Introduction: 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 United States are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated. FDA’s programs are national in scope and effect, and the agency’s activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

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.

21st Century Cures Act Eligibility: This position supports the development, review, or regulation of medical products and is funded 51% or more by Medical Product User fees.

This position reports to (organizational title) Super Office Director, Office of New Drugs.

This position is located in Silver Spring, Maryland.

Functional duties and responsibilities:

The incumbent serves as the Deputy Director for Analgesics, Controlled Substances and Substance Use Disorders within the Office of New Drugs (OND). The position is responsible for coordinating, providing input, and direction on efforts and regulatory programs within OND on programs directed towards analgesia drug development, controlled substances, and disorders related to their use, including treatments for the range of substance use disorders (SUD) and development of overdose reversal agents regulated within...
OND. The incumbent will have direct Office-level technical authority and will coordinate and provide input across OND on all relevant programs on SUD and related reversal agents. The incumbent will also have a key role in supporting and leading efforts in OND for policy development (e.g., guidance development) on the treatment and management of substance use disorders, development of medications for pain management, and reversal agents related to controlled substances.

This incumbent will perform the following:

- Serves as a liaison to CDER and FDA efforts on analgesic drug development, substance use disorders and controlled substance programs and policies, as well as serving as a key OND representative to external groups (e.g., patient stakeholders, academic groups, other governmental organizations, industry) that are engaged in development of treatments for pain, for SUD, and policy development regarding controlled substances.
- Under the direction of the Office Director, coordinates and provides office-level guidance to OND office and divisional leadership on development programs focused on controlled substances and analgesic drug development.
- Leads policy development and associated guidance development for analgesics, SUDs including on opioids, psychedelics, stimulants, alcohol, and other such disorders regulated in OND
- Provide leadership for policy development related to analgesic drug development, controlled substances, SUD or overdose reversal treatments in coordination with OND policy
- Provides OND office-level coordination and technical direction of IND development programs as well as NDA/BLAs targeting analgesic drug development, SUD and overdose reversal for programs regulated by OND
- Coordinates activities with the Office of the Center Director (OCD), Controlled Substance Staff (CSS) on development of policy, research efforts, and other such activities related to analgesic drug development, controlled substances, SUD, overdose prevention and management.
- Serves as the OND representative on the Real World Evidence (RWE) subcommittee for research/studies focused on controlled substances, SUD treatment, and overdose prevention and management
- Serves as the point person to assure OND delivery of relevant agency priorities on controlled substances in conjunction with CSS and CDER staff.
- Represents OND in CDER or FDA working groups focused on analgesic drug development, controlled substances, SUDs, and overdose prevention and management with other OND SMEs as appropriate
- Acts as liaison with other government agency groups involved in policy development on analgesic drug development, controlled substances, SUD, and overdose reversal such as working with National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Drug Abuse (NIDA), Department of Defense (DoD) and other relevant organizations
- Coordinates OND research efforts focused on analgesic drug development, controlled substances, SUD or OD reversal agents
- Works with OND offices and divisions to coordinate and support advisory committees and other external meetings on analgesic drugs, controlled substances, SUD, or overdose prevention or management (e.g., workshops, symposia) to assure high quality and productive meetings
- Coordinates with legislative affairs (Office of Legislation in CDER) to respond to inquiries on activities for analgesics, controlled substances, SUD and overdose prevention and management.

**Supervisory responsibilities:** Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff (including supervisors and team leads if appropriate) performing the work and functions of the organizational unit.

**Organizational Management:** Assists in managing a Super Office.
**Program Management:** Runs a program of singular discipline focus in the Center. Oversees or coordinates multiple functional activities.
**Resource Management:** Monitors and reports on resources needed to run a Division in the Center.
**Personnel Performance Management:** Counsels and rates immediate subordinates.
**Human Capital Management:** Identifies employee competency gaps.

**EEO responsibilities:** 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 Center 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.

Other factors. Provide details on the following areas for the position:

- **Knowledge:**
  - **Qualifications:** Highly skilled at applying all aspects of occupational specialty. May be proficient at one or more aspects of other occupational specialties.
  - **Breadth of Knowledge:** Medium
  - **Depth of Knowledge:** Deep

- **Complexity of work:**
  - **Problem Solving:** Solves problems of all complexities for a program. Identifies and reports on trends and interdependencies of problems across multiple functions in a program.
  - **Decision Making:** Decides outcome of operational activities on multiple related projects. Reviews and concurs on operational decisions based on set of data points and findings outcomes.
  - **Statement Making:** Creates draft statements regarding the outcome of operational activities on multiple related projects.

- **Coalition building:**
  - **Coordination:** Oversees coordination of work among projects in support of a functional discipline. Creates and facilitates internal and/or cross-functional teams that collaborate to accomplish complex, challenging scientific and/or operational objectives. Coordinates work with external organizations.
  - **Thought Leadership:** Curates and refines best practices.

- **Impact:**
  - **Impact on Work Being Performed:** Work impacts a program.
  - **Level of Autonomy:** Defines standard procedures to be used to accomplish work.
  - **Scope of Work (Impact on Consumer):** Determines definitions of successful or unsuccessful outputs of activities. Recommends approval or disapproval of a medical product.
  - **Impact on Organization:** Approves assignment of work to projects.
  - **Risk Management:** Identifies risks to program success.

**Position’s Desired Skills, Experience, or Education:**

**Education Requirements:**

- **Physician Series, 0602 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; Association of American Medical Colleges; Liaison Committee on Medical Education; Commission on Osteopathic College Accreditation of the American Osteopathic Association, or an accrediting body recognized by the U.S. Department of Education 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, 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.

- **Desired Skills, Experience, or Education:**
  - Advanced post-graduate training in specialties relevant to analgesic drug development, SUD (e.g., extensive experience in, and/or residency in psychiatry, neurology, or post-residency fellowship training in addiction medicine or related fellowship training) or having completed a residency in internal medicine.
  - Direct clinical experience in the management of patients with pain disorders and/or SUD.
  - Experience in drug development to include participation in design and conduct of relevant clinical trials
  - Experience in development of analgesic drugs and/or drugs for treatment of SUD.
• Experience in policy development, program development, and coordination of efforts in pain management, and/or the treatment of SUD, and/or policies and programs related to controlled substances
• Ability to apply knowledge of regulatory environments related to the regulation of drugs and related policy.
• Ability to apply knowledge of leadership principles and concepts regulating and evaluating new drugs and biological products.
• Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities and spearhead important program initiatives.

Supervisory Certification:
I certify that this is an accurate statement of the major duties and responsibilities of this position and its organizational relationships, and that the position is necessary to carry out Government functions for which I am responsible. This certification is made with the knowledge that this information is to be used for statutory purposes relating to appointment and payment of public funds, and that false or misleading statements may constitute violations of such statutes or their implementing regulations.

Name: Peter Stein, M.D., Director, OND

Peter P. Stein -S
Digitally signed by Peter P. Stein -S
Date: 2023.08.07 07:58:11 -04'00'

Signature

08/07/2023
Date
Position Designation Record

Department
Agency
Supplemental Duty
Position Title
Position Description
Series and Grade/Pay Band
Position Description Number
Designator’s Name & Title

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPT OF HHS-FOOD AND DRUG ADMINISTRATION
Deputy Super Office Director
602 Band F
S-23-1107
Peter Stein, M.D., Office Director, OND

Final Position Designation and Investigation

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<tr>
<td>Adjusted Position Designation Points from Step 3</td>
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Summary

National Security
No national Security Duties

Suitability

<table>
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<tr>
<th>Duties</th>
<th>Degree of Potential for Compromise or Damage</th>
</tr>
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| Government operations – rulemaking, policy, and major program responsibility (includes regulation or policy making, directing, implementing, advising and audits) | Severe impact  
One or more of the following:  
• Senior management duties or assignments that do not rise to the level of an automatic High-Risk condition  
• Substantial responsibility for approving regulations and/or rule-making agendas for significant government programs impacting the public’s trust  
• Independent responsibility for planning or approving continuity of government operations  
• Sets policy for significant government programs impacting the public’s trust |
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<tr>
<th>Duties</th>
<th>Degree of Potential for Compromise or Damage</th>
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|        | • Independent agency spokesperson concerning delicate controversial matters impacting the public’s trust  
|        | • Serves in advisory role to senior agency officials who complete one or more of the above duties |
| Public safety and health services, regulation, enforcement, and protection (Food safety and inspection, occupational health and safety, transportation safety, environmental safety and hazard mitigation) | Severe impact  
|        | Immediate, significant, and independent responsibility for protecting the public’s health and safety in areas outside of national security, such as:  
|        | • Food safety and inspection  
|        | • Occupational health and safety  
|        | • Transportation safety enforcement  
|        | • Environmental safety  
|        | • Environmental hazard mitigation |
| Protection of personal, private, controlled unclassified, or proprietary information-with the potential to damage the public’s trust (includes access to or processing of personal information such as that protected by the Privacy Act (PA) of 1974, exempt from disclosure under the Freedom of Information Act (FOIA), financial data, or privileged information involving the award of contracts, contractor proprietary information, etc.) | Moderate impact  
|        | Access and control over personal, private, proprietary, or controlled unclassified information, the unauthorized disclosure of which could negatively impact the public’s trust, through serious damage/harm to:  
|        | • The integrity or efficiency of the service  
|        | • Individuals or business entities  
|        | • Government programs or operations impacting the public’s trust |

**Adjustment for Scope of Program and Correlation to Extent of Impact**

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<tr>
<th>Program Scope and Impact</th>
<th>Impact</th>
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| Adjustment for Scope of Program and Correlation to Extent of Impact | Agency Impact  
|        | • Program operations affect only one agency. Misconduct or damage would have potential for a local impact on the agency, and/or the individuals or private entities affected by the agency. |
| Level of Supervision | Ability to act independently |
| Adjustment for level of supervision or other controls | Limited or no supervision - ability to act independently in almost all areas almost all of the time  
|        | • Occasional review from a perspective of major policy issues by a superior who likely has no relevant expertise in the technical aspects of the duties performed. |

Designator’s Name: Peter Stein, M.D., Office Director, OND  
Designator’s Signature: Peter P. Stein, M.D.  
Date: 07/10/2023
Fair Labor Standards Act Status Determination Questionnaire for Managers and Supervisors

Employee:

Position: Title  Dep Super Office Dir.  Pay Plan GS Series 602  Grade  F
Office:  OND/IO  S-23-1107-F

Employment Status: Full-Time
Work Schedule: 8 Hour
Supervisor: Peter Stein, M.D.  Contact Number: 301-796-1700

Purpose: This questionnaire is to be used by managers and supervisors to assist Classifiers in determining whether or not the named employee should be coded as exempt or non-exempt from the Fair Labor Standards Act (FLSA). The provisions of the FLSA apply to employees coded as non-exempt. The Fair Labor Standards Act status of the employee is often the key to deciding whether certain duties are compensable as "hours of work" and as to the rate of pay the employee should be compensated. Overtime entitlements also depend on this status, as may compensation for travel time. It is assumed that all federal employees are covered by the FLSA (Non-Exempt) unless they clearly fall under one of the following exemptions. Job titles and PDs are not determinative of an employee’s status, rather it is the duties that the employee actually performs on a regular and recurring basis that serve as the determining factor. Please provide detailed explanations in the spaces provided for all “Yes” answers.

1. Yes  No

☒  ☐ Is the employee is a supervisor or manager? (regularly direct two or more employees, and has the authority to hire or fire (or the employee's recommendations as to the hiring, firing, advancement, promotion, or any other change of status of other employees, are given particular weight))? 

If yes, list examples of duties to support this:
Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director.

2. Yes  No

☒  ☐ Does the employee exercise discretion and independent judgment with respect to matters of significance while performing office or non-manual work directly related to the agency's management or general business operations? (The exercise of discretion and independent judgment involves the comparison and the evaluation of possible courses of conduct, and acting or making a decision after the various possibilities have been considered. Employees who simply apply well-established techniques or procedures described in manuals or other sources within closely prescribed limits to determine the correct response to an inquiry or set of circumstances will be nonexempt. The term “matters of significance” refers to the level of importance or consequence of the work performed. Some examples: Has authority to commit the employer in matters that have significant financial impact; Has
authority to waive or deviate from established policies and procedures without prior approval; Has authority to negotiate and bind the organization on significant matters)

If yes, list examples of duties to support this:
Leads policy development and associated guidance development for analgesics, SUDs including on opioids, psychedelics, stimulants, alcohol, and other such disorders regulated in OND

3. Yes No
   ✔   Is the employee's primary duty in the performance of work requiring advanced knowledge in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction? The work must include the following three elements:
   A. The employee must perform work requiring advanced knowledge (predominantly intellectual in character and including work requiring the consistent exercise of discretion and judgment). Advanced knowledge cannot be attained at the high school level;
   B. The advanced knowledge must be in a field of science or learning which includes the traditional professions of law, medicine, theology, accounting, actuarial computation, engineering, architecture, teaching, various types of physical, chemical and biological sciences, pharmacy, and other similar occupations that have a recognized professional status;
   C. The advanced knowledge must be customarily acquired by a prolonged course of specialized intellectual instruction in a field where specialized academic training is a standard prerequisite for entrance into the profession – to address this element, please identify specifically the type and level of specialized instruction required for the position.

If yes, list examples of duties to support this:
The position is responsible for coordinating, providing input, and direction on efforts and regulatory programs within OND on programs directed towards analgesia drug development, controlled substances, and disorders related to their use, including treatments for the range of substance use disorders (SUD) and development of overdose reversal agents regulated within OND.

4. Yes No
   ✔   ☐ Is the employee's primary duty in the performance of work requiring invention, imagination, originality, or talent in a recognized field of artistic or creative endeavor? The work performed must be "in a recognized field of artistic or creative endeavor," including such fields as music, writing, acting, and the graphic arts. Employees engaged in the work of newspapers, magazines, television, or other media are not exempt creative professionals if they only collect, organize, and record information that is routine or already public, or if they do not contribute a unique interpretation or analysis to a news product.

If yes, list examples of duties to support this:

5. Yes No
   ☐   ✔ Is the employee a skilled worker in the computer field? The exemption for employees in computer occupations does not include employees engaged in the manufacture or repair of
computer hardware and related equipment. Rather, the exemption applies to computer employees whose primary duties consist of:

A. The application of systems analysis techniques and procedures, including consulting with users, to determine hardware, software or system functional specifications;

B. The design, development, documentation, analysis, creation, testing or modification of computer systems or programs, including prototypes, based on and related to user or system design specifications;

C. The design, documentation, testing, creation or modification of computer programs related to machine operating systems;

D. A combination of the above, requiring the same level of skills.

If yes, list examples of duties to support this:

Supervisor’s Signature ______________________ Date:

Peter P. Stein -S

Digitally signed by Peter P. Stein -S
Date: 2023.07.10
09:53:32 -04'00'
CYBERSECURITY WORKSHEET

Center: CDER  Office: OND/IO  PD#: S-23-1107-F
Title: Deputy Super Office Director  GS Series: 0602  Grade: F
Supervisor: Peter Stein, M.D.
E-mail: peter.stein@fda.hhs.gov  Contact Number: 301-796-1700

Purpose: The Federal Cybersecurity Workforce Assessment Act of 2015 (FCWAA) requires Federal agencies to assess their cybersecurity workforce in real time and track gaps within the workforce. This questionnaire is to be used by managers and supervisors to assist Classifiers in determining the positions Cyber Security Code. Job titles and series are not determinative of a positions code, rather it is the duties that the employee actually performs on a regular and recurring basis that serve as the determining factor. Please check the box that is associated with the position and provide a detailed explanation in the spaces provided below.

☐ Securely Provision
Specialty areas concerned with conceptualizing, designing and building secure IT systems, with responsibility for some aspect of the system development.

☐ Operate and Maintain
Specialty areas responsible for providing support, administration and maintenance necessary to ensure effective and efficient IT system performance and security.

☐ Protect and Defend
Specialty areas responsible for the identification, analysis and mitigation of threats to internal IT systems or networks.

☐ Analyze
Specialty areas responsible for highly specialized review and evaluation of incoming cybersecurity information to determine its usefulness for intelligence.

☐ Oversight and Development
Oversight and Development – Specialty areas providing leadership, management, direction, and/or development and advocacy so that all individuals and the organization may effectively conduct cybersecurity work.

☐ Investigate
Specialty areas responsible for the investigation of cyber and/or crimes of IT systems, networks and digital evidence.

☐ Collect and Operate
Specialty areas responsible for denial and deception operations and collection of cybersecurity information that may be used to develop intelligence.

☑ Not Applicable

Supervisor / Manager Signature: _________________  Date: 2023.07.10 09:53:49 -04'00'
1. Office of New Drugs (DCDG).

A. Develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process.

B. Reviews Investigational New Drug (IND) applications for all classes of drug and therapeutic products for human use with the exception of generic drug applications and recommends appropriate action with respect to safety and effectiveness of clinical trials.

C. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) for drug products and Biological License Applications (BLAs) for human use. (In this document, the term NDA subsumes BLA, as well).

D. Coordinates and/or reviews and decides on the appropriate action, including approval or disapproval, of all applications for Over-the-Counter (OTC) drug products, OTC drug monographs, prescription drug switches to OTC drug status, and other OTC-related drug products, except for generic drug applications.

E. Develops and implements standards for the safety and effectiveness of prescription drug and therapeutic products for human use and (OTC) drugs.

F. Incorporates data from the Food and Drug Administration (FDA), surveillance programs conducted to collect and evaluate the effects and use trends of marketed drug and therapeutic products.

G. Provides direction and policy formulation for pharmacology/toxicology-related issues for the Center.

H. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical experience and reports submitted by IND sponsors, by NDA applicants, and from other sources.
I. Partners with other FDA components, Department of Health and Human Services organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products to carry out these functions.

J. Oversees the FDA’s Radioactive Drug Research Committees Program through the Office of Oncologic Diseases.

K. Develops in coordination with other FDA components guidance for staff, sponsors and the public that describes the FDA’s interpretation of or policy on regulatory issues that involve the Office of New Drugs (OND) offices.

L. Provides oversight of OND’s Clinical Data Scientist program, which provides support to OND review divisions in the form of safety data sufficiency and integrity assessments, preliminary safety analyses, the preparation of standardized safety tables and figures, safety data verification in clinical study reports, integrated summary of safety, and draft labeling, exploratory/in-depth safety analyses during the review process.

2. Authority and Effective Date.

The functional statements for the Office of New Drugs were approved by the Secretary of Health and Human Services on September 25, 2019.