

# Title 21 Vacancy Announcement Department of Health and Human Services (HHS) Food and Drug Administration (FDA) Office of the Commissioner (OC) Office of Policy, Legislation, and International Affairs (OPLIA) Office of Global Policy and Strategy (OGPS) Immediate Office (IO)

**Application Period:** February 23, 2023 – March 09, 2023

<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:** Associate Director Series: 0602

**Location(s):** Silver Spring, MD **Salary:** Starting at \$210,000

Work Schedule: Full Time

Full Performance Band Level: Band F

Cures Band: Band F

**Travel Requirements:** Up to 50%

**Bargaining Unit:** 8888

<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.

Working under OPLIA, the Office of Global Policy and Strategy (OGPS) mission is to protect and enhance the public health of Americans by assuring global considerations are fully integrated

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into the Agency's policies and operational activities. The mission of the Office of Global Policy and Strategy (OGPS) is to protect and promote the public health of Americans by effectively advancing FDA's public health mission globally. OGPS performs foreign inspections, and provides executive oversight, strategic leadership, and policy direction on FDA's global engagements including information sharing, international standards development, trade relations, and collaboration activities with partner regulatory authorities or multilateral institutions.

# **Duties/Responsibilities**

As Associate Director (Physician), the incumbent serves as the Senior Advisor to the Associate Commissioner for Global Policy and Strategy on global health matters. Other duties include:

- Serving as a member or leader of Agency inter-Office and Center committees and working groups involved in medical, scientific, and regulatory issues associated with global health, policy and/or strategy matters.
- Developing OGPS policy positions for multinational, global health bodies (e.g., World Health Organization and United Nations global and regional/continental bodies), non-governmental organizations (e.g., the Bill and Melinda Gates Foundation), and societal organizations (e.g., International Federation of Pharmaceutical Manufactures and Associations).
- Using professional clinical and scientific expertise as well as global health diplomacy in advancing mutual OGPS priorities and partnerships with bilateral, regional, continental, and global regulatory authorities.
- Leading technical and scientific engagements between FDA and regulatory authorities which are developing or strengthening their drug and vaccine evaluation and review programs.
- Advising the Associate Commissioner on emerging policy issues related to global health trends and outbreaks including analysis of regulatory issues resulting from the spread of infectious diseases such as HIV/AIDS, Ebola, Coronavirus, and M-pox.

Supervisory Responsibilities: Non-Supervisory Position

## **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.

- Financial Disclosure is 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 at a later time. Top Secret Security Clearance Required.
- One year probationary period may be required.

#### **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.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following required qualifications. Please note: Additional education and experience listed that is not indicated as required 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: Degree: Doctor of Medicine, Doctor of Osteopathic Medicine or equivalent from a school in the United States or Canada. This degree must have been accredited by the Council on Medical Education of the American Medical Association (external link); Association of American Medical Colleges (external link); Liaison Committee on Medical Education (external link); Commission on Osteopathic College Accreditation of the American Osteopathic Association (external link), or an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained.

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates (external link), a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination. For more information please see: OPM Occupational Series Qualification Requirements
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<u>Desired Education</u>: In addition to the education requirement, our ideal candidate will possess additional credentials in pharmacy, clinical research, and/or global health.

<u>Professional Experience</u>: Experience serving as an internationally recognized global health, policy, and clinical research expert with demonstrated success in managing complex programs; experience working in international settings and clinical care; and experience and leadership working in USG interagency (e.g., Health and Human Services, Department of State, Department of Defense, United States Agency for International Development).

#### <u>Desired Professional Experience</u>: Our ideal candidate will possess:

- Successful ability to collaborate with team members to develop consensus.
- Experience providing consultation, sharing results and best practices.
- Experience coordinating program activities, and leading program initiatives.
- Demonstrated experience in participating in and representing working groups for knowledge sharing and best practices.
- Knowledge of Agency policies and scientific methods related to global health policy and strategy.
- Experience and/or specialty training in clinical trial design, review, and execution.
- Additional experience in pharmacy, clinical research, and/or global health.

## **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: This position requires a *Top Secret* security clearance and the incumbent has access to documents and facilities related to national security.

# **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: <a href="https://www.fda.gov/about-fda/jobs-and-training-fda/ethics">https://www.fda.gov/about-fda/jobs-and-training-fda/ethics</a>.

# **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 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: Submit resume or curriculum vitae with cover letter by March 09, 2023 to: <a href="Jessica.Lacey@fda.hhs.gov">Jessica.Lacey@fda.hhs.gov</a>. MUST VERIFY U.S. CITIZENSHIP WITH APPLICATION EMAIL. CONSIDERATION WILL NOT BE GIVEN IF U.S. CITIZENSHIP STATEMENT IS NOT INCLUDED IN APPLICATION EMAIL. Candidate resumes may be shared with hiring official within the Office of the Commissioner, Office of Global Policy and Strategy with a similar job vacancy. Candidates can opt out of this process by annotating resume with "do not share". Please reference Job Reference ID: CURESFY23AssociateDirector.

#### **Announcement Contact**

For questions regarding this Cures position, please contact Jessica Lacey, 301-796-7462.

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

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