

Opportunity Title: FDA Rare Disease and Orphan Product Fellowship

Opportunity Reference Code: FDA-OOPD-2021-02

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

Reference Code FDA-OOPD-2021-02

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
- One educational or professional recommendation

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

If you have questions, send an email to ORISE.FDA.OC.other@orauf.org. Please include the reference code for this opportunity in your email.

Application Deadline 6/28/2021 3:00:00 PM Eastern Time Zone

Description *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.

An opportunity is available at the U.S. Food and Drug Administration (FDA), Office of the Commissioner (OC), Office of Orphan Products Development (OOPD) located in Silver Spring, Maryland.

The mission of OOPD is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

Under the guidance of a mentor, the fellow will gain an understanding of orphan product regulation and perform related research. The research will explore topics including rare pediatric disease designations, patient-FDA interactive meetings, and patient access considerations for orphan drugs. The projects will include a mix of qualitative and quantitative research. This training relates to our public health mission and will further the fellows' understanding of rare diseases and the patient experience, and how that knowledge is used to inform rare disease drug development and regulatory decisions.

Anticipated Appointment Start Date: July 1, 2021; start date is flexible

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.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.



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FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should have received a master's or doctoral degree in one of the relevant fields, or be currently pursuing a doctoral degree. Degree must have been received within the past five years.

Preferred skills:

- Strong analytical and critical thinking skills
- Demonstrated written and oral communications skills
- Experience in quantitative and/or qualitative data analysis

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
 - **Life Health and Medical Sciences** ([46](#) 👁)
 - **Other Non-Science & Engineering** ([2](#) 👁)
 - **Social and Behavioral Sciences** ([28](#) 👁)

Affirmation I have received a master's or doctoral degree within the past 5 years, or am currently pursuing a doctoral degree.