Opportunity Title: Public Health and Regulatory Research Fellowship - FDA OPHSA
Opportunity Reference Code: FDA-OPHSA-2019-0002

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-OPHSA-2019-0002

How to Apply A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 3/31/2019 12:00:00 AM Eastern Time Zone

Description An opportunity is available at the U.S. Food and Drug Administration (FDA), Office of Public Health Strategy and Analysis (OPHSA) in Silver Spring, Maryland.

FDA is responsible for protecting and promoting public health through regulation of a wide range of products including medical products, food and tobacco. OPHSA is located in the Office of Policy, Planning, Legislation, and Analysis, in the Office of the Commissioner. OPHSA serves as a resource to the Agency for quantitative and qualitative research and analysis on emerging issues and for advancing work on priority public health initiatives. OPHSA does this through its work on initiatives such as opioids, drug pricing, and transparency, as well as by developing and executing research to link agency activities and outputs to public health outcomes.

Under the guidance of a mentor, potential training projects for OPHSA ORISE fellows include research and analysis of:

1. Impact of FDA approved first generic drugs on competition and pricing:
The ultimate impact of generic drugs on drug prices depends not only on when FDA approves Abbreviated New Drug Applications (ANDAs), but also on whether and how soon generic drugs are marketed following FDA approval. Greater understanding of the current generic drug landscape and especially of the marketing status and history of first-approved generics could help the Agency identify targets for action to reduce hurdles to generic drug competition and enhance price competition. The fellow may be involved in a multi-phase study that seeks to determine the characteristics and marketing status of all first generics approved by FDA since 2010, as well as their impact on generic drug competition and pricing.

2. Synthetic opioid epidemic
Recent evidence indicates that synthetic (illicit) opioids are now responsible for more overdose deaths in the United States than prescription opioids. Based on FDA's work, we have a good idea of the volume of legal opioid analgesics being prescribed for pain in the US. However, there are very little data from which to estimate the volume of illicit opioids in the country, whether produced domestically or entering the U.S. The fellow may be involved in a research project to better characterize the volume and contribution of illicit, synthetic opioids to the opioid epidemic.

3. Data from National Poison Control Centers
FDA uses consolidated data from all poison control centers in the US to better understand the

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potential harm experienced by millions of Americans following exposure to drugs, dietary supplements, or other substances regulated by the Agency. The fellow may be assigned to undertake a new or continue an existing analysis of poison center data to better understand the public health impact of dietary supplements, anticoagulant drugs, opioids, or tobacco/nicotine products, among other FDA-relevant topics.

4. FDA's impact on Global Health
The fellow may participate in a project to help FDA better understand how the Agency has and can impact global health. One example is a potential detailed analysis of FDA's contribution to global fight against HIV via its tentative approval program under the US President's Emergency Plan for AIDS Relief (PEPFAR).

Deadline for application is March 31, 2019 but applications will be reviewed on a rolling-basis. Early submission of applications is strongly encouraged. A selection may be made at any time during the review process.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

The qualified candidate must have received a public health related doctorate degree from an accredited institution (or expected within a year): Such as RN, PA, MD, PharmD, PhD or other similar disciplines. Degree must have been received within five years of the appointment start date.

Individuals who have completed a clinical residency program are encouraged to apply. Experience conducting quantitative research (primary data collection, secondary analysis, mathematical modeling, etc.) is highly desired.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 12/13/2019 12:00:00 AM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (18 👁)
  - **Mathematics and Statistics** (1 👁)