

Title 21 Vacancy Announcement Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Office of Regulatory Policy (ORP) Division of Information Disclosure Policy (DIDP)

Application Period: January 28, 2022 – February 10, 2022

<u>Area of Consideration:</u> United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Scientific Redactor Series: AD-0696

Location(s): Silver Spring, MD Salary: Starting at \$74,950

Work Schedule: Full-Time

<u>Cures Band(s):</u> Band A <u>Full Performance Band Level:</u> Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

<u>Relocation Expenses Reimbursement</u>: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.

Additional information on 21st Century Cures Act can be found here:

21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

The Office of Regulatory Policy's (ORP), Division of Information Disclosure Policy, is responsible for control, management, coordination, and development of CDER's disclosure activities. Qualified candidates clear important and sensitive CDER responses to requests received under the Freedom of Information Act as amended, and by careful evaluation ensure that all such responses are accurate and contain only information that is considered disclosable as provided under the Freedom of Information Act and FDA's implementing regulations. CDER/ORP/DIDP is conducting a search for talented leaders for the position of **Scientific Redactor**.

Duties/Responsibilities

- Applies redaction skills and good judgment in appropriately redacting scientifically rich information and documents by identifying and removing confidential information before public disclosure.
- Informed or awareness of scientific terminology and concepts and may be required to consult with FDA's program areas on important and sensitive issues and inform the supervisor of sensitive and/or challenging requests.
- Ensures that all responses are accurate and contain only information which is
 disclosable as provided under the Freedom of Information Act (FOIA) and FDA policy.
 FOIA requests and other disclosure projects are assessed, evaluated and completed in a
 timely manner. Reviews and organizes materials, documents, and records for disclosure
 to ensure that they are accurate, clear, and concise.
- Evaluates information to ensure that it is complete and accurate and follows up to make sure that agreements and commitments are fulfilled in a timely manner.
- Plan and organize requests for information and manage multiple tasks simultaneously.
 Sets clear priorities, goals and expectations, tracks progress against goals, ensures feedback and addresses problems and issues promptly by maintaining a good working relationship with supervisor and team leader.
- Utilizes processes and methods of collecting and synthesizing information from various sources in an objective, unbiased manner; understands, interprets, and makes sound decisions relative to information disclosure.
- Analyzes information needs, determines an information plan, and, by careful evaluation, ensures that information is within the guidelines provided for under the Freedom of Information Act, Trade Secrets Act, Federal Food, Drug and Cosmetic Act and related statutes and regulations implemented by FDA.
- Maintains an awareness of current developments in CDER and uses this knowledge in the process of assembling appropriate information for disclosure. Seeks information to understand problems, needs and expectations and methodically and systematically establishes reliable data to support disclosure decisions.
- Applies knowledge to appropriately identify issues, problems, or opportunities, and determines if action is needed. Applies investigative techniques to acquire new data. Applies useful, accurate and comprehensive models and methods.

- Works cooperatively with others to share information and to build and maintain mutually beneficial partnerships to accomplish objectives and achieve results.
- Provides support to agency representatives from the Office of Chief Counsel in the
 collection and/or preparation of background information and testimony of FDA officials
 in court cases on defending FDA's position on the disclosure of requested information.
 Prepares recommendation for document request denials for information exempt from
 disclosure.
- Recommendations must include technical justifications and appropriate evidentiary support. Consults with appropriate FDA components to assure that information requests are complete and satisfied in a timely manner. Works as collaborative team member in discussing and addressing issues related to information disclosures.
- Utilizes professional skills to effectively communicate issues and problems, and to work for solutions that all team members can support.
- Coordinates and follows up with staff members on relevant and important issues to accomplish objectives. Maintains good working relationships by actively participating in staff meetings and by meeting regularly with the supervisor and/or team leader for constructive performance feedback and to seek technical guidance.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations later.

Oualifications

To be placed into a Cures position, candidates must meet the following criteria:

- 1. Scientific, Technical, and Professional Fields
- 2. Qualified and Outstanding Candidates

- a. **Qualified** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
- b. **Outstanding** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

To qualify for this Title 21 Cures position, the candidate(s) must meet the following <u>required</u> qualifications. Please note: Additional education and experience listed that is not indicated as <u>required</u> is preferable and desired. Candidates who do not meet the "desired" criteria will <u>not</u> be excluded from consideration for this position.

Education Requirement:

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Degree in health care, physical science, life science, health policy, and/or law

Or

At least 30 college level semester hours.

<u>Professional Experience:</u> Scientific knowledge through higher education and/or work experience to understand, interpret, and make sound decisions relative to disclosure of scientific information that may be considered confidential under the Freedom of Information Act, Trade Secrets Act, and the Federal Food, Drug and Cosmetic Act and related statutes and regulations implemented by FDA.

Education Transcripts

<u>SUBMITTING YOUR TRANSCRIPTS:</u> Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

<u>FOREIGN EDUCATION:</u> If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the <u>U.S. Department of Education website for Foreign Education Evaluation</u>.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/Low Risk

If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly.

Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits. Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

How to Apply: All qualified candidates must submit resume, unofficial transcripts, and cover letter in which you describe why you feel you are uniquely qualified for this position electronically to CDER-ORP-Cures-Hiring@fda.hhs.gov.

Announcement Contact

For questions regarding this Cures position, please contact <u>CDER-ORP-Cures-Hiring@fda.hhs.gov</u>.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer.

