Opportunity Title: Liposome Evaluation Fellowship - FDA NCTR
Opportunity Reference Code: FDA-NCTR-2018-0201

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

Reference Code FDA-NCTR-2018-0201

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.

Description A postdoctoral research opportunity is currently available in the at the National Center for Toxicological (CDER) of the U.S. Food and Drug Administration (FDA) to pursue characterization of various physico-chemical attributes and biological effects of liposomal and nanomaterial formulations.

This project provides ORISE fellows for FDA's generic drugs program to collaborate with other investigators (in and out of FDA) in addressing the 5 GDUFA research areas. The objectives of the projects are to produce review policy recommendations and advice in guidance for industry in using new scientific approaches to either make generic products available or to improve the quality and consistency of approved generic products. The five FY2017 topic areas are: 1) Post-market Evaluation of Generic Drugs 2) Equivalence of Complex Products 3) Equivalence of Locally Acting Products 4) Therapeutic Equivalence Evaluation and Standards 5)Computational and Analytical Tools.

The participant will have the opportunity to analyze data from external research studies to provide findings of complex generic products and ensure generic substitution; conduct analysis of internal FDA data to help develop equivalence standards for complex generic products and evaluate post-market data; conduct laboratory research to characterize complex reference products and evaluate approved generic products; and build databases and quantitative physiological and mechanistic models to support new approaches to bioequivalence.

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 Jefferson,

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AR area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Qualifications Applicants must have received a doctoral degree in material science, nanotechnology, chemistry, cancer models, toxicology, pharmacology, biochemistry or biology within five years of the desired starting date, or completion of all requirements for the degree should be expected prior to the start date. Knowledge in advanced nanomaterial characterization tools, methods, and in vitro or in vivo studies desired. Prior experience with liposomes is highly desired.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Science & Engineering-related** (1 👁)