



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 New Drugs (OND)

Application Period: April 26, 2024 – May 31, 2024

Area of Consideration: 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: Physician (Surgical Oncologist)

Series: AD-0602

Location(s): Silver Spring, MD

Salary: \$165,000 - \$262,150

Work Schedule: Full-Time

Cures Band(s): Band C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: 3591

Relocation Expenses Reimbursement: You WILL NOT 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) 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 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 and prescription drugs, including

biological therapeutics and generic drugs.

The mission of the Office of New Drugs (OND) is to protect and enhance the health of the public through the review and evaluation of scientific data submitted by pharmaceutical manufacturers in support of both New Drug (NDA) and Investigational New Drug applications (INDAs), and to determine if candidate drugs are safe and effective.

Duties/Responsibilities

As a **Physician (Surgical Oncologist)**, the incumbent will be responsible for providing regulatory oversight for investigational studies during drug development and making decisions regarding marketing approval for new (innovative or non-generic) drugs, including decisions related to changes to already marketed products. Duties will be focused on optical imaging drugs used intraoperatively to identify pathology such as cancer.

- Serves as a Physician within a clinical review division to determine whether clinical trials of new drugs in humans related to a therapeutic area are soundly conceived, and supported by prior animal testing and other controls adequate to justify tests in humans review applications by manufacturers for permission to market new drugs for general use should be approved based on an evaluation of the evidence of their safety and effectiveness; and ensure proposed labeling contains truthful claims for safety and effectiveness, and adequate directions for use and warnings against misuse.
- Reviews supplements and amendments to previously approved NDAs, which must be thoroughly reviewed for efficacy and safety in acting on a supplement; review periodic reports submitted by sponsors on drugs approved for marketing; review adverse reaction and other safety reports. Make medical decision in each case as to whether the indicated population of a previously approved NDA should be expanded, whether changes in the labeling reflecting new safety information is required, and whether the information submitted and otherwise available supports approval of the supplement.
- Reviews the summaries of pharmacologists and chemists as part of the decision-making process and determine whether or not to approve an application. Make science-based recommendations that an NDA or a supplement submission be approved, is incomplete on specific points, or not be approved such an IND be continued, modified, or placed on clinical hold.
- Assigned work is in the area of medical specialty, in as much as this is practicable based on the types of applications received. Drug submissions assigned for review will include drugs whose evaluation will be challenging and complex and require mature professional judgment. Physicians within the Division are considered to be the Agency's foremost specialists in assigned therapeutic areas and indications, and in appropriate clinical trial design for evaluation of drugs intended to treat such conditions.

Supervisory Responsibilities: N/A

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 at a later time.

Qualifications

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 not be excluded from consideration for this position.*

Education Requirement:

Physician, AD-0602 Series:

Education: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *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.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Desired Education: Our ideal candidate should be American Board of Surgery (ABS) certified/eligible. Specific training and board certification/eligibility in surgical oncology is desirable.

Desired Professional Experience: Our ideal candidate will possess experience in surgical oncology. Experience with optical imaging drugs is desirable.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: 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.

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 more information about this requirement, please visit the [Recognition of Foreign Qualifications | International Affairs Office \(ed.gov\)](#)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/ Moderate-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 qualifications is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

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

Submit resume or curriculum vitae with cover letter to OND-Employment@fda.hhs.gov by **May 31, 2024**. Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Job Reference Source Code ID: 24-030EG** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact OND’s Admin Analysis Staff at OND-Employment@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.

