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

1. Agency Position No.: 11F018

2. Reason for Submission: [X] Redescription [ ] New [ ] Reestablishment [ ] Other
Explanation *(Show any positions replaced)*: In lieu of CSO GS-696-13 Pd# 11F007

3. Service: [ ] Hdqtrs [X] Field

4. Employing Office Location: Multiple

5. Duty Station: Multiple

6. OPM Certification No.:

7. Fair Labor Standards Act: [X] Exempt [ ] Nonexempt

8. Financial Statements Required: [ ] Executive Personnel Financial Disclosure [ ] Employment and Financial Interest

9. Subject to IA Action: [X] Yes [ ] No

10. Position Status: [X] Competitive [ ] Excepted *(Specify in Remarks)* [ ] SES (Gen.) SES (CR)

11. Position Is: [ ] Supervisory [ ] Managerial [X] Neither

12. Sensitivity: [ ] 1–Non-Sensitive [ ] 2–Noncritical Sensitive [ ] 3–Critical [ ] 4–Special Sensitive

13. Competitive Level Code: 24NX

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	CONSUMER SAFETY OFFICER	GS	0696(42)	13	[signature]	7/6/2011
c. Second Level Review						
d. First Level Review						
e. Recommended by Supervisor or Initiating Office	Consumer Safety Officer (Drug Specialist)	GS	0696	13		

16. Organizational Title of Position *(if different from official title)*: Drug Specialist

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: All Field Offices

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:
Signature: Date:

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: [signature] Date: 7/11/11

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: GS-685, GS-690, GS-696 and GS-893

Typed Name and Title of Official Taking Action: Frances Reynolds, Human Resources Specialist, BCSD
Signature: Frances Reynolds 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 No Promotion Potential

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

CONSUMER SAFETY OFFICER (DRUGS)
GS-696-13 PAGE 1

INTRODUCTION

This position is located in an FDA District Office or Resident Post, and represents the highest level of expertise in a district for the inspection of firms engaged in the manufacture, processing and control of human or veterinary pharmaceutical products, for compliance with FDA laws and regulations. Assignments will involve inspections/investigations across District lines. As a Program Manager, is a primary source of expertise in an assigned geographical area who resolves the most difficult, controversial and complex inspectional problems which involve a combination of scientific and regulatory responsibilities.

MAJOR DUTIES

1. Program Manager

Plans, conducts and directs highly technical, complex and multi-faceted inspections and in-depth investigations, is highly skilled in interview techniques as well as criminal investigation techniques and routinely makes recommendations to regional and district management officials as to whether or not an establishment engaged in the manufacture of pharmaceuticals (human or veterinary) is in compliance regarding Current Good Manufacturing Practices (CGMP) issues. Reviews reports of inspections and investigations for violations and determines the sufficiency of the evidence. Independently acts upon the full range of violations within the area of expertise including emergency situations, uncooperative industry officials, ambiguous or dubious evidence and lack of precedents and guidelines. Meets with industry representatives to exchange information and to provide advice and guidance regarding those aspects of review with deficiencies. Industry officials are sometimes hostile or uncooperative and require considerable tact and firmness to obtain needed information.

As a principal source of expertise within a geographical area provides extensive advisory, liaison and consultative services for drug programs to regulated industries, State agencies, other Federal agencies and Agency management. Advises on new advances in technology related to drug products, new programs, laws and regulations, significant court decisions, and any new trends or scientific findings involving drug products. Because of the incumbent's expertise in this area, review and evaluation of test methods and new automated methods of processing and analysis is routine. Meets with hostile or uncooperative industry representatives to exchange information and to provide advice and guidance regarding those aspects of the application, notice, amendment, supplement or report which fall within area of review with emphasis on deficiencies. Interactions require considerable tact and firmness to obtain needed information regarding submissions.

Manages the review of previously approved products to determine whether they should continue to be permitted in light of current scientific safety criteria. Coordinates the collection of data, manages the scientific review and recommends a course of actions.

Researches and prepares final background and decision papers for the signature of the Director. Prepares memoranda, briefings, and other background material concerning substantive issues, findings, conclusions and proposed solutions to keep the Director and appropriate staff involved at key decision points. Research involves reviewing reports and publications for relevant information; and organizing, analyzing and summarizing the information.

Serves on task forces and study groups charged with considering problems or directions in the area of expertise. Consults with staff members at all levels of the organization to achieve consensus on issues and resolve any disagreements on standards. Represents the agency on inter-agency review committees charged with reviewing Federal policies and making recommendations for consistency across agency lines.

Serves as an expert witness in area of expertise in court cases dealing with regulated products. Evaluates and makes recommendations on necessary regulatory action required for complaints and product problem reports. Prepares reply stating Agency concerns in regulatory reviews.

Conducts inspections of both domestic and international pharmaceutical establishments.

2. Inspections and Investigations

Assignments cover the largest manufacturers in the District and some smaller firms where new or unusual features are present. The investigator conducts inspections and investigations of facilities where only limited guidance documents are available; proposed or new regulations must be used to evaluate the industry; or the inspection or investigation may result in considerable attention and review in the media, Congress, or other forces inside or outside the Agency. Inspections cover all the types of products and problems within the area of assigned responsibility. Investigates and evaluates the adequacy of complex manufacturing practices to determine compliance with GMP regulations.

The investigator conducts the more complex, technical investigations and inspections of establishments in the area of assigned responsibility and prepares proposed or final EIR endorsements. Reports are developed and in most instances accepted with little or no review of format or content. The investigator may be assigned to long term investigations and grand juries with only limited oversight from the supervisor; may be designated as the lead Agency representative of multi-agency/multi-organization investigations; and is assigned to either assist in or directly monitor or manage compliance programs for sample collection programs or inspection programs. The investigator has frequent and direct contacts with U.S. Attorneys, the FBI and OCI, other Federal agencies, and Grand Juries.

Independently performs investigations involving complaints of injury or death attributable to products regulated by the FDA. Investigations of injuries require special coordination and a high degree of insight and knowledge. The information which initiates such investigations is often minimal and the veracity unknown requiring innovation, ingenuity, and diplomacy. These situations are often unstructured and

require contacts with many and diverse individuals, institutions, and firms. Mature judgment must be used to make field decisions on the nature and extent of follow-up investigations. Plans and decides how the investigation should proceed, when the investigation is complete, and what reporting is required. Analyzes results, decides when an investigation is complete or what additional work may be required. The investigator is expected to provide timely and accurate feed back to District and Headquarters management as well as effective guidance to other district staff assisting in the investigation.

3. Instructor and Team Leader

Develops and implements formal training programs for Agency personnel, industry, and state/local officials, and provides technical expertise to industry representatives. Conducts on-the-job training for Consumer Safety Officers and others GS-12 grade level and below and other training for investigators, supervisors, compliance officers, district or regional personnel, and industry regarding technical and scientific matters, inspectional/investigational issues, policies, and laws affecting the regulation of the pharmaceuticals industry.

Serves as a principal advisor or team leader in a field of regulatory and compliance expertise. The incumbent is responsible for planning, coordinating and evaluating the programs and activities for a professional regulatory field.

Factor 1 - Knowledge Required by the Position

Mastery of the concepts, principles and practices of pharmaceutical production, manufacturing controls, and formulations to serve as a technical authority on the properties, analysis, behavior, and the impact of these on the safety and effectiveness of products; recognize any discrepancies or inconsistencies between information reported and made available and the true nature of the manufacturer being inspected or investigated; and, provide written analyses of data and in-depth fault analysis evaluations and product failures aimed at preserving and protecting the public health.

Comprehensive knowledge of the Food, Drug, and Cosmetic Act, implementing rules and regulations, and court precedents which apply to the area of assigned responsibility. Skill to interpret these laws, policies, etc, and their application to the broad field of pharmaceuticals.

Comprehensive knowledge of and skill in selecting, adapting, and applying investigative methods and negotiating techniques. The incumbent must be an expert in terms of developing evidence when situations are encountered that may result in regulatory action.

Broad knowledge of a variety of various scientific and technical disciplines are necessary to carry out tasks related to the regulation of the pharmaceutical (human/veterinary) industry.

Knowledge of written and verbal communication practices and principles to prepare and present written reports, findings, and recommendations; develop analyses that are used for presentations and as instruments for negotiations; conduct negotiations with industry representatives and other government agencies; and, develop formal training programs.

Factor 2 - Supervisory Controls

The supervisor sets the overall objectives and resources available. The employee and supervisor, in consultation, develop the deadlines, projects and work to be done. The employee, having developed expertise in the pharmaceutical area, plans and carries out duties and responsibilities with a substantial degree of independence; resolving most of the conflicts which arise; coordinating the work with others, as necessary; and interpreting policy on own initiative in terms of established objectives. In most assignments, the employee also determines the approach to be taken. Methodology may not always be defined and the employee uses judgment to determine the best methodology with considerable tact and firmness. The employee keeps the supervisor informed of overall progress and potentially controversial matters. Completed work is reviewed only from an overall standpoint in terms of meeting objectives, compatibility with Agency policy and priorities, and effectiveness in meeting requirements and expected results.

Factor 3 - Guidelines

Guidelines include enabling legislation, associated rules and regulations, broad policy, scientific literature, and precedents. These guidelines are often not specific in dealing with unusual or serious cases and problems. The employee is required to be resourceful, enterprising, and experienced in deviating from or extending traditional methods and practices and developing solutions to problems where precedents are inapplicable.

Factor 4 - Complexity

Assignments involve a combination of scientific, consumer protection, and regulatory responsibilities which calls for a number of atypical inspection or investigative approaches applicable to a wide variety of regulatory functions or intensive analyses and evaluations of pharmaceutical programs. Determinations on approaches are influenced by precedents drawn from ongoing improvements in program concepts; advancements in sciences and industry; new health, product and environmental problems; or disagreements in enforcement procedures. Duties regularly involve providing expertise in regulatory programs. The incumbent must also be able to effectively represent the District and Agency in meetings with other high level Federal, State and local health officials, and representatives of regulated industry and industry organizations and must be able to successfully present and negotiate the Agency's and District's position on highly sensitive issues. The work is more difficult than work which is regularly

performed by journeyman Consumer Safety Officers because the legal and regulatory concepts utilized by the incumbent of this position are correspondingly more complex and/or unprecedented.

Factor 5 - Scope and Effect

Work involves providing professional expertise in the field of pharmaceutical (human/veterinary) manufacturing by furnishing advisory, planning, or reviewing services on specific or peripheral problems, projects, programs, and functions. Conduct of duties and responsibilities that are identified in Major Duty #1, result in the establishment of limited precedents that affect field and industry program activities in other geographic areas.

Factor 6 - Personal Contacts

Contacts are with officials, managers, professionals, or executives of other agencies and outside organizations. Contacts are often characterized by unstructured settings.

Factor 7 - Purpose of Contacts

Contacts are for the purpose of influencing or persuading other professionals to adopt technical findings and approaches of studies concerning problems in which there are conflicting opinions, resolving disagreements and differences with public and private organizations or experts in a field of science when there are conflicting interests and opinions, or justifying program proposals and economics to top public and private officials.

Factor 8 - Physical Demands

To perform the work of this position, the Consumer Safety Officer must posses a valid driver's license in order to drive a Government or privately owned motor vehicle.

Must possess a valid official government passport.

This position requires:

- the need to work long and possibly unscheduled hours;
- exposure to all kinds and extremes of weather and noise;
- the need to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel and climb;
- the ability to maintain the vision, hearing, and olfactory requirements necessary to perform inspectional work; and
- the need to travel up to approximately 50 percent of the time, which may require the Consumer Safety Officer to be away from the regular duty station for up to two or three weeks at a time.

Factor 9 - Work Environment

Most work is performed in an adequately lighted and climate controlled office. On-site investigations and inspections may involve exposure to moderate risks or discomforts such as high levels of noise, dust, moving parts of machinery, irritant fumes, etc. Protective clothing and gear, and observance of safety precautions are required.

POSITION NUMBER: //F018
TITLE, SERIES AND GRADE: Consumer Safety Officer (Drugs)
GS-696-13
ORGANIZATIONAL LOCATION: FDA, ORA, Field District Office

EVALUATION STATEMENT

REFERENCE(S):
1) GS-685 Public Health Program Specialist Series (11/80)
2) GS-690 Industrial Hygiene Series (10/80)
3) GS-696 Consumer Safety Series (6/72)
4) GS-893 Chemical Engineering Series (6/72)

DETERMINATION OF SERIES AND TITLE

This position serves as a District Drug Specialist who is recognized for expert knowledge of the pharmaceutical industry. It is organizationally located in a Field District Office. The purpose of the position is to provide the district's highest level of expertise in resolving the most complex and difficult inspectional and regulatory problems resulting from inspections and investigations of pharmaceutical manufacturers (human or veterinary) and related products. Recommendations made to FDA regulated industry are expected to have industry-wide impact.

The incumbent is responsible for conducting the more sophisticated inspections and assisting in the development of the District's inspectional and regulatory strategies and recommendations for dispositions of cases. The incumbent serves as focal point for educational, training, and guidance activities involving the regulations, products, policies and programs of the Pharmaceutical industry targeted to industry officials, public organizations, and technical publications.

As a program expert, provides advice to the District and Regional FDA Director, and to key headquarters officials. Input from this expert is critical to the formulation and implementation of policies at all levels of the agency, as well as state, local, and other federal officials involved in the program.

Certain of these functions involve work very similar to that covered by the GS-685, Public Health Advisor Series in that they involve advising and assisting private sector organizations and on program and administrative matters relating to the development, implementation, operation and administration of public health activities. The 685 Series, however, excludes work that does not require full professional education and training in medical, social or other disciplines or work involving compliance and regulatory activities as they relate to the enforcement of the Food, Drug, and Cosmetic Act and its amendments.

The GS-696 Consumer Safety Series includes professional positions concerned with enforcing the laws and regulations protecting consumers from foods, drugs, cosmetics, fabrics, toys and household products and equipment that are impure, unwholesome, ineffective, improperly or

deceptively labeled or packaged, or in some other way dangerous or defective. These positions require knowledge of various scientific fields such as chemistry, biology, pharmacology and food technology. The GS-696 standard describes three types of functions in which Consumer Safety Officers may be engaged: Inspection and Investigation, Compliance and Other Functions. According to the standard, "Other Functions" include coordinating programs with State and local governments; developing, coordinating and participating in programs designed to improve voluntary compliance of private industry; and, coordinating and advising on requests to market and test new drugs.

We believe that the position is properly covered by the GS-696 Consumer Safety Series. The authorized title for nonsupervisory positions in this series is Consumer Safety Officer.

DETERMINATION OF GRADE

In the GS-696 Consumer Safety Series, the actual grade level criteria focuses on the Inspectional and Investigative and the Compliance functions of the occupation. For example, the GS-12 level describes two types of inspectional and investigative assignments and the GS-13 level describes Consumer Safety Officers performing compliance work in the district offices.

Page 7 of the Consumer Safety Series notes: "Nonsupervisory positions above those levels described in the grade-level criteria are too few in number and too individualized to develop specific grade-level guidance. However, position that have duties and responsibilities that clearly exceed the grade levels described in this standard should be classified to the appropriate higher grade by extending the criteria of this standard and applying sound classification principles."

The first Major Duty describes the Program Management duties and responsibilities that are evaluated at the GS-13 grade level. Major Duties two and three describe duties and responsibilities that are evaluated at the GS-12 level.

This position performs inspections and investigative assignments that exceed those described at the GS-12 level in the GS-696 Standard. The incumbent of this position is a recognized expert on the Pharmaceutical Industry. As a District expert, the incumbent will resolve the most complex and difficult inspectional and regulatory problems of Pharmaceutical programs and related activities and serve as a primary technical advisor to District managers and staff concerning the whole range of issues associated with Pharmaceuticals. The incumbent operates independently, under the general supervision of the District Director. The incumbent resolves inspectional issues that are novel and where there is limited precedence available for guidance.

This work matches, both in terms of the Nature of Assignment and the Level of Responsibility, the criteria described at the GS-13 level in the GS-696 standard. The GS-696 standard describes (p 16-17) GS-13 consumer safety officers in the district offices as a primary source of expertise within the geographic area covered by the district on the interpretation of the laws, regulations, and programs. They advise the managers, inspectors and laboratory analysts on a wide range of regulatory

questions. They review reports of inspections, investigations, and laboratory analyses for violations, determine the sufficiency of the evidence (requesting further investigation where necessary) and recommend appropriate legal actions. They independently act upon the full range of violations occurring within the district, including those that involve emergency situations, uncooperative industry officials, ambiguous or dubious evidence, and lack of precedents and guidelines. By comparison, GS-12 employees primarily deal with routine compliance issues and problems for which precedents and guidelines have been established.

The Introduction to the Position Classification Standards (August 1991) indicates (p 20) that "If the work assigned to a position is covered by criteria in standard for a specific occupational series, evaluate the work by that standard...If there are no specific grade level criteria for the work use an appropriate general classification guide or criteria in a standard or standards for related kinds of work." Since the grade level criteria in the GS-696 standard addresses compliance work but not inspectional and investigative work at the GS-13 level, we also referenced other related standards.

The professional standards for certain scientific specializations provide a better match with the duties and responsibilities of this job. The GS-893 Chemical Engineering Series covers positions that involve work in chemical engineering, including research, development, design, operation, evaluation and improvement of processes, plants, equipment, methods, or products. This standard evaluates two factors, Nature of Assignments and Level of Responsibility. Page 22 of the standard indicates that GS-13 chemical engineers may be technical advisors for a specialized area of a broad and varied chemical engineering program. The duties and responsibilities of this position match the description of GS-13 chemical engineers (p 22-25) who must apply originality since assignments are characterized by unique or controversial problems. The nature of their assignments demands that GS-13 chemical engineers, in particular, as compared to lower level engineers, keep abreast of the technological advances in chemical engineering. GS-13 chemical engineers prepare their own work plans and establish their own guidelines within the framework of prescribed policy; applicable criteria are typically absent (p 25).

We also referred to GS-690 classification standard to evaluate the position, since it is representative of this type of position and provide criteria related to the duties of the position. The GS-690 standard is written in the Factor Evaluation System format and it provides a Benchmark description of a GS-13 expert position (Benchmark GS-690-13-2).

The position when applied to the factors in the GS-690 Series resulted in the following evaluation:

Factor Level 1-8	1550 points	**See Remark Below*
Factor Level 2-4	450 points	
Factor Level 3-4	450 points	
Factor Level 4-5	325 points	
Factor Level 5-4	225 points	
Factor Level 6-3	60 points	
Factor Level 7-2	50 points	

Factor Level 8-1	5 points
Factor Level 9-1	5 points
Total Points	3120 points

* This position matches Factor Level 1-8 of the GS-690 standard (p 16-17) which describes mastery of the professional concepts, principles and practices of industrial hygiene; a knowledge of new developments to solve novel or obscure problems; and ability to extend and modify existing techniques. Typically the employee is recognized by the agency as being an expert in the broad practice of industrial hygiene or in a major specialization.

According to the Grade Conversion Chart, 3120 points equates to a GS-13.

CONCLUSION

The grade for this position is a GS-13 since the evaluations against the GS-690, GS-696 and GS-893 Series equate to the GS-13 grade level. The final classification of this position is Consumer Safety Officer (Drugs) GS-696-13.

Tanya Reynolds 7/6/2011
HR Specialist

Rockville Human Resources Center
Fair Labor Standards Act (FLSA)
CHECKLIST

Date: 7/6/2011

A. REQUIRED POSITION INFORMATION:

Position Title: Consumer Safety Officer (Drug Specialist)
Pay Plan/Series/Grade: GS-696-13 (e.g. GS-0301-12)
Organization: FDA/ORA/Office of the Regional Food and Drug Director
All Field Offices
Administrative Code: DBR% (e.g. GAGA)
PD Number: 11F018 (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)

[X] 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**

[signature] 7/1/11

Name and Title of Immediate Supervisor — Date
David K. Elder
Acting Deputy Associate Director for Regulatory Affairs for Field Operations

Frances Reynolds 7/6/2011

Frances Reynolds
Human Resource Specialist
Name and Title of RHRC Classifier — Date

9/17/08