VACANCY ANNOUNCEMENT
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)

Scientific Redactor
Office of Regulatory Policy (ORP)
Division of Information Disclosure Policy (DIDP)
AD-0696

The Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), Office of Regulatory Policy (ORP), Division of Information Disclosure Policy is recruiting for the position of Scientific Redactor. The Scientific Redactor receives direction in the performance, management, coordination and clearance of assigned disclosure activities. Applies professional redaction skills and judgment in appropriately redacting scientifically rich information and documents by identifying and removing confidential information before public disclosure.

ORGANIZATION BACKGROUND

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating manufacturing, marketing, and distribution of tobacco products to protect the public health.

The Center for Drug Evaluation and Research (CDER), Office of Regulatory Policy's (ORP), Division of Information Disclosure Policy is responsible for control, management, coordination, and development of the 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 ensures that all such responses are accurate and contain only information which is considered disclosable as provided under the Freedom of Information Act, the Privacy Act, and FDA's implementing regulations.

Major Duties/Responsibilities

- The incumbent applies redaction skills and good judgment in appropriately redacting scientifically rich information and documents by identifying and removing confidential information before public disclosure.
- The incumbent must have an 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 (FOI), the Privacy Act and FDA policy. FOI requests and other disclosure projects are assessed, evaluated and completed in a timely manner. The incumbent 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.
- The incumbent is expected to 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.

Research:

- The incumbent 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, Privacy 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.

Collaboration:

- 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 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.

Desired Experience and Qualifications:

- Minimum Education Requirement: Meets the Office of Personnel Management (OPM) Individual Occupational Requirements (IOR) for Scientific Redactor, 0696. Please review the entire IOR to confirm the minimum education requirements at the following link: Consumer Safety Series, 0696

- Two or more (2+) years of experience in a relevant drug or biologic scientific field such as biology, microbiology, medical technology, biochemistry, chemistry, clinical pharmacology, pharmacology, pharmaceutical science, immunology, and/or biostatistics, consumer/drug law, scientific redaction or editing, or privilege review and eDiscovery. Competitive candidates will have at least 30 college level semester hours or a college level degree in health care, physical science, life science, health policy, and/or law.

- 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, Federal Food, Drug and Cosmetic Act and related statutes and regulations implemented by FDA.

- Ability to work independently and as a contributing, collaborative team member.

- Ability to organize time effectively, determine priorities, and move work forward.

Location:
Silver Spring, Maryland

Salary and Incentives:

Compensation will be commensurate with qualifications and experience. Optional incentives may be authorized.

Area of Consideration:

Applications will be accepted from all qualified applicants.

Application Procedures:

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.

Conditions of Employment:

U.S. Citizenship is required

This position is being filled under an excepted 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 the authority. Additional information on 21st Century Cures Act can be found here.

Ethics Requirements: This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/default.htm.

Security and Background Requirements: 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.

EEO Responsibility: The incumbent is responsible for furthering the goals of equal employment opportunity (EEO) by taking positive steps to assure the accomplishment of affirmative action objectives and by adhering to non-discriminatory employee practices in regard to race, color, religion, sex, national origin, age, or handicap. Specifically, as a manager, incumbent initiates non- discriminatory practices and affirmative action for the area under his/her supervision in the following: 1) merit promotion of employees and recruitment and hiring of applications; 2) fair treatment of all employees; 3) encouragement and recognition of employee achievements; 4) career development of employees; 5) full utilization of their skills.

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.

How You Will Be Evaluated:

A review of your resume and supporting documentation will be made to determine if you are qualified for this job based on how well you meet the desired qualifications above. If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview.

Benefits:

As a new or existing federal employee, you and your family may have access to a range of benefits. Your benefits depend on the type of position you have - whether you are a permanent, part-time, temporary or an intermittent employee. You may be eligible for the following benefits, however, check with your agency to make sure you're eligible under their policies. You can find information about each program at www.opm.gov.