TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Regulatory Policy (ORP)
Division of Information Disclosure Policy (DIDP)

Position: Scientific Redactor

Pay Plan-Series: AD-0696

Location(s): Silver Spring, Maryland

Travel Requirements: N/A

Application Period: 01/18/2022 – 02/04/2022

Salary: Starting at $72,750 (Cures Band A-C)

Area of Consideration: United States Citizens or Nationals

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

Special Notes: 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 compensated under the provisions of the authority. Additional information on 21st Century Cures Act can be found here.

Introduction:

The Food and Drug Administration (FDA) 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 are safe, and effective.

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 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.

Position Summary:

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.

Professional Experience/Desirable Qualifications:

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 (FOIA) and FDA policy. FOIA 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, 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 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.

Key requirements will include:

- 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.
- 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.

Desirable Education:

- 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.

Conditions of Employment:

U.S. Citizenship is required

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 278) 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 Clearance: 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 Requirement: 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. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.

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 employment objectives and by adhering to nondiscriminatory employee practices in regard to race, color, religion, sex, sexual orientation, national origin, age, or disability. Specifically, as

supervisor, incumbent initiates nondiscriminatory practices and affirmative employment outreach activities for the area under his/her supervision in the following: (1) merit promotion of employees and recruitment and hiring of applicants; (2) fair treatment of all employees; (3) encouragement and recognition of employee achievements; (4) career development of employees; and (5) full utilization of their skills.

- The incumbent, in conjunction with his/her supervisor, develops an affirmative
- employment plan for the area supervised including appropriate objectives and goals; and monitors and periodically assesses progress. Keeps informed of, supports, and communicates to employees EEO policies, plans and programs. Seeks out and utilizes available resources, including appropriate personnel generalists/specialists, EEO specialists, and training resources in conducting these responsibilities. Incumbent will be appraised on the effectiveness of his/her performance. Click here to find out additional information about the Equal Employment Opportunity (EEO) for federal employees & job applicants.

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.

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