Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
Office of Food Additive Safety (OFAS)
Toxicologist

Application Period: 08/18/2023 – 09/01/2023

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: Toxicologist

Series: 0415 (Toxicology)

Location(s): Remote Eligible

Salary: Starting at $112,015

Work Schedule: Full Time

Full Performance Band Level: Band C

Cures Band(s): Band C

Travel Requirements: Up to 25%

Bargaining Unit: 3591, National Treasury Employees Union

Relocation Expenses Reimbursement: 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.

CFSAN is responsible for planning, developing, and administering policies and programs for protecting and promoting the public health by ensuring that the nation's food supply is safe,

secure, sanitary, wholesome, and truthfully and otherwise properly labeled, and that cosmetic products are safe and truthfully and otherwise properly labeled.

Duties/Responsibilities

The Office of Food Additive Safety is responsible for the safety review of food additives, color additives, food contact substances, Generally Recognized as Safe (GRAS) substances, food from new plant varieties, and animal cell cultured foods and serves as the Center focal point for scientific and policy support for the development of Food and Drug Administration (FDA)-initiated regulations on matters pertaining to the provisions of the food and color additive sections of the Federal Food, Drug, and Cosmetic Act.

The toxicologist for OFAS provides a source of scientific evaluations and consultation. The incumbent is responsible for the review of industry submissions and administering regulatory and policy issues associated with industry submissions, such as petitions for food and color additives, food contact notifications for food contact substances, GRAS notices, and biotechnology notifications. The incumbent provides comments on and participates in formulating guidelines for science policy concerning food substances. The incumbent also provides comments in response to requests for advisory opinions sent to the Agency concerning food substances.

- Performs extensive review of sponsor's submission to recommend a regulatory course of action. Makes a safety assessment of new manufacturing processes or changes in current manufacturing processes used in foods.
- Recommends to the Office/Center/Agency regarding the relative safety or hazards foods.
- Recommends to the Office/Center/Agency regarding the relative safety or hazards of a food substance.
- Reviews and evaluates sponsor's submissions to determine the safety of food substances within the context of applicable laws, policies, and regulations.
- Performs expert scientific analyses of complex results from toxicological and/or pharmacological testing of food substances and then derives scientific conclusions relating the scientific analyses to the safety evaluation of food substances.
- Prepares scientific responses to letters of inquiry from the regulated industry and other interested persons. Participates in scientific conferences with industry scientists, academics, scientists from other FDA offices, and other Federal agencies where aspects of toxicology data related to the safety of food substances are discussed.
- Reviews scientific data packages from citizen petitions, consumer safety advocacy groups, and other sources (e.g., literature publications and other U.S. and foreign government documents) that provide direct or supplemental information related to food substances.

- Provides scientific guidance and advice in area(s) of expertise to industry, other Federal agencies, universities, foreign governments, and other organizations on the safety of food substances.
- Reviews the scientific literature on subjects related to area of expertise, toxicological principles, and food technology to keep abreast of the current scientific literature and up-to-date knowledge in areas of expertise.
- Performs reviews and evaluations of regulated substances to update data reviews and conclusions based upon new data, new issues, or new manufacturing technology.
- Provides expert scientific guidance and mentoring in area of expertise to other scientific colleagues in the Office in the form of one-on-one training, workshops, or seminars.
- The incumbent may be expected to formulate guidelines pertinent to validation of studies.
- Prepares necessary memoranda or documents for FDA actions and interacts with members of other laboratories or divisions in the Center as well as with scientific/executives and legal officials of licensed establishments regarding contaminations.
- Represents the Center by developing and giving presentations at scientific meetings and other forums. In this capacity, effectively conveys current Center and Agency thinking on scientific and policy issues.
- Initiates and participates in educational opportunities for other Center personnel including reviewers, scientists, and managers.
- Interacts with other governmental agencies to standardize and validate assays and interacts with other FDA personnel and industry representatives regarding regulatory issues.
- On occasion may undertake independent research, including publishing articles in professional journals, to keep abreast of current trends relative to work assignments. Familiarity with the current literature in toxicology and other related fields to stay abreast of the scientific/technical developments in toxicology and related fields as they pertain to food substances.

Supervisory Responsibilities: This is not a 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.
- 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:

Toxicology Series, 0415:
Degree: toxicology; or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology. OPM Occupational Series Qualification Requirements

Professional Experience:
Evaluating the results of toxicological studies, and developing toxicological presentations for meetings.

Desired Professional Experience:

- Expertise in oral and written communication skills including the ability to capture complex scientific discussions in writing.

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 U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Background Investigation/Security Clearance Requirements: A background investigation is required. All employees must pass a security background 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. Please refer to the Ethics Clearance Requirements section. 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.

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

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

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 and a copy of transcripts (with foreign credentials evaluation, if applicable) by the closing date as identified above to CFSAN-Cures@fda.hhs.gov. Candidates can opt out of this process by annotating resume with "do not share".Please reference Job ID: ***"OFAS Toxicologist"*** when applying.

Announcement Contact

For questions regarding this Cures position, please contact CFSAN-CURES@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.