

POSITION DESCRIPTION (Please Read Instructions on the Back)

1. Agency Position No. **11F023**
 6. OPM Certification No.

2. Reason for Submission
 Redescription New Hdqtrs Field
 Reestablishment Other

3. Service
 Hdqtrs Field

4. Employing Office Location
Multiple

5. Duty Station
Multiple

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

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

Explanation (Show any positions replaced)
 In lieu of PD# 01F026

13. Competitive Level Code
01NX

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)	12	<i>fd</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

a. First Subdivision
Food and Drug Administration

b. Second Subdivision
Office of Regulatory Affairs

c. Third Subdivision
Office of the Regional Food and Drug Director

d. Fourth Subdivision
Field Laboratory

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 *David K. Elder* 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)

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.

Typed Name and Title of Official Taking Action
Frances Reynolds
Human Resources Specialist, BCSD

Signature *Frances Reynolds* Date **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 No Promotion Potential

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

BIOLOGIST
GS-0401-12

INTRODUCTION

The incumbent of this position is a Biologist in an FDA/ORA field laboratory and is assigned analyses requiring a high degree of expertise in: (1) the typical full range of commodities regulated by FDA; (2) a broad commodity area, i.e., foods, drugs, etc., or (3) a combination of both commodity and instrumentation area which may include the use of computers interfaced with analytical instruments.

MAJOR DUTIES

1. Analytical Duties

- Responsible for analyzing difficult, novel and complex samples. Many of these assignments require development or modification of methods.
- Before analyzing a sample, reviews background material such as the Collection Report (CR), labeling, Establishment Inspection Reports (EIR) as available, Consumer Complaint Reports, pertinent Agency regulations, Federal laws, and any other relevant material.
- Determines the general approach necessary to obtain the requested information, taking into consideration the requirements established by Agency regulations and Federal laws. If no official method exists, searches the established methodology manuals and chemical literature to find an applicable method. If a method is not found, conducts the necessary method development or modification of existing methods to analyze and provide appropriate validation. This includes responsibility for quality control and quality assurance data for the method. The analyst regularly participates in collaborative efforts with other scientists and laboratories.
- Interprets and evaluates the results of analysis to determine the validity and scientific significance and to ensure that all the necessary information was obtained. Is responsible for instrument QA and is able to troubleshoot instrumentation for needed calibration repairs. Writes reports stating the results and conclusions documenting the nature of any regulatory violations. Testifies in court or in other formal or informal reviews concerning the science produced by the incumbent. Such testimony is necessary and is able to support the credibility of the work conducted by the incumbent.
- Incorporates safety related issues and environmental concerns into the conduct of scientific activities. Responsible to assuring that the analysis and methods development work maintains the environmental integrity of the work site and products analyzed.
- Provides training for lesser-experienced scientists on the precedents, analytical methods and instrumentation related to the particular scientific discipline of the position.

2. Planning

- Identifies needs for development of new methods and approaches. Plans and carries out project to satisfy these needs. Provides advice concerning methodology problems encountered in the analysis of novel and complex samples to scientists in other Federal agencies, state organizations and private industry.
- Participates in determining the analytical instrument and equipment needs of the laboratory; evaluates new instruments and changes in the currently used instruments and equipment pertinent to the scientific work of the position; and recommends to laboratory management the purchase of new instruments and equipment.
- When assigned, reviews internal analytical packages of other scientists to determine if the science meets agency and management expectations embodied in appropriate policy and program guidelines.

3. Inspections and Audits

- As assigned, accompanies Agency personnel on inspections and serves as a technical advisor. This includes evaluating the scientific sufficiency of the quality control methods and equipment used in the facility being inspected, as well as analytical data..
- The Biologists advice is considered to be technically sound and can be relied upon in making decisions supporting regulatory action.
- May be called upon to participate in complex inspections of domestic or foreign firms falling within area of expertise and will normally be accompanied by another Analyst or Investigator.

Performs other duties as assigned.

Factor 1 - Knowledge Required by the Position

Professional knowledge of Biology, theories, practices and established methodology sufficient to analyze complex and unprecedented samples and as needed to develop and modify analytical methods. Included in this is sufficient skill and ability to calibrate and operate various instruments and computer systems in a laboratory.

Knowledge of established 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 the 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

The supervisor (or as appropriate a team leader or self-directed work group coordinator) assigns work in

terms of general objectives and resources. Work is evaluated in terms of scientific adequacy and adherence to FDA policies and goals. The Biologist may originate projects in consultation with the supervisor (or alternates as listed above).

Factor 3 - Guidelines

The guidelines include precedents, scientific literature, laboratory procedures and methodology manuals, instrument handbooks, and agency policies and regulations having limited application to work assignments. The regulatory scientist uses initiative, resourcefulness and knowledge of the field to adapt and develop new approaches and methods.

Factor 4 - Complexity

Assignments cover a full-range of typical analytical projects and include difficult, complex, or unusual samples and analytical requests received in the laboratory. Typically, the specific data needed and the approach taken to obtain this 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

The work primarily involves serving as a scientific "generalist" responsible for analyzing the typical full-range of products or samples. The results of work efforts affect the scientific accuracy and adequacy of the Agency's regulatory investigating, monitoring and related compliance programs segments.

Factor 6 - Personal Contacts

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

Factor 7 - Purpose of Contacts

The purpose of the personal contacts is to justify, defend and give advice concerning the work performed and the methods developed or modified. Typically, the persons contacted are working towards mutual goals; however, there may be instances when the scientist's methodologies and conclusions are controversial and persons must be influenced and persuaded to accept them as authoritative.

Factor 8 - Physical Demands

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.

Must possess a valid official government passport.

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

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.

PD# 11F023

EVALUATION STATEMENT

REQUESTED POSITION TITLE/SERIES/GRADE: Biologist GS-401-12

ORGANIZATIONAL LOCATION: DHHS, FDA, Office of Regulatory Affairs (ORA), Office of Regulatory Operations (ORO), Field Laboratories

BACKGROUND: As a result of recruitment needs and requirements, this position is being established as a rewrite of Interdisciplinary Scientist PD# 960H02/01F026 into individual series.

ANALYSIS AND EVALUATION OF THE POSITION

References:

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

Determination of Series and Title:

This Biologist position involves scientific duties and responsibilities that are closely related those found in the GS-401 Series which "...covers manage, supervise, lead, or perform professional research, or scientific work in biology, agriculture, or natural resources management that is not classifiable to another more specific professional series in the Natural Resources Management and Biological Sciences Group, 0400." Regulatory and control work involves testing such items as food products, antibiotics, sera, and antitoxins for conformance to legal standards for purity, potency, and safety. The work also involves establishing such standards for inspecting facilities that produce biological products for conformance with approved methods and procedures. In accordance with titling practices found in the Job Family Standard for Professional Work in the Natural Resources Management and Biological Sciences Group, GS-0400 the proper title for this position is Biologist. Therefore, the appropriate title and series for this position is Biologist GS-401.

Determination of Grade:

Grading Information is found in the Job Family Standard for Professional Work in the Natural Resources Management and Biological Sciences Group, GS-0400. Because the Guide is in the FES format, this evaluation is in and meets the requirements of that format. The following pattern is typical of the factor levels to support GS-12: 1-7, 2-4, 3-4, 4-4 or 4-5, 5-4, 6-3, 7-3, 8-1 or 8-2, and 9-1 or 9-2. Factor Level 3 and Factor Level 5 define the differences between the GS-11 and 12 grade levels and are essential in order to sustain the GS-12 grade level. See the attached FES Evaluation Statement.

Factor 3-Guidelines. The subject position meets level 3-4 for the following reasons: (1) As stated in the PD, the absence or generality of guidelines impacts the Biologist's ability to comprehend and work with technological advances in both products and instrumentation. (2) New types of products technology as well as the increased importation of products from other countries has resulted in a level of food, drug and cosmetic product diversity never before seen and expected to increase in the coming years. The

Biologist must recognize new domestic and import manufacturing procedures and analyses and account for them in the analytical protocol. (3) Further, tampering, counterfeiting and product substitution represent an increased regulatory burden in FDA testing protocol. Each of these regulatory categories often requires extensive analytical evidence to support regulatory action. The analytical protocol for most samples must be developed on a case by case basis taking into account any manufacturing or background information obtained from FDA or other sources. Regardless of specialty, forensic methods have become a significant part of the Biologist's job.

Factor 5-Scope and Effect. The subject position meets level 5-4 since the Biologist is working in a particularly narrow and specific specialty field or a significantly broad or general field. Biologist furnishes advisory, planning or reviewing services on specific or peripheral problems, projects, programs and functions. The findings establish limited precedents that affect field and industry program activities in other geographic areas. Considerable resistance to change is overcome with successful proofs which show the scientific merit of the recommended requirements.

The final grade determination is GS-12 based on a total of 2920 points (GS-12 point range: 2755-3150).

CONCLUSION

Based upon the discussion above and the accompanying FES evaluation, the final title, series and grade is: Biologist, GS-0401-12.



Frances Reynolds
Human Resource Specialist



Date

POSITION EVALUATION SUMMARY WORKSHEET

Organization DHHS/FDA/ORFDD/Field Laboratory

Position # 11F023

Evaluation Factors		Factor Level Used (FL#, etc.)	Points Assigned	Comments
1.	Knowledge Required By the Position	1-7	1250	
2.	Supervisory Controls	2-4	450	
3.	Guidelines	3-4	450	See Narrative
4.	Complexity	4-5	325	
5.	Scope and Effect	5-4	225	See Narrative
6/7.	Personal Contact and Purpose of Contacts	3C	180	
8.	Physical Demands	8-2	20	
9.	Work Environment	9-2	20	
S U M M A R Y	Total Points		2920	
	Grade Conversion		GS-12	

Additional Remarks:

Title, Series, and Grade Assigned: **Biologist GS-401-12**

Prepared by: *Frances Reynolds*
 Frances Reynolds, Human Resource Specialist

Date: 7/6/2011

**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/ORL/ORFDD/Field
Laboratory
Any Field Laboratory
Administrative Code: DBR% (e.g. GAGA)
PD Number: 11F023 (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