



## Career Opportunities at the FDA

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**NISS Virtual Career Fair**  
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**U.S. FOOD & DRUG**  
**ADMINISTRATION**

# Agenda

- Brief history of FDA
- Organizational Structure
- The role of the statistician at FDA / CDER
- Job Opportunities at the Office of Biostatistics
- Advice to students

# Brief History

- Pure Food and Drugs Act (1906)
  - Prohibited interstate commerce in adulterated and misbranded food and drugs
- Food, Drug, and Cosmetic Act (1938)
  - Drugs must be shown to be safe
- Kefauver-Harris amendment (1962)
  - All new drugs applications must show “substantial evidence” of effectiveness in addition to safety

# FDA Legal Foundation

US Constitution

US Law

US Regulation

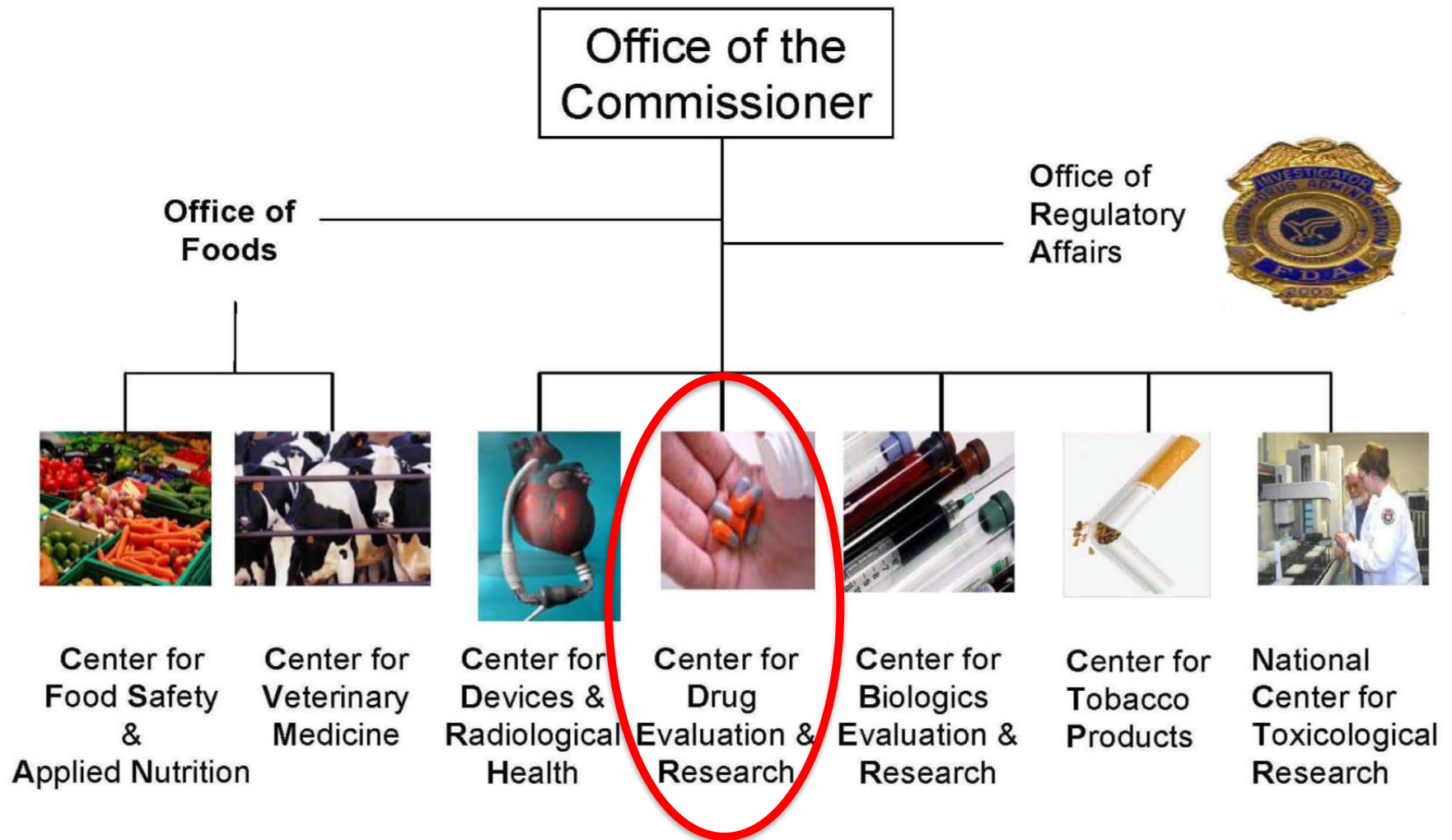
FDA Guidance



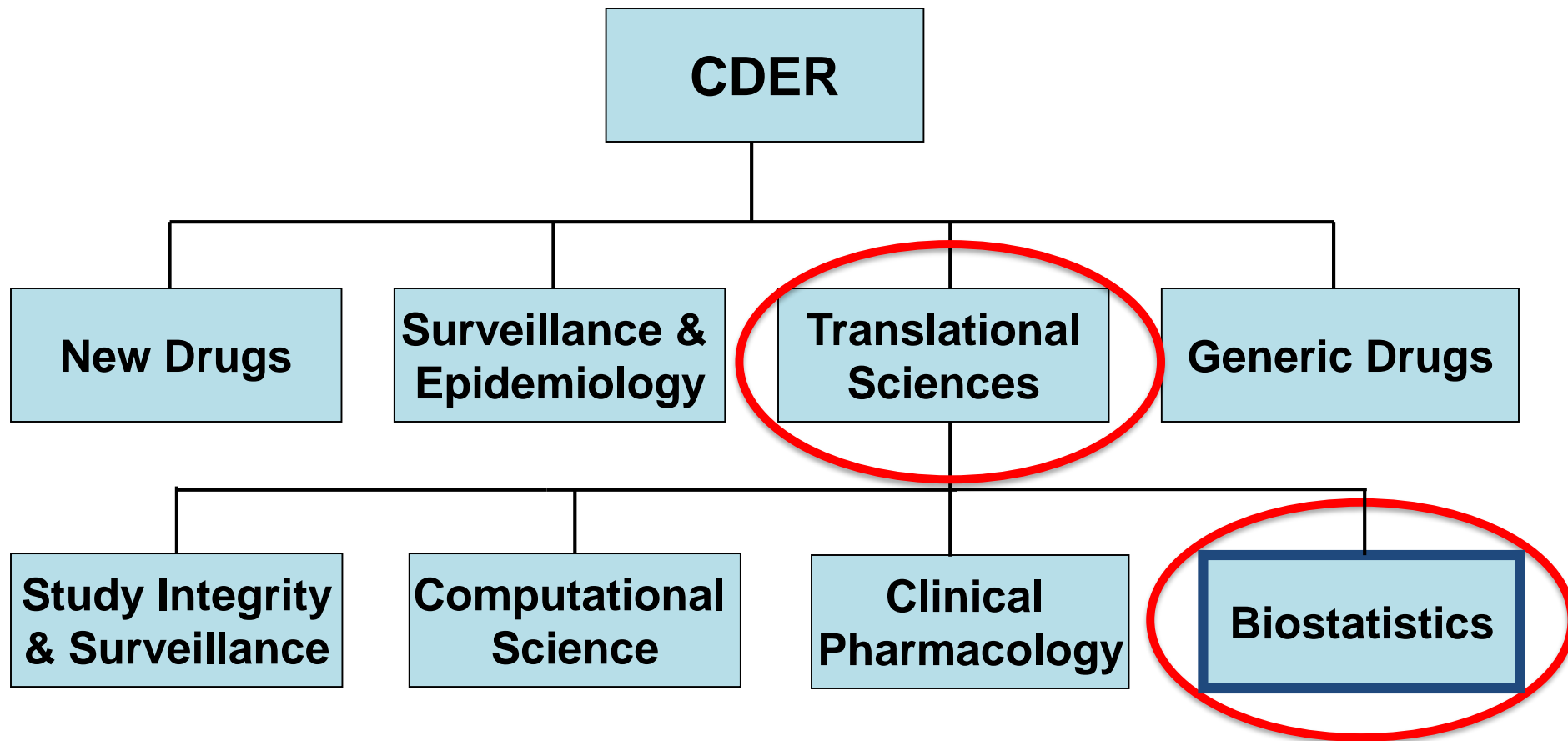
# What Does FDA Do?

- Ensures that human and veterinary drugs, vaccines and other biological products and medical devices are safe and effective
- Ensures that foods are safe and properly labeled
- Ensures cosmetics and dietary supplements are safe and properly labeled
- Regulates tobacco products

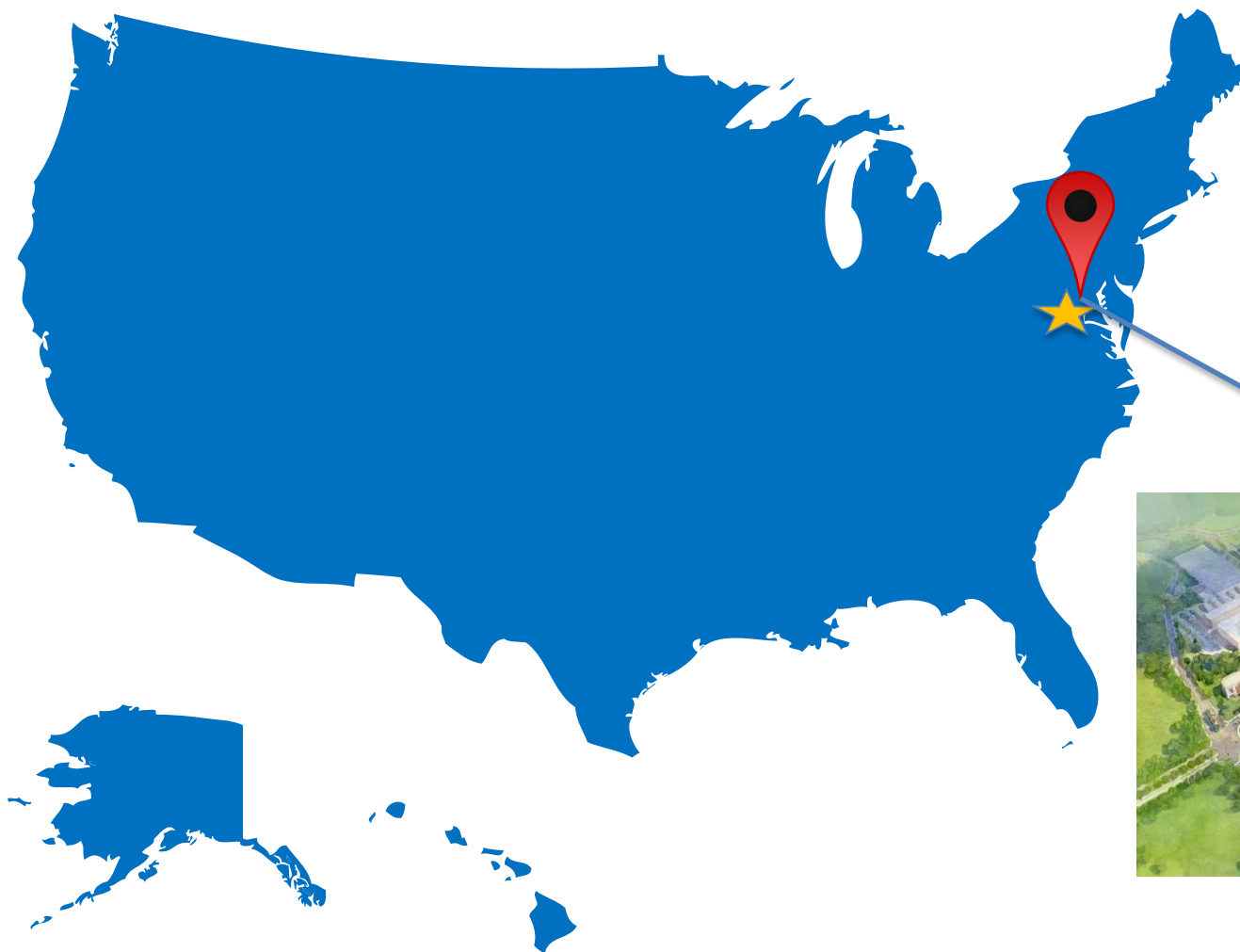
# FDA Organization



# Center for Drug Evaluation and Research



# FDA Location: White Oak Campus Silver Spring, MD





# Office of Biostatistics

## Mission



- Provide statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs for the American people.
- Protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.

# The role of the statistician

- Review regulatory submissions
- Check for data quality and completeness
- Conduct statistical analyses
- Participate in Advisory Committee meetings
- Develop guidance documents for sponsors
- Conduct statistical research
- Present at scientific meetings
- Advise sponsors on study design and analysis

# Opportunities for statisticians and data analysts





# Opportunities at FDA

- The Office of Biostatistics is actively recruiting
  - Mathematical Statistician (Ph.D. in Statistics)
  - Statistical Analyst (MS in Statistics)

## **Skills required**

- Strong technical skills
- Strong statistical/scientific computing skills
- Experience with SAS and/or R
- Excellent oral and written communication skills
- Interpersonal and teamwork skills
- Strong problem-solving skills
- Creativity and innovation

If you are interested in working for the FDA, send your resume to:

[CDEROTSHires@fda.hhs.gov](mailto:CDEROTSHires@fda.hhs.gov)

# Opportunities for Students



- ORISE summer internship positions available for advanced PhD graduate students
- Engage in projects on topics relevant to OB scientific needs
- Gain hands-on experience under the guidance of a mentor

Past research project areas have included:

- modeling and simulation
- adaptive designs
- Bayesian design
- meta-analyses
- benefit-risk analyses
- subgroup analyses
- biosimilars
- development of statistical methods and software tools

# Opportunities for Students



Information on the summer internship program can be obtained in AMSTAT NEWS at:

<https://stattrak.amstat.org/2019/12/01/2020-internship-listings/>

- If interested send CV and cover letter to:

[CDER-OTS-OB-Recruitment@fda.hhs.gov](mailto:CDER-OTS-OB-Recruitment@fda.hhs.gov)

# Opportunities for Faculty

- Research collaboration
- Special Government Employees
  - Consultant on specific projects
  - Expert opinion on FDA guidance
- Advisory Committee Membership
  - Provide FDA with independent opinions and recommendations on new drug applications
  - Committee membership consists of subject matter experts, including clinicians, pharmacists, patient representatives, and statisticians.

# Advice for Students



- The Office of Biostatistics (OB) is a very rewarding place to deploy skills in biostatistics and statistical programming.
- OB offers a great opportunity to apply the most sophisticated techniques in biostatistical analysis.
- Working at OB has many characteristics of academic research.
- Statisticians are not only reviewing state-of-the-art regulatory submissions but also developing fundamentally new statistical approaches.





Thank you  
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