

**CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF RESEARCH RESOURCES  
EVALUATION PLAN FOR RESEARCH SCIENTISTS**

**I. PURPOSE**

This Evaluation Plan establishes the responsibilities and procedures to be followed in evaluating the scientific qualifications and contributions of (1) CDER research scientists proposed for promotion to GS-14 and above; (2) candidates for vacant research scientist positions at GS-14 and above in the CDER; and (3) in the mandatory three year review of CDER research scientists at GS-14 and above.

**II. STRUCTURE OF THE PANEL**

**A. Members**

The Panel will consist of seven members.

1. Three members of the Panel, including the Chair, will be Scientists from CDER at the Division Director or senior scientist level and above.
2. Three members will be scientists from outside CDER.
3. The Division of Human Resources Management (DHRM) will make available a Position Classification Specialist who, as the seventh member, will be a full voting member of the Panel and offer guidance in the review cases.

An Executive Secretary for the Panel, provided by the CDER, Office of Management (OM), will report to the Chair, and will be without vote.

Five of the panel members present at a meeting including the Chair, the DHRM representative, and at least two members from outside CDER constitutes a quorum.

**B. Advisory Participants**

The Panel will have the authority to call in other scientists, personnel specialists, and any others who can assist in the review process.

**III. RESPONSIBILITIES**

**A. Director, CDER**

1. Appoints the Panel Chair.
2. Approves transmittal of cases to the Panel.

**B. Panel Chair**

1. Selects research scientist members of the Panel.

2. Conducts orientation meetings with the Panel members to establish guidelines for the review of cases, orient new members, and provide guidance in instances that are not specifically covered by this Plan.
3. Receives case material. Decides with the DHRM representative whether cases may be appropriately reviewed by the Committee, and if so, whether the submissions are complete. May exercise the right to return cases with no action or for additional information.
4. Calls and chairs Panel meetings.
5. Assigns cases to appropriate Panel members for in-depth reviews prior to scheduled meetings.
6. Insures that Panel discussions and recommendations are kept confidential.
7. Writes Panel recommendations for submission to the Director, DHRM on the disposition of cases.
8. Speaks for the Committee in communications with Center management, supervisors, sponsors, applicants, and any others having business with the Panel.

**C. Peer Review Panel**

1. Meets on an as needed basis when determined appropriate by the Chair.
2. Reviews case material.
  - a. Each case will be carefully reviewed. The evaluation will be based on scientific merit, and the achievements and contributions of the candidate. All appropriate information such as letters from distinguished scientists, reports of supervisors, publications, and case documentation will be used. Questions that arise during the review may be referred to the Director, office of Research Resources, the recommending official, or the position classification specialist assigned to the Panel.
  - b. If necessary, interviews or meetings with the recommending supervisor or persons with knowledge of the scientist's achievements and contributions will be conducted.
  - c. A simple majority of those present will determine the final recommendation of the Panel on the disposition of a case.
  - d. A Panel member who is also the recommending supervisor may discuss but not vote upon the case being sponsored.
  - e. The Chair will summarize the Panel findings and submit a recommendation to the Director, DHRM. Upon acceptance, the Chair will notify the Director, CDER, the Director, ORR, and the recommending supervisor.

**D. Position Classification Specialist**

1. Applies the Research Grade Evaluation Guide to the cases being considered by the Panel and prepares an evaluation statement which relates the criteria of the Guide to the scientific qualifications and contributions of the scientist. This will be done after the conclusion of the Panel meeting.
2. Informs the Panel, through the Executive Secretary, of any modifications or changes in the Research Grade Evaluation Guide and any other criteria used in the evaluation of research scientists.
3. Processes actions after final decisions have been made.

**E. Executive Secretary to the Panel**

1. Receives cases from recommending officials.
2. Coordinates and schedules meeting dates with the Chair and confirms the dates with Panel members.
3. Duplicates and distributes case material to Panel members.
4. Manages Panel membership at direction of Panel Chair.

**IV. PROCEDURAL STEPS**

- A. Immediate supervisor and the candidate prepare case material and recommend personnel action to the Director, CDER through supervisory channels.
- B. Cases approved by the Director, CDER, will be forwarded to the Panel Chair.
- C. All cases must be received by the Panel Chair at least 30 days before a Panel meeting. Those scientists scheduled for cyclical, mandatory reviews will be notified in writing and will be allowed at least 60 days to prepare their cases.
- D. The Panel Chair reviews all cases and makes an initial evaluation of the documentation. Cases that are accepted will be given to the Executive Secretary of the Panel for distribution and scheduling of meetings.
- E. Prior to a Panel meeting, each Panel member will review each case and reach a tentative opinion based on the criteria in the Research Grade Evaluation Guide.
- F. As assigned by the Panel chair, scientist Panel member(s) will conduct in-depth reviews prior to the Panel meeting, and will obtain any additional information that will help the Panel to better understand and evaluate a case.
- G. Panel meetings will be conducted in accordance with accepted guidelines. Panel discussions are considered to be confidential, and Panel recommendations and decisions will be promptly distributed through official channels.

- H. A simple majority vote by those Panel members present at a meeting will determine the final recommendation by the Panel on the disposition of a case.
- I. After reviewing the cases, the Panel will return each case with a written recommendation to the Director, DHRM. Upon acceptance by the Director, DHRM, the Panel chair will notify the Director, CDER, Director, ORR, and the sponsoring supervisor of the final decision.
  - 1. If approved:
    - a. An evaluation statement will be prepared by the Position Classification Specialist.
    - b. Executive Secretary will forward necessary paperwork to initiate personnel action.
  - 2. If not approved:
    - a. Cases will be returned with a written statement detailing the specific reasons why the case was not approved.
    - b. A case may be resubmitted at any time. However, the resubmission must clearly show any changes or additions that address the points raised in the decision made by the Panel.
  - 3. If additional documentation is required:
    - a. The case will be returned through the Director, ORR, to the sponsoring supervisor.
    - b. The Executive Secretary will receive and distribute any additional information to Panel members.
    - c. Such actions must be resubmitted to the Panel within 60 days after being returned.
  - 4. All research scientists covered by this plan may appeal the final classification of their positions through established PHS and OPM classification appeal procedures.

**V. DOCUMENTATION REQUIREMENTS**

- A. The immediate supervisor in conjunction with the candidate prepares an original package and six copies for submission to the Panel.

The package must contain, in the order shown, the following:

- 1. Transmittal memorandum to the Panel Chair, from the Director, CDER, giving the reason for the submission.
- 2. Memorandum, of Recommendation (Supplement 1) to the Panel Chair, through the Director, CDER, from the immediate supervisor.

This memorandum should not restate the position description but should amplify the scientist's accomplishments, and cover the following points:

- a. The name, current title, series, and grade of the scientist, and the nature of the action being requested (such as promotion, reassignment, selection, mandatory review, etc.).
  - b. List of accomplishments and contributions to the Laboratory/Center/Agency that support the recommendation.
3. Curriculum Vitae (Supplement 2)
4. Bibliography (Supplement 3)
5. OF-8 cover sheet and position description (Supplement 4)

## SUPPLEMENT 1

### MEMORANDUM OF RECOMMENDATION

The content of this memorandum should include actual accomplishments and current Research situation. The memorandum may begin with a brief paragraph summarizing the scientist's research career by listing total years in research, total number of publications and presentations, and, if deemed appropriate by the supervisor, a general statement about the researcher's scientific reputation and recognition.

Following the introductory paragraph, the most significant recent accomplishments should be described. Each significant accomplishment should be described as concisely as possible with the primary emphasis on what was accomplished and why the accomplishment was significant. In the case of a team effort, it will be necessary to explain exactly what the scientist contributed to the total accomplishment.

Significant accomplishments may take the form of:

1. Literature review and analysis: Ranges from "restated with essentially no change, or reported conclusions from previously published material" to "reviewed, analyzed, interpreted, and synthesized scientific knowledge of broad scope with significant additions to established knowledge."
2. Development of knowledge using scientific principles in theoretical or experimental investigations: Ranges from corroborated existing knowledge in a new situation using new and innovative procedures" to "made a major advance in a scientific field, or provided new technology that opened the way for extensive further development.
3. Application of knowledge to an unknown or previously unexplored area: Ranges from "applied known concepts and/or techniques to deal with a new situation" to "solved a problem of major importance to science, industry, or the public."
4. Methods development: Ranges from "used known concepts to modify and/or develop facilities, equipment or techniques of some importance to research and/or industry methodology" to "extensively developed facilities, equipment or techniques of considerable importance to research and/or industry methodology."
5. Research leadership: Ranges from "maintained the quantity and quality of productivity of a research team" to "caused an extensive increase in the quantity or quality of productivity of a research team" by "better coordination of research, changing the direction of a research program to a more significant area of exploration with resultant impact on science or technology, improving the scientific environment or atmosphere in which the research team functions, increasing the efficiency of the team's research capabilities, or improving the research capability of scientific personnel on the research team."

These types of accomplishments are not meant to be all-inclusive, but are merely illustrative of kinds of accomplishments by FDA research scientists. More important than the type of accomplishment is the quality of that accomplishment.

Each selected accomplishment should be documented by exhibits and/or publications. Exhibits should be chosen with the following in mind:

- the significance of a particular accomplishment may have increased with time,
- while past accomplishments may be important, recent accomplishments show maintenance of research competence, and
- for most situations, one or two carefully selected exhibits will be sufficient to support a well-stated accomplishment.

Whenever an accomplishment cannot be supported by an exhibit or a publication, a statement signed by a knowledgeable authority (such as the supervisor or Division Director) will be acceptable. The statement should elaborate on the accomplishment to provide evidence to support its significance. In addition, the statement should indicate why the accomplishment was not or could not be published.

Many research positions include duties and responsibility that are not specifically research. Accomplishments of this kind that are extensions of research may help to support the significance and impact of the research. Work of this nature that is performed on a regular and recurring basis should be documented in the position description. This includes work such as preparation of handbooks, special assignments, review and inspection work, etc. These accomplishments may be seen as activity similar to research, which assures maintenance of research competence.

## SUPPLEMENT 2

### CURRICULUM VITAE

Each of the following headings must be listed and addressed. Even if there is nothing to report under a heading, include the title of the heading and state "none" or "nothing to report." The reviewers will then know that the heading was not overlooked or inadvertently omitted.

#### Name

Educational Background -- List the name of each institution and the dates attended, majors and minors, and degrees awarded.

Additional Training -- List part-time or short-term training not included in Educational Background. Any Government-sponsored training must be listed under this heading. Give dates and duration of courses, credit hours, course hours, etc.

Professional Experience -- List professional positions held in chronological order giving titles, grade or salary, and dates in each grade or position. Include present position.

Honors and Awards -- List dates and a brief but sufficient description to able the reader to determine significance and prestige. If a cash award was involved, list the amount.

Special Invitations -- These are usually specific invitations to present a paper before scientific or industry groups, prepare a paper or a chapter for a book, conduct a seminar, etc. Be selective since the stature of the group that made the invitation is as important as the receipt of the invitation. For each invitation, list the title of the presentation, date, location, and organization or purpose of gathering. Provide sufficient information for the reader to determine scientific significance. If a paper was subsequently published, cross reference it to the publication list.

Licenses and Certifications -- List professional licenses and certifications showing licensing authority, year granted, current or expired, and brief description of special significance, if appropriate.

Membership in Professional or Honorary Societies -- List each and sE`ow7ates of membership and whether invited or elected, and any offices held.

Offices, Committee Assignments, or Special Assignments Held in Professional and Honorary Societies -- List each and give dates.

Participation in National Scientific Meetings, Technical Conferences, Workshops, seminars, etc. -- List each, give date, location, type of meeting, title of talk or paper if one was presented, or brief description of role or reason for attendance if no paper was presented. Do not include items already listed under Special invitations. If a paper was presented, cross-reference it to the publication list. If the same meeting or conference has been attended a number of times, summarize the information rather than listing individually.

Outside Professional Advisory and Consulting Activities -- List each, give dates, name and type of organization or situation, and type or significance of contribution. Generally, these should be activities outside of FDA that

are not a part of the regular work assignments. If there are numerous activities, summarize information or list activities in recent years only.

FDA Special Assignments and Advisory Activities -- These should be of a technical and professional nature within FDA but outside of the immediate work assignment or organization. Include items such as participation in hearings or testimony preparation, P.L. 83-480 Special Foreign Currency Program involvement, science advisor to General Counsel office, Agency, Center level, or other task force assignments, etc. List each, give dates, and briefly describe the role and significance

## **SUPPLEMENT 3**

### **BIBLIOGRAPHY**

List publications in chronological order, and number sequentially. Give full reference including journal, volume, complete pagination, date, and type of publication. If the information was previously published as an abstract, so indicate by referring to the appropriate abstract. To be listed, a scientific article must have been accepted by the publishing agent.

Publications other than referred articles in scientific journals or bulletins should be identified as one of the following:

- Thesis
- Abstract
- Review Article
- Book
- Book Chapter
- Conference or Society Proceeding
- Patent
- Popular Publication
- Technical Research Report (a written report that requires clearance for public release)
- Other (give specific identification)

## SUPPLEMENT 4

### POSITION DESCRIPTION FORMAT

The following format should be followed.

#### I. INTRODUCTION

Begin the position description with an introductory paragraph describing the organizational relationships and general characteristics of the position.

#### II. DUTIES AND RESPONSIBILITIES

##### A. The Research Situation

Identify the field of research and outline specifically the problems, research objectives, and lines of investigation that constitute the scientist's research activities or program. If the assignment is part of a team approach, be specific in showing the scientist's part. If the assignment includes research leadership, the broad objectives of the research group should be included.

The research assignment reflects the scientist as well as the job. Here is one place where the scientist enters the "person-in-the-job" concept because research scientists have their own capabilities and ideas. In research, these capabilities and ideas may expand the scope and effect of a position. For example, capabilities may permit changing or modifying a research approach. The research assignment should state specifically the research plan(s) and expected results that the scientist and technical supervisor have mutually agreed should be conducted by the scientist during the next few years.

##### B. Supervisory and Team Leadership

Describe the type of technical leadership exercised by the scientist in selecting problems, defining objectives, organizing, planning, evaluating and reporting, either as an active member of a cooperative research team or by directly supervising research scientist. Indicate the number, titles, range of grades, and location of the scientists and other employees supervised, and outline supervisory responsibilities of an administrative nature.

##### C. Guidelines and Originality

Guidelines and originality deal with information similar to that required by the research assignment. Guidelines speak to the extent and nature of available written guides, the intrinsic difficulty in applying them, and the degree of judgment required in their selection and adoption. Originality is the requirement for, and demonstration of, original interpretation or translation of findings to solutions of problems.

##### D. Other Duties and Accomplishments

Many research positions include duties and responsibilities that are not research in nature. However, because they reflect the mission of the Agency as officially delegated to scientists in

research positions, they are properly documented in the position descriptions when performed on a regular and recurring basis. This includes work such as preparation of handbooks, special assignments, application reviews, consultation on compliance cases, etc. Non-research accomplishments that are extensions of research may help to support the significance and impact of the research.

**E. Qualifications and Scientific Contributions**

**III. SUPERVISION RECEIVED**

Identify the supervisor by title or working responsibility. Describe the nature and purpose of the supervision. If technical supervision is received from someone other than the immediate supervisor, identify by title and show the kind of responsibility for the work. The description should clearly define:

- the degree of responsibility which the scientist has for selecting problems, defining specific objectives, organizing, planning, executing, interpreting, and reporting research,
- the kinds of actions that require approval of the supervisor or technical leader, and
- the nature and extent of commitment authority when dealing with professional, nonprofessional, or other cooperating or interested groups.