

POSITION DESCRIPTION (Please Read Instructions on the Back)

2. Reason for Submission <input checked="" type="checkbox"/> Redescription <input type="checkbox"/> New <input type="checkbox"/> Reestablishment <input type="checkbox"/> Other		3. Service <input type="checkbox"/> Hdqtrs <input checked="" type="checkbox"/> Field		4. Employing Office Location Multiple		5. Duty Station Multiple		1. Agency Position No. 11F021	
Explanation (Show any positions replaced) In lieu of PD# 98F066		7. Fair Labor Standards Act <input checked="" type="checkbox"/> Exempt <input type="checkbox"/> Nonexempt		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		6. OPM Certification No.	
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 00NX		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)	09	R	7/6/2011
c. Second Level Review						
d. First Level Review						
e. Recommended by Supervisor or Initiating Office						

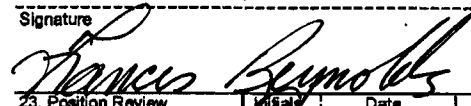
16. Organizational Title of Position (if different from official title) _____

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 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.	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)
Typed Name and Title of Official Taking Action Frances Reynolds Human Resources Specialist, BCSD	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 7/6/11	

23. Position Review	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-0401-09

INTRODUCTION

This trainee is the "first full performance" grade level in a GS-5/7/9/11/12 Biologist career ladder in an FDA/ORA Field laboratory. The incumbent is required to be well versed in analytical methodology and have sufficient grasp of the theoretical and practical limitations to select appropriate methodology for conducting a variety of analyses. The incumbent is eligible for non-competitive promotion dependent upon meeting applicable qualification requirements and satisfactory demonstration of the ability to perform the duties at the GS-11 level.

MAJOR DUTIES

- Independently performs scientific analyses and tests on a broad range of official samples submitted to the field laboratory. Is responsible for independently selecting established methods and procedures and then carrying out the analyses and tests to make determinations for regulatory monitoring and enforcement purposes. The assignments typically consist of applying established technology in routine ways to well-defined, moderate sized projects. May also work in support of larger projects using less established technology.
- Plans and carries out routine assignments. Selects and makes minor adaptations to procedures and accepted practices and handles unexpected conditions arising in the normal course of the work.
- Prepares scientific reports identifying the sample and stating the methods and procedures used, any modifications of the method including validation data, and the results.
- Participates in firm inspections with an experienced investigator to assist, observe and evaluate manufacturing processes, practices and conditions.

Factor 1 - Knowledge Required by the Position (FL 1-6 = 950 points)

Professional knowledge of Biology, theories, and practices applicable to the scientific discipline to which the incumbent is assigned sufficient to independently select precedents, methods, and procedures and to carry out established analyses and tests. Included in this is sufficient skill and ability to operate various instruments and computer systems in a laboratory.

Practical 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 established 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 2-3 = 275 points)

The supervisor makes assignments defining the objectives, priorities, and deadlines for the work and assists the incumbent with unusual situations that do not have clear precedents. The incumbent handles the routine problems encountered in accordance with previous training and accepted practices. Completed work is reviewed for technical soundness and conformance with the assignment's requirements. When the sample is in violation of regulation, the final report is reviewed more closely and the analysis may be repeated by another scientist in the laboratory.

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 4-3 = 150 points)

The assignments consist of analyses on a variety of food, drug, and cosmetic samples utilizing different and unrelated processes and methods. The incumbent considers various factual factors of the sample, the information requested, and regulatory tolerance levels to select the appropriate established methods and procedures to use. Usually problems encountered can be solved by minor adaptation or modification of the methods and procedures.

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

The work involves the scientific analysis and testing of foods, drugs and cosmetics by independently performing established analyses and tests. The results of the work affect the scientific adequacy and accuracy of regulatory field investigations and studies.

Factor 6 - Personal Contacts (FL 6-2 = 25 points)

The personal contacts are with scientist and physical science technicians in the immediate organization and other field laboratories and with agency inspectors/investigators who submit samples.

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

The personal contacts are to discuss methodological problems and possible solutions, to obtain more information about the sample, the information requested, and to report the progress and results of the work.

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 regulatory scientist 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: 1915

GRADE CONVERSION: GS-09 (1855-2100 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-407-9/1/12 (e.g. GS-0301-12)
Organization: HHS/FDA/ORFDD/Field
Laboratory
Any Field Laboratory
Administrative Code: DBR% (e.g. GAGA)
PD Number: 11F021 (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


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

7/11/11
Date


Name and Title of BCSO Classifier

7/6/2011
Date

9/17/08