Opportunity Title: Assessment of Alcohol Dose Dumping Potential Fellowship - CDER
Opportunity Reference Code: CDER-FDA-CDER-2016-0125

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

Reference Code CDER-FDA-CDER-2016-0125

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 research opportunity is available in the Office of Pharmaceutical Quality/Office of New Drug Products at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

Alcohol Induced Dose dumping refers to the unintended, rapid release of a significant fraction of a controlled release drug in presence of alcohol within a short period of time. This malfunction involved with an extended release formulation can lead to severe side effects due to overdose and also can lead to fatal consequences. In vitro alcohol dose-dumping studies provide the basis for determining whether in-vivo BA/BE studies in the presence of alcohol are warranted. Based on data available to the Agency for some few studies for which in-vitro and in-vivo data in the presence of alcohol have been submitted, the results in-vitro and in-vivo studies do not always correlate. This reveals the inability of current in-vitro dissolution tests to predict the in-vivo alcohol induced dose dumping potential. This problem has not been thoroughly studied or corrected so far and hence demands more research in this area.

We will use in silico modeling and simulation (e.g. DDDPlus and GastroPlus) as an aid to identify the possible causes for the conflicting in-vitro and in-vivo alcohol dose dumping potential; seek collaboration for the conduct of in vitro alcohol dose-dumping studies in the presence and absence of surfactant guided by the results of the in silico modeling and simulation; update the in-vitro tests guidelines accordingly to ensure the predictability of the in-vitro dose dumping studies for identifying the potential of in-vivo alcohol dose dumping in the presence of alcohol.

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 12 months, 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

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participation in this program. The appointment is full-time at FDA in the Silver Spring, MD 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 pharmaceutical sciences within five years of the desired starting date, or be currently in a degree granting program at an accredited U.S. college or university. Qualified masters and bachelors level degrees may also be considered.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)