

POSITION DESCRIPTION (Please Read Instructions on the Back)

1. Agency Position No. 11F022
 6. OPM Certification No.

2. Reason for Submission <input checked="" type="checkbox"/> Redescription <input type="checkbox"/> New <input type="checkbox"/> Hdqtrs <input checked="" type="checkbox"/> Field <input type="checkbox"/> Reestablishment <input type="checkbox"/> Other Explanation (Show any positions replaced) In lieu of PD# 98F068		3. Service <input type="checkbox"/> Hdqtrs <input checked="" type="checkbox"/> Field		4. Employing Office Location Multiple		5. Duty Station Multiple		8. Financial Statements Required <input type="checkbox"/> Executive Personnel Financial Disclosure <input type="checkbox"/> Employment and Financial Interest		9. Subject to IA Action <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
7. Fair Labor Standards Act <input checked="" type="checkbox"/> Exempt <input type="checkbox"/> Nonexempt		10. Position Status <input checked="" type="checkbox"/> Competitive <input type="checkbox"/> Excepted (Specify in Remarks) <input type="checkbox"/> SES (Gen.) SES (CR)		11. Position Is <input type="checkbox"/> Supervisory <input type="checkbox"/> Managerial <input checked="" type="checkbox"/> Neither		12. Sensitivity <input type="checkbox"/> 1-Non-Sensitive <input type="checkbox"/> 2-Noncritical Sensitive <input type="checkbox"/> 3-Critical <input type="checkbox"/> 4-Special Sensitive		13. Competitive Level Code OONX				14. Agency Use	

15. Classified/Graded by	Official Title of Position	Pay Plan	Occupational Code	Grade	Initials	Date
a. Office of Personnel Management						
b. Department, Agency or Establishment	BIOLOGIST	GS	0401 (14)	11	<i>PR</i>	7/6/2011
c. Second Level Review						
d. First Level Review						
e. Recommended by Supervisor or Initiating Office						

16. Organizational Title of Position (if different from official title) _____
 17. Name of Employee (if vacant, specify) _____

18. Department, Agency, or Establishment Department of Health and Human Services		c. Third Subdivision Office of the Regional Food and Drug Director	
a. First Subdivision Food and Drug Administration		d. Fourth Subdivision Field Laboratory	
b. Second Subdivision Office of Regulatory Affairs		e. Fifth Subdivision	
19. Employee Review-This is an accurate description of the major duties and responsibilities of my position.		Signature of Employee (optional)	

20. **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.

a. Typed Name and Title of Immediate Supervisor		b. Typed Name and Title of Higher-Level Supervisor or Manager (optional) David K. Elder, Acting Deputy Associate Commissioner for Regulatory Affairs for Field Operations	
Signature	Date	Signature	Date
		<i>DK Elder</i>	7/1/11

21. Classification/Job Grading Certification. I certify that this position has been classified/graded as required by Title 5, U.S. Code, in conformance with standards published by the U.S. Office of Personnel Management or, if no published standards apply directly, consistently with the most applicable published standards. Typed Name and Title of Official Taking Action Frances Reynolds Human Resources Specialist, BCSD		22. Position Classification Standards Used in Classifying/Grading Position USOPM Job Family Standard for Professional Work in the Natural Resources Management and Biological Sciences Group, GS-0400 (9/2005) Information for Employees. The standards, and information on their application, are available in the personnel office. The classification of the position may be reviewed and corrected by the agency or the U.S. Office of Personnel Management. Information on classification/job grading appeals, and complaints on exemption from FLSA, is available from the personnel office or the U.S. Office of Personnel Management.	
Signature	Date		
<i>Frances Reynolds</i>	7/6/11		

23. Position Review	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date
a. Employee (optional)										
b. Supervisor										
c. Classifier										

24. Remarks
 BUS: 0076 Promotion Potential to GS-12 PD# 11F023

25. Description of Major Duties and Responsibilities (See Attached)

BIOLOGIST
GS-0401-11

INTRODUCTION

This is a senior trainee position for a Biologist in an FDA/ORL field laboratory and is expected to bring full professional competence in his/her discipline to bear in carrying out analyses and interpreting the significance of test results. The incumbent is assigned scientific analyses on a wide range of samples including those that are difficult, complex, or unusual. This position is a senior trainee level position in a GS-5/7/9/11/12 career ladder. Promotion to the GS-12 is dependent upon meeting all promotion requirements.

MAJOR DUTIES

- Performs the full range of Biology on a variety of samples, including the difficult, complex or unusual samples submitted by agency personnel in connection with regulatory monitoring and enforcement activities.
- Before analyzing a sample, reviews the background material submitted with the sample, agency reports on similar samples or situations, and pertinent regulations.
- Determines the approach, methods, and procedures to use in order to obtain the information requested, taking into consideration the requirements established by Agency regulations and Federal law.
- Modifies the methods and procedures as needed to satisfy special requirements and to solve problems. Includes performing the analyses on known samples to validate the modification.
- Performs additional or check analyses independently to verify that sample results are actionable.
- Writes a report that identifies the sample, shows the methods and procedures used, any modifications with validation data, the results and their interpretation, and whether the sample appears to be in violation of any agency regulation.
- Provides training for less experienced scientists on the precedents, analytical methods and instrumentation related to the particular scientific discipline of the position.
- As assigned, accompanies Agency personnel on field inspections/investigations and acts as a technical advisor.

Performs other duties as assigned.

Factor 1 - Knowledge Required by the Position (FL 1-7 = 1250 points)

Professional knowledge of the scientific principles, theories, practices, and established methodology sufficient to perform the full range of duties involved in analyzing a wide variety of drug, food, and cosmetic samples.

Knowledge of established FDA laboratory procedures, the FD&C Act and related regulations, other laws, and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory actions.

Knowledge of practices and related problems associated with the raw materials, products or manufacturing for the industries or commodities in the area of assigned responsibility.

Factor 2 - Supervisory Controls (FL 2-4 = 450 points)

The supervisor assigns the work by setting the overall objectives and the resources available. The incumbent is then responsible for planning, organizing and performing the work; determining the best approach and methods to use making modifications as needed; and interpreting the results. The completed work is reviewed from an overall standpoint for feasibility and effectiveness in meeting the assignment's requirements.

Factor 3 - Guidelines (FL 3-3 = 275 points)

The guidelines include precedents, scientific literature, laboratory procedures and methodology manuals, instrument handbooks, and agency policies. These guides are not always specifically applicable to the assignment at hand. Judgment must be used to interpret and adapt the guidelines to specific cases. The incumbent will analyze results and recommend changes.

Factor 4 - Complexity (FL 4-4 = 225 points)

The assignments include the difficult, complex, or unusual samples and analytical requests received in the laboratory. Typically, the specific data needed and the approach to be taken to obtain these data are uncertain. To make these decisions and to interpret the final results, the work requires evaluation and interpretation of data from a wide range of sources such as the background material submitted with the analytical request, reports on similar samples or problems, technical references, and trade literature, in addition to consideration of pertinent regulations. Adaptation or modification of the established methods and procedures is often required in order to plan and carry out the work.

Factor 5 - Scope and Effect (FL 5-3 = 150 points)

The work primarily involves fulfilling a range of conventional analytical requests by applying established precedents and methods to the scientific analyses of a variety of foods, drugs, or cosmetics and making method modifications if necessary. The work efforts affect the scientific adequacy and accuracy of regulatory field investigations and studies.

Factor 6 - Personal Contacts (FL 6-3 = 60 points)

The personal contacts are with scientific personnel in the Agency, other governmental and state organizations, and private industry.

Factor 7 - Purpose of Contacts (FL 7-2 = 50 points)

The personal contacts are to discuss with other scientists methodological problems, possible solutions, and method modification projects in addition to reporting the status of the work and the results.

Factor 8 - Physical Demands (FL 8-2 = 20 points)

The work requires prolonged standing, lifting of large or heavy samples or equipment. Work may involve exposure to chemical and biological hazards that may require special safety precautions. The Biologist may need to use protective clothing and equipment. Persons with physical limitations may, as appropriate, be accommodated by other employees.

To perform the work of the position, the employee must possess a valid driver's license in order to drive a Government or privately owned motor vehicle to inspections and investigations.

Candidates for this position must complete a statement regarding their physical ability and may be required to undergo physical examination because the position requires:

- the need to work long and unscheduled hours;
- exposures to all kinds of extremes of weather and noise;
- the need to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel, and climb;
- the need to meet the vision, hearing and olfactory requirements necessary to perform the work of the position; and
- the need to travel, as required by management needs, may require the incumbent to be away from the regular duty station for up to two to three weeks at a time.

Factor 9 - Work Environment (FL 9-2 = 20 points)

The work involves regular and recurring exposure to irritant chemical and biological hazards. Special safety precautions are required, and the Biologist may be required to use protective clothing and gear such as a laboratory coat, safety glasses, latex gloves, mask, etc.

When serving as an Investigator, inspection and sample collection duties are performed either inside buildings and other structures, outdoors or both depending on the type and location of the facility. As a consequence, employees are exposed to a variety of environmental conditions including extremes of heat, cold or humidity; excessive noise; excessive dust; uneven surfaces and slippery floors; and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, etc. During these periods, employees must eat and sleep in primitive conditions with little or no privacy. As Investigators, incumbents must travel into and work in areas that have been the subject of violence and that are otherwise considered unsafe.

TOTAL POINTS: 2500

GRADE CONVERSION: GS-11 (2355-2750 point range)

Reference: *USOPM Job Family Standard for Professional Work in the Natural Resources Management and Biological Sciences Group, GS-0400 (9/2005)*

Bethesda Client Services Division
Fair Labor Standards Act (FLSA)
CHECKLIST

Date:

7/6/2011

A. REQUIRED POSITION INFORMATION:

Position Title: Biologist
Pay Plan/Series/Grade: GS-401-9(11)/12 (e.g. GS-0301-12)
Organization: HHS/FDA/ORA/ORFDD/Field Laboratory
Any Field Laboratory
Administrative Code: DBR% (e.g. GAGA)
PD Number: 11F022 (e.g. HQ1234)

B. NON-EXEMPT CRITERIA (5 CFR 551.203)

Position classified at GS-04 or below
 Meets one of the requirements for nonexempt.

Explain: _____

C. EXEMPTION CRITERIA

1. Executive Exemption Criteria (5 CFR 551.205)

A. Primary duty of position is management or supervision.
 Meets requirements of management or supervision position.

OR

B. Meets 80% Test (Alternate to A. - applies to certain positions only).
 Meets requirement of 80% Test

Explain: _____

2. Administrative Exemption Criteria (CFR 551.206)

A. Primary Duty is Management, General Business Functions, or Supporting Services.
 Meets requirements of Administrative Exemption Criteria

OR

B. Meets 80% Test (Alternate to A. - applies to GS-05 and GS-6 - see below).
 Meets 80% Test

Explain: _____

3. Professional Exemption Criteria (5 CFR 551.207, 208, 209, 210)

A. Primary Duty is Work Requiring Advanced* Knowledge in a Field of Science or Learning. Note: "Advanced" means education above high school level.

OR

B. Meets 80% Test (Alternate to A. - applies to GS-05 and GS-6 - see below).

Explain: _____

D. FINAL DETERMINATION (Circle One):

Non-Exempt

Exempt

David K. Elder
Name and Title of Immediate Supervisor
David K. Elder, Acting Deputy Associate Commissioner
for Regulatory for Field Operations

Date

7/1/11

Thomas Reynolds
Name and Title of BCSD Classifier

Date

7/6/2011