



**Supervisory Physician (Ethicist)**  
**Department of Health and Human Services (DHHS)**  
**Food and Drug Administration (FDA)**  
**Office of the Commissioner (OC)**  
**Office of Clinical Policy and Programs (OCPP)**  
**Office of Pediatric Therapeutics (OPT)**

**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 Clinical Policy and Programs (OCPP), Office of Pediatric Therapeutics (OPT) 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 mission of the Office of Clinical Policy and Programs (OCP) is to advance the public health by developing, leading, and executing programs and cross-cutting initiatives that support FDA’s centers in making effective, safe, and innovative medical products available to the American people. OCP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, caregivers, their advocates, and the FDA community.

The Office of Pediatric Therapeutics (OPT) provides ethical expertise for scientific and regulatory issues involving the therapeutic and diagnostic initiatives in pediatrics across all of FDA's Centers. The incumbent provides independent review of pediatric research ethics issues and participates in the planning, management, and implementation of pediatric bioethics activities across all of FDA's Centers. Activities will include pediatric research ethics consultation, providing pediatric ethics training to stakeholders within and outside of the agency, and guidance development pertaining to a wide range of pediatric research ethics issues. The incumbent will have supervisory responsibilities for select staff within OPT.

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

**Overview**

Open & Closing Date: August 16-30, 2024
Salary Range: \$195,000 - \$250,000
<a href="#">Band: E</a>
Occupational Series: 0602
Duty Location: Remote Position
Remote Job: Yes
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 E
Supervisory Status: Supervisor
Security Clearance: n/a
Drug Test: n/a
Position Designation: Non-Sensitive/Moderate Risk
Trust Determination Process: Public Trust

**This job is open to:** All Sources

### 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:

As a Supervisory Physician and pediatric ethics expert, the incumbent provides ethical expertise for scientific and regulatory issues involving the therapeutic and diagnostic initiatives in pediatrics across all of FDA's Centers. The incumbent serves as a principal advisor to the OPT Office Director, FDA review divisions and other Center managers on whether proposed pediatric clinical trials meet ethical and regulatory requirements and are designed appropriately. The incumbent provides independent review of pediatric research ethics issues and leads the planning, management, and implementation of pediatric bioethics activities across all of FDA's Centers. Activities will include pediatric research ethics consultation, providing pediatric ethics training to stakeholders within and outside of the Agency, and guidance development pertaining to a wide range of pediatric research ethics issues. As a Supervisory Physician with an extremely high level of medical expertise, the incumbent is responsible for planning and evaluating the activities of the Pediatric Ethics Program of the Office of Pediatric Therapeutics. This responsibility requires the incumbent to maintain close personal contact with the "state of the science" and research ethics literature in order to inculcate the most advanced theories and practices in the fields into premarket and post market review activities. The incumbent is responsible for reviewing ethical issues in performing pediatric clinical trials that have a national or international impact.

The Supervisory Physician leads or serves as a member of task forces and study groups called to consider problems or direction in the field of pediatrics and research ethics, including guidance development. As required, conceives of the mission of such groups, develops propositions for study, and speaks for the Pediatric Ethics Program, Office, and Center on matters in pediatric research ethics and pediatric product development. When appropriate, the incumbent represents the ethics program in the field of pediatrics by providing consultations, opinions, advice, and endorsements to the regulated industry and the professional and academic communities. The incumbent maintains continuing liaison with other organizations within the Center and the Agency, the Department, and other agencies. The incumbent will serve as a member of the FDA Pediatric Review Committee and participate in outreach activities with external stakeholders. As products are identified that would offer a health benefit to the pediatric population, the incumbent will work with the responsible Offices and Divisions to ensure that pediatric study plans, protocols, and Written Requests are adequately designed and ethically appropriate. The incumbent will facilitate resolution of differences in pediatric ethics

that may exist between EMA and FDA. The incumbent will have responsibility for the Pediatric Ethics Subcommittee of the FDA Pediatric Advisory Committee, including the identification of appropriate experts to become Special Government Employees, the development of appropriate topics in collaboration with the FDA product Centers, and the analysis and follow-up of subcommittee discussion and recommendations. The incumbent is responsible for training new medical reviewers in the Agency on compliance with agency regulations and recognized standards in pediatric ethics.

The incumbent represents FDA at national and international meetings where pediatric ethical issues and/or pediatric clinical trials and product development is discussed. The incumbent keeps Agency officials informed of all current and emerging pediatric ethical and international issues.

#### Supervisory Responsibilities:

The incumbent supervises the staff within OPT. 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 **OPT Supervisory Physician (Ethicist)**, 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.

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 30, 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: Brenda Harmon ([Brenda.Harmon@fda.hhs.gov](mailto:Brenda.Harmon@fda.hhs.gov)) by COB of announcement closing date**