



Office Director
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of the Chief Medical Officer (OCMO)
Office of Public Health Preparedness and Response (OPHPR)

Summary:

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of the Commissioner (OC), [Office of the Chief Medical Officer \(OCMO\)](#), [Office of Public Health Preparedness and Response \(OPHPR\)](#) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

Become a part of the Department that touches the lives of every American.

At the [Department of Health and Human Services \(HHS\)](#) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.

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.

Office of the Commissioner (OC) is responsible for the efficient and effective implementation of FDA's mission. To assist in those responsibilities, OC contains Super Offices that support specific organizational focus areas and administrative offices that manage operational staff needs. OC also oversees the newly established FDA Reimagined Human Foods Program.

The Office of the Chief Medical Officer (OCMO) provides executive leadership, coordination, and oversight for FDA cross-cutting clinical and regulatory policy matters, and public health preparedness and response activities on behalf of the Commissioner. OCMO promotes the development of safe, effective, and innovative medical products for patients through agency-wide collaboration on combination products, improvement of evidence generation practices, ethical conduct of clinical research, orphan product development, and pediatric therapeutics. OCMO fosters clinical community of practice and clinical career development across the Agency and serves as primary liaison to clinical societies and other clinician stakeholder groups.

The Office of Public Health Preparedness and Response (OPHPR) provides leadership, coordination, and oversight for FDA’s national and global public health preparedness and response portfolios including consumer safety reporting, health emergencies, and medical product and critical food shortages and applicable supply chain issues.

Title 21 Band F GS-15+ equivalent or T38 Physician Tier Coverage/Grade Determinant (See Job Aid Below)

Minimum – **\$210,000**

Maximum – **\$325,066**

Overview

Open & Closing Date: July 25-August 23 (Extended)
Salary Range: 602 series: \$210,000-\$325,066 601 series: \$181,551-\$260,823
<u>Band: F</u>
Occupational Series: 0602 or 0601
Duty Location: Silver Spring, MD
Remote Job: No
Telework Eligible: Yes
Travel Required: No
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: *DO NOT CHANGE
Promotion Potential: Band F
Supervisory Status: Supervisor
Security Clearance: TS/SCI
Drug Test: n/a
Position Designation:
Trust Determination Process: Public Trust

This job is open to: FDA-Wide

Hiring Path Clarification Text:

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.

Duties:

Serves as the Office Director providing technical, clinical, and administrative oversight for OPHPR. Initiates and implements new policies, systems, procedures, and organizational structures to properly align with organizational responsibilities. Develops and coordinates the implementation of FDA-wide plans, procedures, and strategies for consumer safety reporting, health emergencies, medical product and critical food shortages and applicable supply chain issues in support of, and in collaboration with FDA Centers and Offices, and with external US government, international partners, and other interested parties. Coordinates policy engagement and FDA's role in response to outbreaks, epidemics and pandemics which includes interaction with White House, HHS, and other entities, in close collaboration with FDA Centers and Offices. Coordinates agency-level policy engagement to prevent, detect and respond to shortages of medical products and critical foods. Coordinates cross-cutting activities within the FDA, working closely with Center and Office leads; supervises primary focal point for shortage and supply chain coordination within OC and with HHS, the White House, and other US government partners.

The Office Director coordinates the business process alignment and development for any new consumer safety reporting management technology systems; adjudicates issues of complex jurisdiction and coordinates response to consumer-related health safety signals that involve multiple Centers or otherwise require an agency response. Serves as the focal point, on behalf of the Commissioner, for the Department of Health and Human Services' Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to protect the civilian population and the Department of Defense medical countermeasure (MCM) programs to support the warfighter and critical health policy issues that impact national security including the National Biodefense Strategy. Develops and coordinates the implementation of crosscutting FDA policies and procedures to facilitate: (1) MCM development efforts; (2) access to available MCMs when necessary, through an appropriate access mechanism, such as FDA's Emergency Use Authorization (EUA) or export mechanisms; (3) assessment of MCM safety and effectiveness for national and international emergencies; (4) safeguarding MCMs from adulteration or disruption of supplies during public health emergencies; and (4) global health security by helping to advance global regulatory frameworks for MCMs.

Supervisory Responsibilities:

The incumbent supervises the staff within OPHPR. The incumbent provides guidance, direction, resolves disputes and strives to ensure that members of each team have what is necessary to perform their jobs to the best of their abilities.

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 (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. Specifically, as a manager, the incumbent initiates nondiscriminatory practices and affirmative action for the Office in the following: (1) merit promotion of employees and recruitment and hiring; (2) fair treatment of all employees; (3) encouragement and recognition of employees' achievements; (4) career development of employees; and (5) full utilization of their skills.

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.
- 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. Please go to <http://www.sss.gov> for more information.
- One-year probationary period may be required.
- One-year supervisory 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. TS/SCI Clearance must be obtained to be eligible for position.

- **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.

Qualifications

Qualifications will be based on the minimum years of relevant experience, rather than specialized experience, for determining and validating a Title 21 candidate's band. This standard applies across all Title 21 positions. (Please use this [Link](#) for reference).

In order to qualify for the **OPHPR Office Director**, you must meet the following requirements:

Basic Qualification Requirements:

Physician, 0602 Requirements: Must possess a M.D. degree, official transcripts are required. 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.

Requirements for 601 series: Bachelor's/Graduate/higher level degree: major study in an academic field related to 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.

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 employee, you are not exempt from transcript requirements.

TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. You must submit an official transcript, unofficial transcript, or a list including courses, grades earned, completion dates, and quarter and semester hours earned. Transcripts must identify a degree type, date degree conferred, and identify the major if using education to meet basic degree requirements.

Education must be accredited by an accrediting institution recognized by the [U.S. Department of Education](#) in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by the U.S. Department of Education.

If you are using education completed in foreign colleges or universities, see the [Foreign](#)

Education section below for additional requirements.

Electronic Transcript Caution: If you have obtained your transcripts electronically, the file might contain security measures that could prevent our application system from reading the file. Therefore, you should consider asking the institution to provide the file in a non-secured electronic format. Alternatively, you could scan or take a photo of the printed copy of the transcript. If your uploaded transcript cannot be read by our system, you may receive consideration and credit for the information we can access.

See the [Application Manager Documentation](#) for tips on submitting your paper-based documents.

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](#).**

To be acceptable, the foreign credential evaluation must include/describe at a minimum, the following information: (1) The type of education received by the applicant; (2) The level of education in relation to the U.S. education system, and state that its comparability recommendations follow the general guidelines of the International Evaluation Standards Council; (3) The content of the applicant's educational program earned abroad, and the standard obtained; (4) The status of the awarding foreign school's recognition and legitimacy in its home country's education system; and (5) Any other information of interest such as what the evaluation service did to obtain this information, the qualifications of the evaluator, and any indications as to other problems such as forgery.

For 0602 positions, you must provide an Educational Commission for Foreign Medical Graduates (ECFMG) certification to meet the foreign education requirement.

Note: Some positions require the completion of specific courses or a specified number of credit hours. Therefore, the foreign credential evaluation should provide information similar to that of an official transcript, to include a list of the courses taken, quarter and/or semester hours awarded, the cumulative grade point average (GPA), honors received, if any, date degree awarded.

Applicants can request an evaluation from a member organization of one of the two national associations of credential evaluation services listed below:

1. [National Association of Credential Evaluation Services](#) (NACES)
2. [Association of International Credentials Evaluators](#) (AICE)

Credential evaluations are not free, and applicants are responsible for the cost of the selected service.

For more information about this requirement, please visit the [U.S. Department of Education website for Foreign Education Evaluation](#).

Additional Conditions of Employment:

- **Pre-employment physical required:** No
- **Drug testing required:** No
- **License Required:** No
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** 8888
- **Telework eligible position:** Telework is at the discretion of the supervisor.
- **Remote eligible position for highly qualified candidates at the discretion of the supervisor.**
- **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.
- **Financial disclosure statement, OGE-450, required:** Please be advised that this position may be subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. Applicants are advised to seek additional information on this requirement from the hiring official before accepting this position.

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>.

Additional Information:

- **Additional selections may be made for similar positions within the commuting area(s) of the locations listed through this vacancy announcement.**
- **If you are serving, or have served in the last 5 years (from 12/01/2023) 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.

All requirements must be met by the closing date of this announcement [August 23, 2024]; only education and experience gained by this date will be considered. You must continue to meet all requirements throughout the entire hiring process.

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.

If you are referred to the hiring manager for consideration, you may be further evaluated based on an interview; review of requested work samples, writing samples, most recent performance evaluation(s), or professional references; or results of an oral presentation or work-related test.

Failure to comply with any of the additional assessment requirements will result in removal from further consideration.

Please follow all instructions carefully. Errors or omissions may affect your eligibility.

Send applications to: Jessica Bennett (Jessica.Bennett@fda.hhs.gov) by COB of announcement closing date