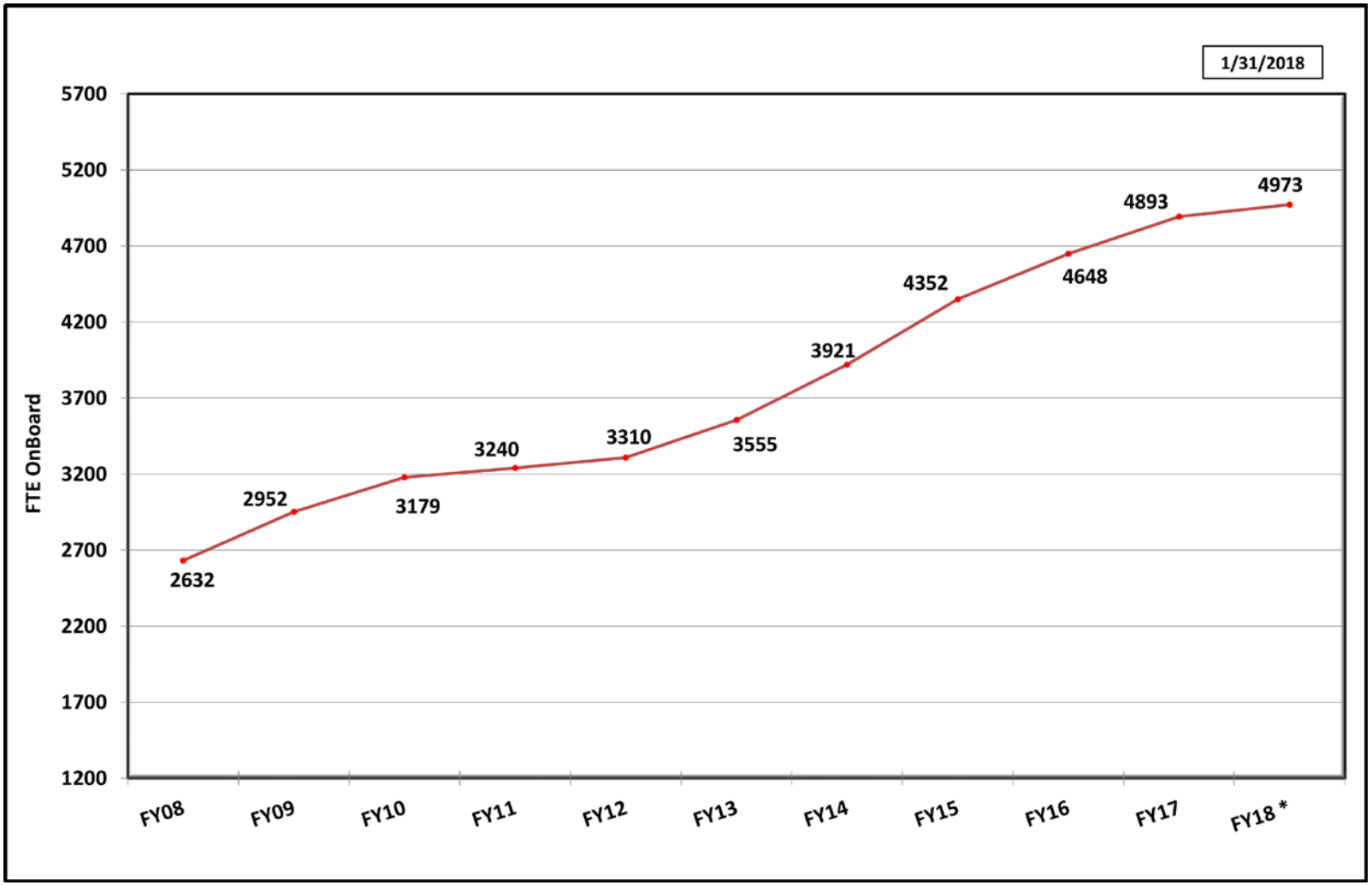
CDER Offices

- **Office of Management (OM)** - delivers highly effective, responsive and timely management resources and services to the FDA Center for Drug Evaluation and Research (CDER). OM leads CDER's administrative management operations.
- **Office of Medical Policy (OMP) -** leads the development, coordination, and implementation of medical policy programs and strategic initiatives.
- **Office of New Drugs (OND) -** ensures that safe and effective drugs and biologics are available to the American people. OND reviews drug applications, interacts with the pharmaceutical industry and ultimately decides whether the benefits of a drug outweigh the known risks.
- **Office of Pharmaceutical Quality (OPQ) -** mission is to assure that quality medicines are available for the American public. OPQ integrates assessment, inspection, surveillance, policy, and research activities to strengthen pharmaceutical quality on a global scale.

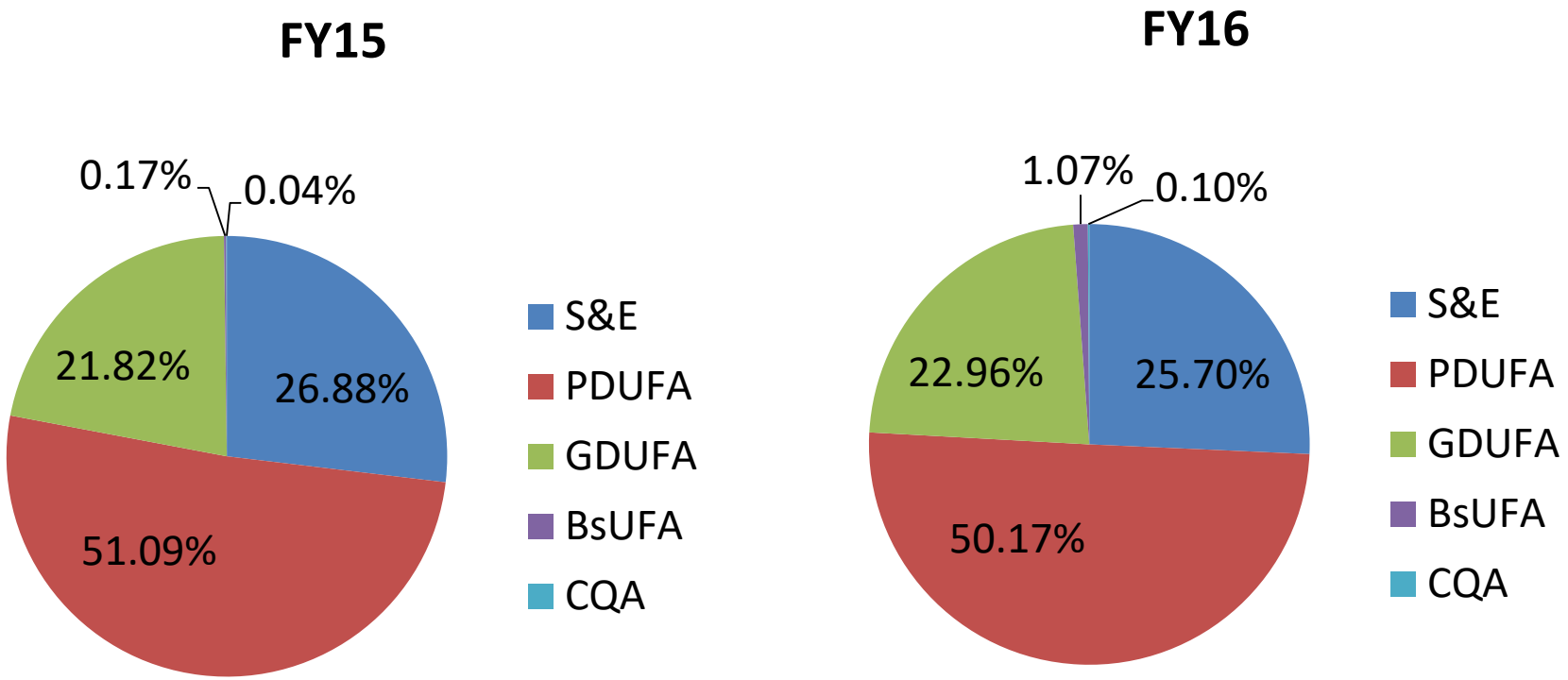
CDER Offices

- **Office of Regulatory Policy (ORP) -** provides oversight and leadership to the Center in the development of policies and procedures related to the regulation of human drugs.
- **Office of Strategic Programs (OSP)** - leads Center-wide strategic and operational planning and analysis.
- **Office of Surveillance and Epidemiology (OSE) -** monitors and evaluates the safety profiles of drugs available to American consumers using a variety of tools and disciplines throughout the life cycle of the drugs. OSE maintains a system of post-marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug development process.
- **Office of Translational Sciences (OTS) -** supports translational medicine efforts for CDER and leads the areas of technology transfer, data mining, health information technology, science and research oversight, and knowledge management.

CDER OnBoard Trend FY08-FY18



FY 15 and FY 16 Funding Type Spend



What CDER buys

- Information Technology
  - Subscriptions
  - Database management
  - Software maintenance
- Lab equipment
- Lab supplies
- HR services
- Research studies
- Services
  - Scanning
  - Training

How Do We Buy It

- Strategic sources
- IGCE
- 8(a)
- IAA
- Federal Supply schedule
- IT vehicles
  - STARS II, CIOSP3 (SB), NASA SEWP)

What can small businesses do

- Respond to Sources sought notices
- Work with FDA small business rep
- Read solicitations carefully
  - Decide if it makes sense to submit proposal
  - Ask questions about solicitation
- Proposal
  - Make sure the proposal is written for the solicitation and not a standard proposal
  - Make sure it is thorough and addresses all parts
- Partner
  - with 8(a)
  - large businesses
  - Other small businesses
- Work closely with COR
- Perform above expectations


time for questions