



**Title 21 Vacancy Announcement
 Health Communication Policy Analyst
 Department of Health and Human Services (HHS)
 Food and Drug Administration (FDA)
 Center for Biologics Evaluation and Research (CBER)
 Office of Communications, Outreach and Development (OCOD)
 Division of Disclosure and Oversight Management (DDOM)
 Congressional Oversight Branch (COB)**

Summary:

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Overview:

Area of Consideration: Public
Open & Close Dates: 10/30/2024 – 11/13/2024
Position: Health Communication Policy Analyst* <i>*Multiple selections can be made from this announcement</i>
Salary: Starting at \$82,764 and is set to commensurate with education and experience
Bands: A/B
Occupational Series: 0601
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: 25% or less
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: Yes
Promotion Potential: Band B
Supervisory Status: No
Security Clearance: Yes - Background Investigation
Drug Test: No
Bargaining Unit: 3591

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain

incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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](#)

Duties:

The incumbent serves as the Health Communication Policy Analyst for the Congressional and Oversight Branch (COB) within the Division of Disclosure and Oversight Management (DDOM) under the Office of Communications, Outreach and Development (OCOD). This position reports to the Congressional and Oversight Branch (COB) Branch Chief. The incumbent performs segments of routine, health policy and communications related assignments and projects that cut across many Offices, Centers, or Agency activities, organizations, and programs. The incumbent coordinates with key officials within CBER and FDA.

Specifically, the Health Communication Policy Analyst will:

- Draft routine communications of a broad range of policies concerning the application of any of FDA's enabling legislation and pertinent regulations in relation to products or programs within the Center's jurisdiction.
- Work with COB's senior staff to analyze new and proposed legislation to disseminate to leadership and provide Center comments and clearance on relevant areas.
- Work closely with COB team members to determine the potential impact of legislation on Office or Center activities and programs, on industry, and upon the consumer relating to statutory requirements specific to Biologics License Applications (BLAs), Investigational New Drug (IND) Applications, New Drug Applications (NDAs), device Pre-market Approval Applications (PMAs) and 510(k) Applications for an array of biological products, both investigational and licensed.
- Work closely with senior staff for guidance to coordinate communications between the Center, and the Office of the Commissioner (OC), other Centers, Departments and Agencies outside of FDA, and key high-level staff for the purpose of Center input and clearance.
- Coordinate timely responses to established routine correspondence received from the OC and others on biological products and information pertaining to CBER.
- Coordinate responses that can be of highly technical nature for communication to the public including health care providers and consumers, working closely with senior staff for guidance.
- Support experienced staff in briefings and meetings and assists with preparing background material (including testimony and briefing memos) for use by the Center Director and other CBER leadership for hearings and briefings.
- Research information on Congressional activities, legislative actions, and oversight activities relevant to the Center programs to draft comments for more senior staff members review in response to Congressional hearings, testimony, and reports.
- Transmit routine documents in response to Congressional or oversight document requests where these requests may be voluminous and require scientific technical knowledge to determine responsiveness and suitability for release.
- Work with COB's senior staff to summarize and disseminate the results of Congressional and oversight activities from a large volume of information to be used by leaders and staff throughout CBER to manage programs and policies based on Congressional directives and legislation and to extract information to prepare a variety of correspondence.
- Work closely with senior staff to coordinate with the OC regarding the General Accountability Office (GAO) and the HHS Office of Inspector General (OIG).

- Provide support in the analysis and evaluation of new audits, studies, requests, reports, and recommendations related to those audits and determines the potential impact on Office and Center activities and programs.
- Coordinate, perform background research, and assist in drafting responses for ongoing long-term studies.
- Track routine document requests related to litigation under the Tort Claims Act.
- Disseminate documents to the FDA Office of Chief Counsel (OCC) or the Department of Justice (DOJ).
- Collect questions from OCC and DOJ for review and response.
- Serve as a Center or Office representative as needed on cross-Agency working groups to assist senior staff members develop policy or communications responses on issues related to Center or Agency priorities.

Requirements:

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- One-year probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: 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 at a later time.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

Qualifications:

Basic Qualification Requirements:

*In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following **requirements:***

- Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education at the time the degree was obtained.

Desired Professional Experience/Qualifications:

The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.

- General knowledge of the Food, Drug and Cosmetic Act, the Public Health Service Act, and the implementing regulations and policies.
- Experience applying standards, regulations or statutes to scientifically rich content.
- Knowledge of biological sciences related to the products regulated by CBER programs which includes fields such as biology, microbiology, medical technology, biochemistry, chemistry, clinical pharmacology, pharmacology, pharmaceutical science, immunology, and/or biostatistics, molecular biology, virology, cell biology, microbiology, genetics, physiology, and anatomy to conduct scientific disclosure analysis of Center records.
- Interpersonal skills sufficient to organize and coordinate thorough, systematic, and professional projects to meet the established and unanticipated needs of the CBER offices, Office of the Commissioner, other Centers, HHS and other Agencies.
- Ability to effectively communicate orally and in writing.

If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.

Foreign Education: 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 further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

How you will be evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement: Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

Equal Employment Opportunity:

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:

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](#).

How to Apply:

Please submit **electronic resume or curriculum vitae** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable), latest PMAP (if applicable), unofficial transcripts, Foreign Credit Evaluation (if applicable), copy of your active medical license/s (if applicable), copy of your board certification/s (if applicable), and letter of interest (Word or PDF)** with **“Title 21 CBER/OCOD/DDOM/COB Heath Communication Policy Analyst”** in the subject line to: CBERHumanCapital@fda.hhs.gov. **Applications will be accepted through 11/13/2024.**

Announcement Contact:

For questions regarding this Title 21 (Cures) position, please contact CBERHumanCapital@fda.hhs.gov.

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

FDA is an equal opportunity employer.

