

**POSITION DESCRIPTION** (Please Read Instructions on the Back)

1. Agency Position No. **11F020**

2. Reason for Submission:  Redescription  New  Reestablishment  Other  
 3. Service:  Hdqtrs  Field  
 4. Employing Office Location: **Multiple**  
 5. Duty Station: **Multiple**  
 6. OPM Certification No.

7. Fair Labor Standards Act:  Exempt  Nonexempt  
 8. Financial Statements Required:  Executive Personnel Financial Disclosure  Employment and Financial Interest  
 9. Subject to IA Action:  Yes  No

Explanation (Show any positions replaced) In lieu of PD# 98F078  
 10. Position Status:  Competitive  Excepted (Specify in Remarks)  SES (Gen.) SES (CR)  
 11. Position Is:  Supervisory  Managerial  Neither  
 12. Sensitivity:  1-Non-Sensitive  2-Noncritical Sensitive  3-Critical  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	<b>BIOLOGIST</b>	<b>GS</b>	<b>0401 (14)</b>	<b>07</b>	<b>RD</b>	<b>7/6/2011</b>
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)

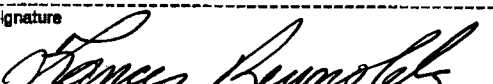
20. **Supervisory Certification.** I certify that this is an accurate statement of the major duties and responsibilities of this position and its organizational relationships, and that the position is necessary to carry out Government functions for which I am responsible. This certification is made with 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**

Signature:  Date: **7/6/11**  
 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.

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 -07**

**INTRODUCTION**

This advanced trainee level is part of a GS-5/7/9/11/12 career ladder for a Biologist in an FDA/ORA Field laboratory. The incumbent, as a part of a planned career development, receives formal and on-the-job training, working with and assisting senior regulatory scientists in the performance of a variety of analyses and experiments necessary for carrying out the mission and functional responsibilities of the FDA. 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-9 level.

**MAJOR DUTIES**

- Performs varied but relatively routine and limited scientific analyses and tests on samples submitted by agency personnel to the field laboratory. The analyses and tests are to determine the composition of substances, presence and identification of filth in food, or compliance of a drug with pertinent quality standards. The results are used by agency personnel for regulatory monitoring and enforcement purposes.
- On the basis of experience and training applies a wide variety of tasks such as selecting samples, interpolating missing data, uncovering clear discrepancies, solving minor problems, and performing analyses in support of projects assigned to higher level scientists.
- Records in detail, the receipt, handling and analysis of samples, including observations, measurements, and computations. If directed, prepares exhibits to illustrate the results of analytical work.
- Participates in firm inspections with an experienced investigator and/or chemist in a training capacity 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.

Knowledge of common methods and procedures, and a skill in calibrating and operating analytical instruments sufficient to perform relatively routine and limited analyses and tests by applying established methods and procedures.

**Factor 2 - Supervisory Controls (FL 2-2 = 125 points)**

The supervisor assigns individual samples with clear instructions as to the data to be obtained. For new or more difficult assignments, the supervisor also provides instructions as to the methods and procedures to apply and the location of source material available for reference. The incumbent is responsible for

independently completing recurring assignments, but refers all deviations and problems not covered by the instructions to the supervisor or a higher level Chemist/Biologist for assistance. The work is reviewed for adherence to instructions and standard laboratory procedures and for technical soundness of the results. New or more difficult assignments are reviewed including in-progress review.

**Factor 3 - Guidelines (FL 3-2 = 125 points)**

The methods and procedures for performing the work are established. Specific guidelines such as established methodology manuals, precedents, and standard operating procedures are available for reference. For each sample, the Biologist must exercise judgment to select the appropriate methods and procedures to carry out the analyses and tests. Situations in which the guides do not apply are referred, typically with a recommended action, to the supervisor or a higher level scientist.

**Factor 4 - Complexity (FL 4-3 = 150 points)**

The assignments involve a variety of analyses and tests. The incumbent exercises judgment in selecting the appropriate methods and procedures, which requires recognition of the existence of and differences among the identity of the sample, its physical state, and the data specified to be determined. The work can be performed by applying established methods and procedures and usually any problems encountered can be solved by minor method modification or adaptation.

**Factor 5 - Scope and Effect (FL 5-2 = 75 points)**

The work involves carrying out established scientific analyses and tests of foods, drugs, and cosmetics according to specific guidelines. The work efforts affect the accuracy and reliability of the scientific analytical services provided by the laboratory.

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

The personal contacts are with scientists and technicians within the laboratory and field investigators and inspectors.

**Factor 7 - Purpose of Contacts (FL 7-1 = 20 points)**

The personal contacts are to receive advice and assistance, to obtain and clarify information 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 regulatory scientist 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:** 1510

**GRADE CONVERSION:** GS-07 (1355-1600 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: 07/06/2011

**A. REQUIRED POSITION INFORMATION:**

Position Title: Biologist  
Pay Plan/Series/Grade: GS-401-5 and GS-7 (e.g. GS-0301-12)  
Organization: HHS/FDA/ORA/ORFDD/Field Laboratory  
Any Field Laboratory  
Administrative Code: DBR% (e.g. GAGA)  
PD Number: LIF020 (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

7/1/11  
Date

Francis Reynolds  
Name and Title of BCSP Classifier

7/6/11  
Date