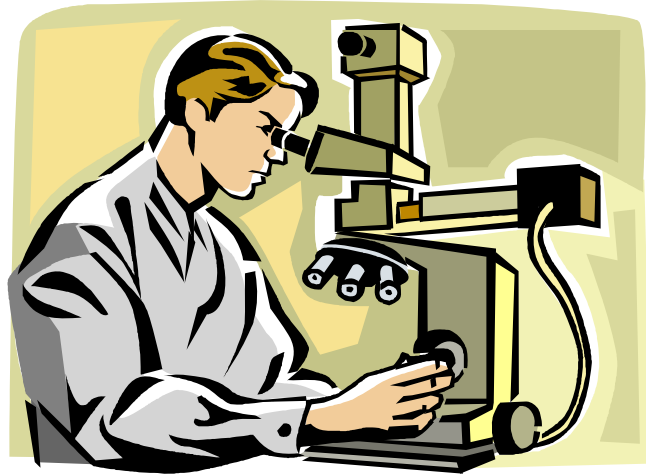


**CENTER FOR FOOD SAFETY AND APPLIED
NUTRITION (CFSAN)**



**EVALUATION PLAN
FOR RESEARCH SCIENTIST**

Updated September 2007

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Orange = Text to be reviewed for currency or deleted

Green = New text to replace orange text

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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)
EVALUATION PLAN FOR RESEARCH SCIENTISTS

I. PURPOSE

This Evaluation Plan establishes the responsibilities procedures, and standards which will be followed at peer review meetings in evaluating the scientific qualifications and contributions of: (1) candidates for vacant research scientist positions at the GS-13 level and above at CFSAN; (2) CFSAN research scientists at the GS-13 level and above proposed for mandatory classification review every three five years or a period determined by CFSAN management; (3) CFSAN research scientists proposed for promotion to the GS-13 level and above (if promoted, new review cycle begins); and/or (4) CFSAN Staff Fellows when they are to be converted to a research scientist position.

This plan does not cover the evaluation of full-time scientific regulatory or compliance positions, Senior Executive Service positions, Senior Biomedical Research Service positions, Title 42 or Title 38 positions, Commissioned Corps Officers, Visiting Scientist positions, or Intergovernmental Personnel Act (IPA) positions (or other positions of a temporary nature). However, at the request of management/personnel authorities the Resources staff, it may be used to provide guidance for the classification of Visiting Scientist or IPA positions by personnel officials the Resources staff.

Under this Plan, the grade of a position is based on the “person-in-the-job” concept. The classification is based on the evaluation by peer review of the accomplishments of the individual and not primarily on the position description. Promotions made under this Plan are Career Promotions and are not subject to competitive promotion procedures.

The positions covered by this plan will be evaluated primarily under the U.S. Civil Service Commission Office of Personnel Management (OPM) Research Grade Evaluation Guide (RGEG). In the case of mixed research/regulatory review positions at the GS-14 level, the Factor Evaluation System (FES) or Narrative Standards may be used in conjunction with the RGEG. These guides are available from personnel officials the Human Resources Staff.

II. POSITIONS COVERED

A. Identification of Research, Mixed Research, Supervisory Research, and Support Positions

There are four types of professional positions that function in a laboratory science environment: (1) research positions, (2) mixed research/regulatory review positions, (3) supervisory research positions, (?) lead research positions and (4) support or service positions. The differences between the types of positions need to be clearly understood, because these positions are treated differently from the standpoint of career advancement and methods of evaluation for classification purposes. “Research” or “Mixed” positions will be classified by peer review. Peer review may also be used, in part, for the classification of some supervisory and lead positions. Support positions are not classified by peer review.

1. Research Positions

The first type of position is the research scientist position. A research scientist position in the Food and Drug Administration (FDA) requires that the incumbent is predominantly (more than 50 percent of the time) engaged in performing or leading all elements of research as defined below, and the RGEG is the classification standard used to determine its grade level. A research position meets the following criteria:

- a. The position is characterized by systematic investigation of theory, experimentation, or simulation of experiments directed toward the development of (a) new or (b) fuller scientific knowledge of the subject studied.
- b. The work is characterized by a scientific process, including problem exploration and definition, planning of the approach and sequence of steps, execution of experiments or studies, interpretation of findings, and documentation or reporting of creativity and critical judgment.
- d. The qualifications, stature, and contributions of the incumbent have a direct, major impact on the level of difficulty and responsibility of the work performed.
- e. Research capability, as demonstrated by research experience and/or graduate education, is a significant requirement in the selection of candidates.
- f. Research positions may include non-laboratory research requiring creativity and critical judgment, such as the use of mathematics, statistics, and risk assessment procedures.
- g. Research publications are the end result of research work and are the primary vehicle by which scientific progress and information are communicated to the scientific community at large. The degree of acceptance by that community is an important indicator of both the quality of the research being performed and the reputation of the scientist.

2. Mixed Research Positions

The second type of position is a mixed position. This type of position is unique to the regulatory environment found in FDA and can encompass a combination of research activity coupled with review, analytical, compliance, or other similar scientific regulatory technical supervisory activities. This position differs from full-time review, analytical, compliance, or regulatory scientist positions found throughout FDA in that it includes basic or applied research duties that are performed less than a majority of the time. Each position of this type will need to be independently analyzed by the appropriate CFSAN line management and the Chairperson(s) and the CFSAN Executive Secretary of the CFSAN Research Peer

Review Panel to determine the most appropriate method of evaluation and classification. The decision as to whether the peer review process, using the RGEG, or the FES, using appropriate classification standards, is applicable may depend on several variables including: percentage of time spent in research versus regulatory and technical supervisory activities; management intent as to how the position should function; relative level of duties performed in a regulatory capacity in comparison to complexity of research assignment; and level of the incumbent's qualifications, scientific stature, recognition, and impact. Since research position classification is based heavily on the impact of the person-in-the-job, and traditional classification places primary emphasis on the level of duties and responsibilities assigned to the position by management, the decision as to which classification approach to use is critical because the final classification decision may be different depending on which criteria are applied.

In many mixed positions, regulatory review and/or technical supervisory activities may be of an equivalent grade as the research duties. However, research duties that occupy less than the majority of an employee's time and are of higher grade value than the work that occupies most of his/hers time may still control the grade of the position and meet the definition of a research position, if all four of the following criteria are met.

- a. The research duties must be "paramount in influence and weight." This means that research must relate to the basic purpose and reason for the very existence of the position.
- b. The research duties must occupy a "substantial" part of the employee's time. Substantial is considered to be at least 25 percent.
- c. The research duties must be assigned on a "reasonably frequent and recurring basis." This requirement excludes one-time duties of an "emergency, incidental, or temporary nature."
- d. The research duties must be so different from the other work that they require a "materially higher" level of qualifications. To meet the requirements of materially higher, "the qualifications must be different in "kind" rather than different in degree of "difficulty."

Qualifications are different in "kind" and therefore materially higher" when the research performed for less than a majority of the time requires specific training, education, and/or specialized experience. An example of the "materially higher" qualifications criteria most applicable to FDA may be found in some scientific research organizations which are responsible for both research and regulatory review work. On occasion, an employee, because of an established expertise in a specialty field, may come to the point of spending a majority of his/hers work time on reviewing industry applications for approval to manufacture and market regulated products or on other regulatory actions. In this situation, the technical qualifications required to perform the research work which has come to occupy less than a majority of the scientist's time may be considered to be "materially higher," and therefore different in "kind."

3. Evaluation of Mixed Positions

Because of the close association between the scientific research and regulatory missions of the FDA, Agency research scientists often perform collateral duties associated with the regulatory review mission of a Center. The result is a mixed duty position in which research and regulatory review work are measured by two very different OPM position classification standards. Both fields of work are similar in many instances; however, comparing a research scientist's publications with those papers and reports which are the result of regulatory review work is inherently different.

Research publications are the end result of research work, and are the vehicle by which scientific progress and information are communicated and shared with the scientific community at large. The degree of acceptance by that community is an all-important indicator of both the quality of the research being performed and the reputation of the scientist. By contrast, regulatory review publications such as papers and reports are seen as evidence, along with other appropriate information, of how complex and what kind of impact the work performed has had on the regulated industry.

“Factor IV. Qualifications and Contributions Contributions, Impact, and Stature” in the RGEG is used to evaluate the publication work of a research scientist. In evaluating the publication record of a research scientist against this factor, it should be remembered that the quality, scientific significance, and contribution of those papers, rather than mere numbers, are most important.

Reports and papers which result from regulatory review work are evaluated in a very different manner from research publications. In the FES classification standards, nine factors evaluate the regulatory review work of FDA scientists. No single factor of these nine addresses publications as in the RGEG. Within the regulatory review field, publications such as papers and reports are seen as evidence, along with other appropriate information, of how complex and what kind of impact the work performed has had on the regulated industry.

The following review mechanism applies only for GS-14 mixed function research scientist positions. The typical full performance level of a scientist performing regulatory review work is GS-13. The grade of a mixed function position below GS-14 can be determined by the level of regulatory review work when that work occupies more than 25 percent of the scientist's time. In those instances that meet the criteria outlined above, the Peer Review Panel can evaluate the position against an appropriate classification standard.

For GS-15 grade level positions, the criteria in the RGEG and the FES scientific classification standards are so demanding that any position being considered for that grade level would be appropriately classified on the basis of the primary functional responsibilities assigned to the scientist. The regulatory review contributions of the research scientist can be considered in all cases Research by

the Peer Review Panel.

4. Combined Peer Review Mechanism for GS-14 Positions

For some CFSAN mixed function research scientist positions, when the scientist has been involved in regulatory review work, the following conditions should be present before the combined peer review mechanism is utilized to evaluate a position:

- a. The research scientist in the position being considered for GS-14 has been so involved in regulatory review work that CFSAN management believes that the scientist has been inhibited from meeting RGEG Factor IV criteria as they pertain to publications; and
- b. CFSAN management has made an initial assessment of the significance of the regulatory review science reports and papers (to include regulations writing) and feels that these meet FES Level 3-5 criteria.

The review process is described in Section V. A Cross-Walk comparison of the RGEG factors with the FES factors is given as Supplement 7.

5. Supervisory Research Positions

In the research situation, team leadership, or supervision direction of a small unit, is commonly based on, and “carried” out by, personal competence in research rather than by supervisory and administrative skill. These include all aspects of technical supervision. Consequently, this Plan provides for the classification of such supervisory positions by the same criteria as non-supervisory research positions and is included in the mixed positions category. Nearly all positions involving direction of larger research organizations (e.g. branch chief, division director), require - in addition to research competence - marked supervisory and administrative ability. This type of a position is therefore to be classified primarily by other criteria, such as the Supervisory Grade-Evaluation Guide, Program Manager, or Administrative Officer Standard, etc. These positions are classified as supervisory positions. Certain personnel actions, such as approval of leave and time cards, can only be performed by individuals in positions classified as “Supervisory.” Research peer review may be used to support, in part, the grade evaluation.

?. Lead Research Positions

Lead positions are not supervisors and do not evaluate employees or approve long term annual or sick leave. However, supervisors can multiply their span of control by installing Lead positions below them in an organization. Leads can: identify, distribute, and balance workload and tasks among employees in accordance with established workflow, skill level, and/or occupational specialization; approve emergency leave for up to three days; eight hours or less for medical appointments; and/or other types of leave as delegated by management; resolve simple, informal complaints of employees and refer others, such as formal grievances and appeals, to the supervisor or an appropriate management official; etc. Lead positions, as a regular and recurring part of their

work, spend at least 25% of their time, leading employees who are permanently assigned to a team. Lead positions are classified by the General Schedule Leader Grade Evaluation Guide.

6. Support or Service Positions

The fourth type of position is the support or service scientist position. This is a scientific professional position that functions in direct support of, or service to, one or more research or mixed positions but does not meet the criteria of a research position as defined previously. That type of position is excluded from coverage under the RGEG and is evaluated and classified by appropriate classification standards. Support or service positions involve performance of limited elements of research work; literature data search; surveys for the purpose of collecting or reporting scientific data; or work limited to the collection, identification, and/or analysis of animal, mineral, biological, or chemical specimens. There may be a few positions which combine service or support work related to research with analytical regulatory activity.

B. Management of Scientific Professional Positions

This plan covers the evaluation of supervisory and non-supervisory research positions and mixed positions where the research qualifications are of paramount importance. How a position is designated, i.e., research, mixed, supervisory, or support will be determined based on program needs and requirements (not the incumbent's qualifications) as determined by managers and supervisors. The designation of particular position(s) should be made known prior to that position being evaluated. For an individual to move from one type of position to another, the individual will have to be reassigned or compete through merit promotion, if promotion potential exists in the new position. To assure equitable classification for all positions, it is imperative that they be properly designated so that appropriate classification standards and procedures are applied.

If a supervisor determines that an employee's current "Research Scientist" position no longer meets the definition of "Research Scientist," as defined in this Plan, the supervisor will prepare a non-research position description. The new description will be submitted, along with an SF52, "Reassignment," the employee's current performance plan, and a memorandum, through the Director, CFSAN, to the appropriate personnel authority Human Resources staff, stating that the duties and responsibilities of the employee's position have changed, the reason for the change, and that "research" is no longer a substantial part of the position. The employee's non-research work will subsequently be evaluated through the normal classification process, rather than the peer review process.

In the event of a disagreement between the supervisor and the employee regarding his/her position meeting the definition of a "Research Scientist," as defined in this Plan, the supervisor should discuss and attempt to resolve the disagreement with the employee. If the disagreement cannot be resolved, the supervisor should refer the employee's non-research position description, through supervisory channels, to the Chairperson(s) of the CFSAN Research Peer Review Panel. The Research Peer Review

Panel Chairperson(s) should identify positions which do not meet the minimum requirements of a research position. Cases so identified will be submitted to the CFSAN Executive Secretary of the CFSAN Research Peer Review Panel for the final inclusion/exclusion determination. In consultation with the CFSAN Research Peer Review Panel Chairperson(s), the CFSAN Executive Secretary of the CFSAN Research Peer Review Panel will determine the inclusion/exclusion of the case. If excluded from peer review, the case will be remanded to the appropriate **personnel authorities** **Human Resources staff** for classification through the normal classification process.

C. Relationship of Employee Performance Plan to the Peer Review Process

Research work will be clearly identified in the employee's position description, as well as in his/her performance plan. Research duties that occupy less than 50 percent of an employee's time, but are of a higher grade value than the work that occupies most of his/her time, control the grade of the position if they meet all four of the criteria described in Section II.A.2. of this Plan. In these situations, the research work should be identified in the employee's current performance plan as a critical element. Managers and supervisors should therefore be aware that an employee's performance plan and position description need to be "linked" to ensure that "research" duties and responsibilities are included in both documents where applicable.

D. Requirements for Self-Nomination

Self-nomination is a request to reconsider the classification of a position covered by the peer review process. The self-nomination process begins only after an employee has contacted his or her immediate supervisor and has requested a management nomination for peer review. If the supervisor declines to make the nomination, the employee who meets the minimum qualifications for promotion has the option of either: 1) initiating a self-nomination, or 2) filing a formal position classification appeal. (See Article 32.) As part of the self-nomination process, the employee must document the meeting with the supervisor, to include the supervisor's name and the date of the meeting.

To proceed with a self-nomination, the employee must apply for peer review through established procedures to the appropriate committee chair. The employee must submit all items that are required by the applicable peer review plan, including scientific and/or technical information. The accuracy and adequacy of information provided to a peer review committee will be verified as part of the normal peer review process. Failure to provide the required documentation will result in the return of the nomination package. Self-nomination packages forwarded to peer review committees will be maintained in the order in which they are received and will be considered in the same order.

Any candidate dissatisfied with the peer review of his/her package by the Panel may resubmit a package. However, a resubmitted package must specifically address the deficiencies identified in committee reports as well as any changes in the employee's position. All resubmissions will be treated as new cases and scheduled for peer review accordingly.

FDA employees have the right to formally appeal the classification of their positions (5 CFR, Part 511, Subpart F). They may appeal within the Agency to the Director, Classification Services Staff (CSS), OHRMS, or directly to the U.S. Office of

Personnel Management (OPM). Appeals must include the documentation described in Article 32, Classification, Section 2-B and C of the CBA. CSS classification appeal decisions may be further appealed to OPM, but OPM classification appeal decisions are final within the Federal government and are binding on the Agency.

III. STRUCTURE OF THE PEER REVIEW PANEL

A. Active Members

The Panel will consist of five or more members. The Director, CFSAN, will select a Chairperson(s), who is usually a senior scientist from CFSAN, to serve on the Panel at his/her discretion for a period not to exceed two consecutive years, and an Executive Secretary for the Panel. The Chairperson(s) will select a cadre of research scientists (or managers/supervisors who administer research) with different expertise at the GS-13 level or equivalent or above to comprise a pool of panel members (Standing Committee) to serve as needed on peer review panels. Three or four of the scientists may be selected for each upcoming panel meeting depending on the expertise needed for review of the candidates. Other recognized research scientists within and outside CFSAN at the GS-13 level or equivalent or above outside this pool of panel members may be selected as needed to complete any peer review panel. If a Commissioned Corps or non-government employee is nominated to serve as a panel member, he/she should be recognized in his/her field of expertise. The Panel should include at least two representatives of the same general peer group (specialty or expertise) as the case(s) to be considered for peer review and will constitute a quorum when four of the panel members are present at a meeting, including the CFSAN Executive Secretary. The research scientists or managers/supervisors chosen to serve on the panel will be selected primarily on the basis of their ability to make valid judgments on research methodology, available literature, the significance and impact of research findings in one or more related fields of expertise, and scientific regulatory and supervisory contributions.

B. Advisory Participants

The Chairperson(s) will have the authority to contact scientists, other than those on the Panel, management/supervisory officials, Human Resources specialists, and others, and invite them to attend the peer review meeting to assist in the review process. Persons who are first or second line supervisors or close associates of the candidate should not be selected as Advisory Participants.

IV. RESPONSIBILITIES

A. The Director, CFSAN, or his/her designee, will:

1. Establish procedures to ensure that mandatory reviews are conducted of all research scientist positions covered by this Plan.
2. Notify appropriate management officials of review priorities.
3. Approve the research scientists or managers/supervisors who administer research as members of the Panel and the Chairperson(s).

4. Approve or disapprove response to the preliminary Career Evaluation Report prepared by the research scientist's supervisor.
5. Review the Center-level Committee reports.
6. Approve transmittal of package to a Committee except for self-nomination.

B. The Chairperson(s) of the CFSAN Research Peer Review Panel will:

1. Establishes the yearly calendar for Committee meetings and coordinates committee calendar with Associate Commissioner for Science to include due dates for submission of packages for consideration at each scheduled meeting in conjunction with the Committee Executive Secretary.
2. Provide advice to managers and supervisors relative to the submission of research scientist cases for peer review.
3. Work closely with the CFSAN Executive Secretary in all aspects of the peer review process from initial case submission through resolution and follow-up of recommended actions.
4. Receive and review research scientist cases from the Director, CFSAN, and coordinate and schedule peer review meeting dates and times with the CFSAN Executive Secretary.
5. Select research scientists or managers/supervisors who administer research as Panel members and assign specific cases to members for in-depth review prior to meetings.
6. Disqualify from participation and voting at the peer review meeting any Panel member or Advisory Participant who is a first or second level supervisor within the same Division or equivalent organizational level of the scientist being reviewed. This applies only to the specific case of his/her employee, not to the other cases under review.
7. Orient all new Panel members in the evaluation process prior to their serving on the Peer Review Panel.
8. Chair Panel meetings and participate as a voting member.
9. Ensure the confidentiality of Panel discussions and recommendations.
10. Speak for the Panel in communications with the Director, CFSAN, or his/her designee, managers/supervisors, applicants, and other individuals concerned with the evaluation process.
11. Share responsibility with the Agency Peer Review Office for preparing the evaluation report of the results of each Panel meeting.
12. As necessary, invite persons to the meeting of the Research Peer Review Panel or

contact them to aid or assist in the review process.

13. Be responsible for the periodic evaluation and assessment of the CFSAN Evaluation Plan for Research Scientists and recommend to the Director, CFSAN, any changes which would improve the peer review process.

C. The Research Peer Review Panel members will:

1. Meet regularly on a yearly schedule established by the Chairperson(s)
2. Conduct reviews of research scientists at the GS-13 level and above.
3. Evaluate each case on the basis of the criteria described in this Plan and the RGEG. While Supplement 1 to the RGEG is a useful summary, it is for illustrative purposes only and must be used only in conjunction with the Guide.
4. If selected as an in-depth reviewer, a member will conduct interviews with the recommending supervisor, Division Director, and others as appropriate prior to the meeting.
5. Recuse themselves from the panel meeting (and not be present during the review) if there is any conflict of interest with a candidate.

D. The CFSAN Executive Secretary of the CFSAN Research Peer Review Panel will:

1. As directed by the Director, CFSAN, notify appropriate management officials when mandatory reviews are due.
2. Provide technical personnel advice to managers and supervisors relative to the submission of research scientist cases for peer review.
3. Work closely with the Chairperson(s) in all aspects of the peer review process, from initial case submission through resolution and follow-up of recommended actions.
4. Receive and review cases from the Chairperson(s); coordinate and schedule meeting date and time with the Agency Peer Review Office and the Chairperson(s); confirm meeting and time with Panel members; and distribute case materials to Panel members for review prior to meeting.
5. Ensure that cases are processed according to the requirements prescribed in this Plan.
6. Provide technical personnel advice at Panel meetings and counsel the Panel of any modifications or changes in the criteria used in the evaluation of Research Scientist cases.
7. Ensure that actions are processed upon receipt of SF-52s after recommendations have been made by the Panel on each case and follow-up on recommended actions.

8. Be responsible for the periodic evaluation and assessment of the CFSAN Evaluation Plan for Research Scientists and recommend to the Director, CFSAN, or his/her designee, any changes which would improve the peer review process.
9. Ensure that SF-52s are prepared and submitted to the appropriate **personnel authorities** **Human Resources staff** to effect actions resulting from peer panel recommendations or decisions.

V. SPECIFIC PEER REVIEW PROCEDURES FOR GS-14 MIXED RESEARCH POSITION

- A. The CFSAN Research Peer Review Panel Chairperson(s) and CFSAN Executive Secretary will determine that the mixed position criteria in Section II are met.
- B. The CFSAN Research Peer Review Panel Chairperson(s) will formally notify FDA's OHRMS, Classification Service Staff (CSS), prior to the assignment of a research in-depth reviewer, that the employee to be reviewed has been performing mixed function work and CFSAN management is recommending promotion to GS-14.
- C. The CFSAN Research Peer Review Panel Chairperson(s) will provide the CFSAN Executive Secretary of the CFSAN Research Peer Review Panel a copy of the documentation supporting FES Factor Level 3-5.
- D. The CFSAN Research Peer Review Panel Chairperson(s) will consult with the CFSAN Executive Secretary Peer Review Panel (OHRMS CSS) to determine which member of the FDA Regulatory Review Scientist Peer Review Committee will be assigned to the case. Typically, this will be a CFSAN employee.
- E. The regulatory review scientific contribution will be reviewed by the individual selected as described in paragraph D above. This individual will also participate in the "in-depth" review of the research scientist's work.
- F. A recommendation will be made at the Research Peer Review Panel meeting concerning how the regulatory review science work affects the final grade of the position being evaluated.

VI. PEER PANEL REVIEW

A. Review and Evaluation

The peer review will be based on individual case material prepared as specified in Section VII (and Supplements) and will include an analysis and evaluation of:

1. The assigned area of research, supervisory, and regulatory functions in terms of the scope of responsibility and inherent difficulty and complexity.
2. The quality and quantity of the scientist's performance as measured by demonstrated originality, competency, accomplishments and standing in his/her research field, and regulatory activities as prescribed in the RGEG.

B. Review of Case Material (PROCEDURAL STEPS)

Prior to the Research Peer Review Panel Meeting

1. The candidate/research scientist will prepare the case material according to the format in Section VII (and Supplements) for his/her immediate supervisor's concurrence.
2. The Division Director will thoroughly review the case material for adequacy, accuracy, and format.
3. If the Division Director concurs, he/she forwards the case material through the Office Director to the CFSAN Executive Secretary in the Office of Management Systems for review. The Executive Secretary will thoroughly review for adequacy, accuracy, and format.
4. CFSAN Executive Secretary sends a complete and accurate Peer Review package to the Director, CFSAN, or his/her designee, to thoroughly review and for signatures. If the Director, CFSAN, or his/her designee has any questions, they should be directed to the CFSAN Executive Secretary for response.
5. When the case materials are acceptable to the Director, CFSAN (or designee), the candidate prepares an electronic copy of the package for submission to the CFSAN Executive Secretary. Confidential letters of recommendation are supplied in electronic format by the Division Director.
6. The CFSAN Executive Secretary enters the electronic package in E-Room and schedules the Research Peer Review Panel meeting.
7. If case material is unacceptable to the Director, CFSAN (or designee), the CFSAN Executive Secretary returns same to the research scientist, for rewrite, corrections, omissions, additions, etc. (The case is to be rewritten and resubmitted to the CFSAN Executive Secretary in electronic format within 15 days of receipt by the research scientist.)
8. The supervisor/or candidate will propose a list of at least three nominees for the in-depth review of the candidate, including a member of the Standing Committee, if possible. These proposed Panel members will not be from the candidate's unit and will be familiar with the field of specialization of the candidate. The Panel Chairperson(s) may select the in-depth reviewer from this list, but is not required to do so.
9. Panel members will conduct in-depth reviews, when assigned, prior to the Panel meeting to obtain any information in addition to the written case material which will help the Panel to better understand a case, and be prepared to discuss same at the scheduled meeting. This in-depth review will include interviews with the employee and his/her supervisor.
10. Panel members will review and evaluate all case material and arrive at a tentative

score, by reference to the RGEG, which is attached to this Plan, prior to the scheduled meeting.

During the Research Peer Review Panel Meeting

1. Attendance at Panel meetings will be limited to Panel members, the Chairperson(s), the Agency Peer Review Office, the CFSAN Executive Secretary, and any other persons specifically designated by the Panel Chairperson(s).
2. Panel meetings will be conducted in accordance with the procedures outlined in this Plan. Panel discussions are considered to be confidential and Panel recommendations and decisions will be distributed through official channels only.
3. Consideration of a case at a Panel meeting should begin by listing the scores given by the individual Panel members as determined independently.
4. The in-depth reviewer will furnish findings to the other Panel members from the in-depth review.
5. After thorough discussion, the Panel will attempt to reach a Panel consensus score, using the RGEG. If a consensus score cannot be reached, the Panel's decision will be based on a majority vote.
6. The Panel's score will result in a recommendation to classify a position to (a) a higher grade, (b) the same grade, (C) a lower grade, or (d) the appropriate grade for a new position. Regardless of the score, the Panel may also recommend (a) resubmission of a case at an earlier date than the mandatory review period; (b) withholding action pending receipt of additional and/or classifying documentation; (c) reclassification to a non-research position; or (d) other appropriate action.
7. If the Panel scores a position in the gap between the research scientists' current grade and the next higher grade level (gray areas), it will be classified at the lower grade level. This policy is based on OPM's guidance that a position cannot be classified at the higher level, unless it substantially meets that level.
8. If the Panel scores a position below the research scientist's current grade level, the Panel will specifically identify the reason(s) for the "problem" and the research scientist's and/or the position's deficiencies in a preliminary Career Evaluation Report and provide management with suggestions for resolving the problem. The Career Evaluation Report will be completed by the Panel Chairperson(s) and forward to the Agency Peer Review Office for concurrence. Upon concurrence, the preliminary Report will be forwarded to the research scientist's immediate supervisor, through the Director, CFSAN, for a written response to the Panel findings and suggestions. The immediate supervisor's response will be addressed and forwarded within 30 days, through supervisory channels, to the Director, CFSAN, for review and approval. Upon approval by the Director, CFSAN, the supervisor's response will be sent to the CFSAN Executive Secretary for inclusion in the final Career Evaluation Report. The final report will be forwarded through supervisory channels, to the research scientist's immediate supervisor. If suitable

corrective measures have not or cannot be identified by the immediate supervisor, the Career Evaluation Report will be documented accordingly and action to downgrade the research scientist will be effected, in accordance with applicable OPM regulations. The nature of the proposed downgrading will depend on the cause of the research scientist's and/or position's deficiencies; therefore, this determination will be made by the Peer Review Panel.

9. If deemed necessary, the Panel Chairperson(s) will contact the recommending supervisor or persons knowledgeable of the scientist's achievements and contributions, to assist in the review process.

After the Research Peer Review Panel Meeting

1. The Peer Review Chairperson(s) will prepare the Career Evaluation Report of the Panel findings and recommendations and submit it to the Agency Peer Review Office for concurrence.
2. The CFSAN Executive Secretary will then distribute the Career Evaluation Report to the immediate supervisor of each employee reviewed, through the Director, CFSAN, or his/her designee.
3. The Career Evaluation Report will include identifying data for each employee reviewed, Panel decisions and recommendations, and a brief summary clearly stating the reasons for the Panel decision and other pertinent information agreed to at the meeting.
4. The candidate's supervisor is required to discuss the Career Evaluation Report with the employee and respond to the CFSAN Executive Secretary, in writing, through the Director, CFSAN, that the discussion has taken place and what understandings were reached particularly regarding constructive suggestions or recommendations by the Panel.
5. The Director, CFSAN, may request the re-review of a specific case by a Panel under unusual circumstances warranting such action (for example, in the event of an unusual conflict in the choice of a Panel member or the receipt of new or additional information or documentation, which in the opinion of the Director, CFSAN, could have affected the Panel's scoring and/or recommendation). The re-review will be conducted following the same procedures as the initial review and in accordance with this Plan. The Director CFSAN, or his/her designee, will work with the chairperson(s) to determine the composition of the Panel for the re-review.

VII. PEER REVIEW OF RESEARCH SCIENTISTS

Documentation Requirements

Cases may be submitted by the Research Scientist's supervisor (voluntarily or at the employee's request) at any time after a research scientist has been in-grade for one year. A position should be evaluated whenever significant changes occur in the level of a research

scientist's assignment(s), recognition, or contributions. The research scientist package must be submitted within 60 days prior to the date of the review for his/her immediate supervisor's concurrence and forward the package through supervisory channels, including the Director, CFSAN, to the CFSAN, Coordinator/Liaison, HFS-670. The original package must contain, in the order shown, the following:

- A. Transmittal memorandum from immediate supervisor, but no lower than Branch Chief, indicating the reason for the review, (i.e., cyclic, promotion, selection, etc.) and forwarded through supervisory channels, including the Director, CFSAN, to the CFSAN, Coordinator/Liaison HFS-670. (See Supplement 1 for sample Transmittal Memorandum.)
- B. Supervisor's Assessment, discussing employee's performance, including external difficulties encountered that had to be overcome, and emphasizing impact of accomplishments. Accomplishments for which there is no other documentation can be supported here.
- C. List of Accomplishments from the Research Scientist (See Supplement 3). This list should **not** restate the position description and *curriculum vitae* but should amplify the research scientist's accomplishments and cover the following points:
 - A brief summary of accomplishments prior to previous peer review.
 - Contributions to FDA and the scientific community since the last peer review should be emphasized. (These can be supported by letters of recommendation).
- D. Curriculum Vitae (See Supplement 4).
- E. Bibliography (See Supplement 5).
- F. OF-8 cover sheet and current and proposed position descriptions (See Supplement 6).
- G. Research scientist's current performance plan. (It is not necessary to submit the supervisory evaluation of the research scientist, only the Plan).
- H. Copies of no more than three recent publications/reports that the employee considers most significant. (The in-depth reviewer, in particular, and other panel members may request copies of additional publications/reports cited).

The individual's original peer review packages should be placed in a binder with tabs dividing each of the supplements. The package should be held together with appropriate fasteners or placed in an individual file folder. After all approvals are obtained, the package is converted to an electronic format and given to the CFSAN Executive Secretary

See the supplements to this Evaluation Plan for examples of the components of a peer review package.

VIII. CYCLIC REVIEW OF RESEARCH SCIENTISTS

Procedures for the Mandatory Five Year Cyclic Review

To ensure that researchers at the GS-13 to GS-15 levels continue to perform their duties that originally supported the assigned grade, FDA requires a cyclical review of research accomplishments. Therefore, each GS-13, GS-14 and GS-15 researcher will undergo a review of their research and regulatory accomplishments once every five years. If the candidate is promoted during the five year cycle, a new review cycle begins. This process also applies to those supervisors at GS-14 or 15 whose grades are based on the research related duties which they perform rather than their supervisory responsibilities. The Research Scientist Peer Review Committee will notify the immediate supervisor of the candidate 120 days before his/her scheduled review date. The package must be submitted within 60 days following this notification. In cases where the time since the previous peer review exceeds five years, employees will be prioritized for review based on length of time since the last review.

Documentation Requirements

The package prepared by the candidate must contain the following information:

- A. Transmittal memo from the immediate supervisor to the Committee Chair. This memorandum must contain the name, title, series, and current grade of the candidate and attest to the accuracy of the package prepared by the candidate.
- B. List of accomplishments and contributions to the Agency, regulated industry, scientific community, and the regulatory process, including scientific achievements (research and regulatory), originality, and quality and reputation in the local, national and/or international scientific/regulatory community (see supplement 3). Only those accomplishments since the last review should be presented.
- C. Description of special expertise, if any.
- D. Career evaluation committee report from last peer review.
- E. Curriculum Vitae (CV)
- F. Bibliography
- G. Current position description of record.

Performance plans, letters of reference or copies of recent publications will NOT be required as part of the package.

IX. **NEW HIRE FOR VACANT RESEARCH SCIENTIST POSITION**

Documentation Requirements

The C.V., bibliography, and any other supporting information (such as letters of

recommendation) for the candidate selected to fill the vacant position are reviewed by an Ad Hoc Committee. This committee is composed of the CFSAN Research Peer Review Committee Chair(s) and experts in the new hire's research area. An individual's selection cannot become final (and the individual cannot enter on duty) until the evaluation process has occurred.

X. APPEALS

Normal classification appeal procedures are applicable to employees covered by the CFSAN Evaluation Plan for Research Scientists. All research scientists may appeal the final classification of their position through the classification appeals system of the Office of Personnel Management (OPM).

Classification appeals directed to OPM should be addressed as follows:

**U.S. Office of Personnel Management
Classification Appeals Office
Washington, DC 20415**

Questions concerning appeal rights and procedures should be directed to the Chief, Classification Services Staff, HFA-406, Office of Human Resources and Management Services, Food and Drug Administration.

EVALUATING MIXED FUNCTION RESEARCH POSITIONS

The following comparison “Cross-Walk” Chart relates the different factors in the RGEG and the FES to each other so that the full range of research and regulatory review work performed by FDA research scientists, including publications, may be compared to each other at the GS-14 level. This is the advanced level at which a scientist should be involved in substantial research and complementary regulatory review work of critical importance to the Agency and the regulated industry.

GRADE LEVEL COVERED:

It is unnecessary to provide a “cross-walk” between the RGEG and FES at GS-13 and below since the typical full performance level of a scientist performing regulatory review work is GS-13. The grade of a mixed function position below GS-14 can be determined by the level of regulatory review work when that work occupies more than 25 percent of the scientist’s time. In those instances the position should be evaluated against an appropriate position classification standard.

It is inappropriate to depend upon a “cross-walk” approach to evaluate work at the GS-15 grade level because criteria in the RGEG and the FES scientific classification standards are so demanding that any position being considered for that grade level would be appropriately classified on the basis of the primary functional responsibilities assigned to the scientist.

The Chart is divided into four parts, which correspond to the four factors in the RGEG in the left column with the corresponding FES factors in the right column. Within each of the four groups, abbreviated descriptions of related research and regulatory review work are presented side-by-side. To sustain GS-14 in the performance of research a scientist can normally be expected to reach degree level D for each of the four prescribed RGEG factors: I, The **Research Situation** **Research Assignment**; II, **Supervision Received** **Supervisory Controls**; III, **Guidelines and Originality**, and IV, **Qualifications and Scientific Contributions** **Contributions, Impact, And Stature**. To support the GS-14 in the performance of regulatory review work, the following pattern of factors in the FES can normally be expected to present: 1-8, 2-5, 3-5, 4-5, 5-5, 6-3, 7-3, 8-1, and 9-1.

CROSS-WALK” BETWEEN RGEF & FES CLASSIFICATION FACTORS

(GS-14: Mixed Research & Regulatory Review)

The RGER guide has four factors for grading the work of researchers. While there is some overlap among the factors, each focuses on a different aspect of the researcher’s work and the relationship between the researcher and the research environment.

RGEF FACTOR

Factor I. Research Assignment, deals with the nature, scope, and characteristics of current research studies assignments. This factor considers: assignment scope and complexity; objectives, and means of accomplishment; problem breadth and depth; availability of related research studies; extent to which objectives can be defined; number of unknowns and critical obstacles; variety and depth of knowledge and expertise required to solve problems; extent and complexity of the required validation process; necessity to translate abstract concepts into easily understood statements of theory or models, and to determine how best to disseminate information or transfer research findings; utility of the end product in solving the initial problem and in opening new areas of investigation; and expected impact of end results, products, or outcomes.

APPLICABLE FES FACTOR

Factor 4 - Complexity, covers the nature, variety, and intricacy of the tasks, process, and methods in the work performed.

Recognized Center authority in an area of advanced scientific or technical difficulty and may assume responsibility for group efforts.

Modifies procedures and interprets policy, selects and evaluates methods and establishes requirements for solving problems.

Resolves problems, modifies procedures, and develops and interprets policy to meet new and novel conditions.

RGEG FACTOR

Factor II. Supervision Controls deals with the researcher's current level of independent performance and the technical and administrative guidance and control the supervisor exercises over research work. Researchers may consult frequently with colleagues and collaborators.

This factor considers the: manner in which the supervisor assigns work; researcher's freedom to determine a course of action; researcher's opportunity for procedural innovation; and degree of the supervisor's acceptance of the researcher's recommendations, decisions, and final products.

APPLICABLE FES FACTOR

Factor 2 - Supervisory Controls, covers the nature and extent of supervisory controls, the responsibility of the scientist, and the review of the completed work.

Working under administrative supervision, independently plans and carries out work.

Supervisor makes assignments in general terms and is kept informed of progress, and reviews issues involving constraints on resources and broad Center policies.

Results and conclusions are normally accepted as authoritative without any significant change.

RGEG FACTOR

Factor III. Guidelines and Originality,

Deals with the creative thinking, analysis, synthesis, evaluation, judgment, resourcefulness, and insight characterizing the work currently performed.

Guidelines consist of literature in the field, procedures, instructions, or precedents and may be adapted or modified to meet the requirements of the current assignment.

Consider: the extent and nature of available written guides; intrinsic difficulty encountered in applying guides in terms of their ready adaptability to the current assignment; and the degree of judgment required in selecting, interpreting, and adapting guidelines.

Originality involves original and independent creation, analysis, reasoning, evaluation, and judgment; and originality in interpreting findings and translating findings into a form usable by others.

Existing theories and methods are of limited usefulness and lacking for major portions of the research conducted.

Originality is required to interpret and relate results to other findings. Significant modifications are made to existing theory and methodology.

APPLICABLE FES FACTOR

Factor 3 .Guidelines, covers the nature of guidelines and the judgment needed to apply them.

Guidelines and precedents are either inadequate or unavailable for most of the questions and problems encountered which involve a number of a typical experiences, studies, and tests with unexpected side effects, injury, toxicity, or sensitive reaction of or to regulated products.

New and novel conditions require modification, development and interpretation of policy, and considerable ingenuity and judgment to select and evaluate methods for solving problems. Ability to coordinate research projects to establish new and revised treatises and guidelines for regulated products.

Sets regulatory policy and develops regulatory guidelines to be followed by others in the Agency and in the regulated industry.

RGEG FACTOR

Factor IV. Qualifications and Scientific Contributions Contributions, Impact, and Stature This factor focuses on the researcher's total contributions, impact, and stature as they bear on the current research assignment.

Impact: Has an impact on scientific and/or societal issues; sets new research directions; develops new methods, techniques, or tools to be used by other researchers; and drives management and policy outcomes.

Stature: Is established when the researcher is recognized by the scientific field and/or society, as indicated by: requests for expert advice/consultation by other professionals and managers; requests to exercise leadership on research teams or projects; invitations to serve on advisory boards; etc.

APPLICABLE FES FACTOR

Factor 1 - Knowledge Required by the Position, measures the nature and extent of the information and which the scientist facts which a scientist must understand to perform the work.

Factor 5 - Scope and Effect, covers the relationship between the nature of the work and the effect of the work both within and outside the Agency.

Factors 6 and 7 - Contacts and Purpose of Contacts to make contacts and the purpose and difficulty in communicating.

Creates, extends, and modifies approaches, precedents, and methods which resolve obscure or unprecedented problems; makes decisions which create new and/or modify existing regulatory policy; and, as the authority in the area of expertise, develops regulatory policy, standards, procedures, and instructions for the guidance of industry and of Agency headquarters and field organizations.

Possessing a mastery in one or more scientific disciplines, the scientist serves as the Center authority in a specialty area or Program field.

Because of the scientist's recognized expertise, serves as Agency representative and liaison with other Agencies, outside professional groups, and the regulated industry to present Agency requirement, discuss controversial technical and scientific points, and endorse regulatory requirements and policies.

SUPPLEMENT 1
TRANSMITTAL MEMORANDUM

DATE:

FROM: First line supervisor, but no lower than Branch Chief or equivalent position

SUBJECT Recommendation for Peer Review Evaluation of (name)

TO: Chairperson, CFSAN Research Scientist Peer Review Panel

Supervisory channels

Through: Director, CFSAN
Deputy Director, CFSAN
Office
Division
Branch is necessary

The attached case material is submitted in accordance with the CFSAN Evaluation Plan for Research Scientists for the purpose of evaluating (name), as required for promotion review.

Employee Information:

Entered on Duty CFSAN (date)
Last Promotion (date)
Last Peer Review (date)
Current Title & Grade (e.g., Research Chemist, GS-13)

(If promotion requested)
Proposed Title & Grade leg., Research Chemist, GS-14

Signature of supervisor

SUPPLEMENT 2
SUPERVISOR'S ASSESSMENT

This document should provide the Peer Review Panel additional information to support the action recommended in the Transmittal Memorandum. It should be used to document any significant factors adversely impacting the employee's performance that the employee overcomes and to emphasize the significance and **impact** of the employee's accomplishments. Accomplishments for which there is no documentation can be discussed here.

SUPPLEMENT 3
LIST OF ACCOMPLISHMENTS

This list should be restricted to actual accomplishments, not future plans or projects. The list may begin with a brief paragraph summarizing the scientist's research career by indicating total years in research, total number of publications, presentations, abstracts, and a general statement about the researcher's scientific reputation and recognition, if appropriate and/or significant.

Following the introductory paragraph, the most significant research accomplishments over the scientist's total career should be selected and listed in chronological order. Accomplishments since the last peer review should be emphasized and identified with an asterisk. Since the emphasis is on significant accomplishments, scientists at lower grades or with shorter research careers may not have had sufficient time to produce a large number of significant accomplishments.

Each significant accomplishment should be described as concisely as possible with the primary emphasis on what was accomplished and why the accomplishment was significant. The impact of the accomplishments on CFSAN's mission is the key point to demonstrate. In the case of a team effort, it will be necessary to explain exactly what the scientist contributed to the total accomplishment. Since the significance of an actual accomplishment sometimes changes with time, these statements should be carefully written. Research team leadership should be emphasized.

To aid in selecting accomplishments at least seven types have been identified. To help judge the quality of an accomplishment, the types and an indication of levels of quality are listed below:

1. Technical Regulatory Review: Ranges from "restated with essentially no change, or reported conclusions from available material" to "reviewed, analyzed, interpreted, and synthesized scientific knowledge of broad scope with significant additions to established knowledge." If the individual is recognized as a "technical expert with regard to regulatory review functions, this must be clearly stated in the list of accomplishments and in the position description.
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 situation" to "solve 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/Technical Supervision: Ranges from “maintained the quantity and quality of productivity of a research team” to “caused an extensive increase in the quality of the research product and 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.”
6. Special Assignments: (These are primarily management-related functions which impact on the research environment. They include such activities as serving as safety or quality assurance officer and EEO, library, and other advisory committees. Management training details should also be described here). Ranges from serving as unit representative to developing new policy/procedures which substantially impact Agency operations.
7. Professional Activities: These are extramural scientific activities such as active participation in scientific societies. These include serving as officer, organizing symposia, serving on technical committees, etc. (not just membership), conducting extramural technical training courses, and conducting collaborative studies and check analysis programs. (Ranges from serving as a member of a technical committee impacting scientific functions to serving as an officer of an international society which significantly impacts international scientific activities.)

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 and impact of that accomplishment

Each selected accomplishment should be referenced to the source documentation, where appropriate. References and exhibits should be chosen with the following in mind:

- the significance of a particular previous accomplishment may have increased with time, and
- while past accomplishments may be important, recent accomplishments show maintenance of technical competence.

Whenever an accomplishment cannot be supported by existing documentation, a statement signed by a knowledgeable authority (such as the supervisor or Division Director) will be acceptable. These can be included in Supervisor’s Assessment. 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, if that is not obvious from the other information provided.

A sample format for presenting significant research accomplishments of scientists is attached to this Supplement.

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

EXAMPLE, SUPPLEMENT 3
LIST OF ACCOMPLISHMENTS

Dr. Adams received her Ph.D. in psychology from New Mexico State University in 1979. Since that time she has worked as a Junior Staff Fellow in the Division of Research at CFSAN. During these 3 ½ years, she has effectively served as the principal investigator on the pilot study for the Collaborative Behavioral Teratology Study (CBTS) has played a critical role in the development of the Memorandum of Need (MON) for the CBTS and in overseeing the performance of the collaborative laboratories. In the remaining half of her time, she has been engaged in independent research with a strong method development focus. Her work has resulted in five published articles, four additional articles now submitted or in CFSAN review, 11 published abstracts, four final reports, and 19 presentations or lectures.

1. After coming to CFSAN in 1979, Dr. Adams served as a Project Officer on contract #222-80-2000(C), "Microprocessor Based Systems to Control and Collect Data from Behavioral Studies." Under this contract, two prototype laboratory systems and a developmental system were developed for use in the pilot for the CBTS. As project officer, Dr. Adams was responsible for the technical direction given to the contractors, and for all debugging and verification of the function of these systems. Upon acceptance, the contractors then fabricated 10 additional systems, two for each collaborative laboratory. Development of these systems resulted in a sophisticated, efficient behavioral teratology laboratory. (Reference 1)
2. Dr. Adams conducted a review of the literature on methods now in use in comparative developmental psychobiology studies as well as studies in developmental toxicology. This resulted a synthesis and integration of the literature which was published as a chapter entitled "Behavioral Assessment of the Postnatal Animal: Testing and Methods Development." (Reference 2)
3. The incumbent's major research focus is on the development or application of new methods for use in studies of developmental toxicology. This focus is critical at this time since behavioral teratology is a newly emerging discipline, and critical issues are the validity, reliability, and sensitivity of behavioral data. Dr. Adams' work is directed at the validation of behavioral techniques used in young animals and at establishing a historical database of normal response values. She also has focused on the development of more sensitive techniques for measuring behavioral deficits in young animals. Her work on the ultrasonic vocalization of young rodents as diagnostic indicators of developmental toxicity is very important because this response is one of the few quantitative behaviors exhibited by neonatal rodents. (References 3-5)
4. Dr. Adams has served as a member of the Project Advisory Group for the CBTS, and as principal investigator on the pilot study. This role led her to play a critical part in the early preparation of the MON for the collaborative study which provided the PAG with a working document for discussion and finalization. Dr. Adams was also primarily responsible for designing the study protocol, writing the Standard Operating Procedures for the conduct of the study, and developing the schedule of work. She also organized and conducted a workshop at CFSAN to train the

technicians from each laboratory. These tasks have been essential for the successful accomplishment of the ongoing collaborative study. This study is important in providing regulatory information to the FDA on the status and/or necessity of behavioral screening systems. (Reference 6)

5. Dr. Adams has served as the principal investigator for the pilot studies for the CBTS. This role involved the scientific direction and management of both conventional teratology and postnatal studies. Due to the long-term nature of this work, it has resulted in one published paper and two posters presented at the Teratology Society meetings. This work has been carefully followed by scientists in industry, academia, and government. (References 7, 9)

SUPPLEMENT 4
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 “nothing to report.” The reviewers will then know that the heading was not overlooked or inadvertently omitted.

Scientist’s Name (Last, First, Middle Initial)

1. Educational Background - List the name of each institution and the dates attended, majors and minors, and degrees awarded.
2. Additional Training - List part-time or short-term training not included in Educational Background. Give dates and duration of courses, credit hours, course hours, etc. Only pertinent scientific and supervisory training should be listed (not safety, ethics, etc.).
3. Professional Experience - List professional positions held in chronological order, giving titles, grade or salary, and dates in each grade or position. Include present position.
4. Honors and Awards - List dates and a brief but sufficient description to enable the reader to determine significance and prestige. If a cash award was involved, list the amount.
5. 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 which 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. Indicate which invitations were made to you personally and which ones were requested of the Agency to send a representative. If a paper was subsequently published, cross-reference it to the publication list.
6. Licenses and Certifications - List professional licenses and certifications showing kind, licensing authority, year granted, current or expired, and brief description of special significance, if appropriate.
7. Membership in Professional or Honorary Societies - List each and give dates.
8. Offices, Committee Assignments, or Special Assignments Held in Professional and Honorary Societies - List each and give dates.
9. Participation in National/International 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. Do not list meetings in which there was no participation other than attendance.

10. 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 which are not part of the regular work assignment. If there are numerous activities, summarize information or list activities in recent years only.
11. FDA Special Assignments and Advisory Activities - These should be of a technical or 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. 480 Special Foreign Currency Program involvement, science advisor to General Counsel Office, Agency level task force assignments, etc. List each, give dates, and briefly describe the role and significance.
12. Other Significant Information - List or present in narrative any information not covered in Items 1-11 above that is considered important in the evaluation of the individual as a research scientist. For example, include any scientific or technical publication or article that has been completed but no acceptance and/or publication date given by the publishing agent. Educational and public relations efforts may also be listed under this item as may be a part of the incumbent's responsibilities (such as EEO counselor, safety committee representative, etc.). A brief description of the intended role of the individual in meeting the goals and objectives of the organization, how well this role is fulfilled, and how effective the individual is in cooperating with others when this is necessary or desirable in the total program can be indicated. Any exceptional or extenuating circumstances that may have affected the quality or quantity of research output (either favorably or unfavorably) should be discussed if not covered under other items in the case material.

EXAMPLE. SUPPLEMENT 4
CURRICULUM VITAE

ADAMS, JANE R.

1. Educational Background:

1971-75 Kansas State University: major, Psychology; minor, Biochemistry; B.S.
1965.

1975-79 New Mexico State University: major, Psychology; minor, Endocrinology;
Ph.D. 1979.

2. Additional Training:

1980 Beckman Instruments; 20-hour short course on radiochemistry

3. Professional Experience:

1979-Present Junior Staff Fellow, FDA, Center for Food Safety and Applied Nutrition,
College Park, MD 20740

4. Honors and Awards:

Undergraduate Research Achievement Award, Kansas State University, 1975
Elected Member, Phi Kappa Phi
Elected Member, Sigma Xi

5. Special Invitations:

(1) Invited to present a talk on "Relay Toxicity and Bioavailability of Residues,"
August, 1975, at the annual meeting of ASP, Chicago, Illinois. (Publication #15)

(2) Invited to chair a seminar on Drug Residues in Animal Tissues, May 1976, for
AOAC, Washington, D.C. (Publication #18)

6. Licenses and Certifications:

Nothing to report.

7. Membership in Professional or Honorary Societies:

1979-present Behavioral Teratology Society (elected)
1979-present Animal Behavior Society (elected)
1979-present International Society for Developmental Psychobiology (elected)
1974-present Psi Chi honorary society in Psychology (invited)

8. Offices, Committee Assignments or Special Assignments Held in Professional and Honorary Societies:

- 1979 Participated in the work group on “Neurological Effects/Behavioral Toxicology for the Evaluation of Current Environmental Research” sponsored by Environmental Protection Agency and Penn State University, April 23-24.
- 1982-1985 Council Member for the Behavioral Teratology Society. This involves serving as a liaison to the Teratology Society and other societies.
- 1982 Nominated for position of Conference Coordinator for the International Society for Developmental Psychobiology (election will be in November).

9. Participation in National/International Scientific Meetings, Technical Conferences, Workshops, Seminars etc.:

- 1974 Presented a paper at the annual meeting of the Rocky Mountain Psychological Association held in Denver, Colorado in May. (Publication #1)
- 1979 Presented a paper at the Teratology meeting held in Sugar Loaf, Michigan in June. (Publication #5)
- 1980 Presented a poster at the Teratology meeting held in Wentworth, New Hampshire in June. (Publication #17).
- 1981 Presented two papers at the meeting of the International Society for Developmental Psychobiology held in Cincinnati, Ohio in November. (Publication #8 and #9).
- 1982 Presented a poster at the Teratology meeting held in Palo Alto, California in June.
- 1983 Presented a poster at the meeting of the International Society for Developmental Psychobiology held in New Orleans, Louisiana in November.
- 1984 Presented a paper at an organizational meeting for the Neurobehavioral Toxicology Society held in Baltimore, Maryland in May.
- 1985 Presented two posters at the Teratology meeting held in French Lick, Indiana in June. (Publication #23)

10. Outside Professional Advisory and Consulting Activities:

Special Consultant to National Academy of Sciences’ Panel for *In Vitro* Toxicology, June-August 1 1985.

11. FDA Special Assignments and Advisory Activities:

1984-85 Member of FDA Working Group on Alternatives to Whole Animal Research.

12. Other Significant Information:

1978-980 The incumbent was the Branch Safety Representative. Her duties including bimonthly safety inspections; writing memos related to said inspections; and conducting follow-up safety inspections.

SUPPLEMENT 5
BIBLIOGRAPHY

List publications in four separate groups:

- A. Refereed publications, including “accepted for publication”;
- B. Books, book chapters, review articles, theses;
- C. Final technical reports, patents, popular publications, other (give specific identification);
- D. Abstracts

In each category, list in chronological order and number sequentially. Give full reference including all authors (as listed on the publication), journal title, complete pagination, and date.

If the work described in an abstract is subsequently published, cross-reference the publication at the abstract citation.

In each group, indicate with a line of demarcation and label publications since the last peer review.

EXAMPLE, SUPPLEMENT 5
BIBLIOGRAPHY

(The format is not critical, but must include the title and all authors given on the publication. Use whatever format is available, e.g., journal formats used in Procite®.)

A. Refereed Research Publications

1. Adams, J.R. and Baker, T.C. (1980) Observations on Eimeria mohavensis from the kangaroo rat. *J. Parasitol.*, 36:59,117-124.

(Published Since Last Peer Review) _____

2. Adams, J.R. (1985) The Effects of depression on coccidiostatic drug resistance in the kangaroo rat. *J. Parasitol.*, 41:150, 121-143.

B. Book Chapters, Reviews, Theses

(Published Since Last Peer Review) _____

1. Adams, J.R., Anderson S.J., and Jones, J.H. (1985) Physiologic response of pocket gophers to climatic change. *Proc. VI Int. Biometerological Congr.*, pages 30-49. (Review Article)

C. Other Publications

1. Adams J.R., Dow, S.N. and Jones, J.H. (1982) Rabbit feeding on demand. *Rabbit Growers J.*, 79(11), 79-82. (Popular Publication)

(Published Since Last Peer Review) _____

2. U.S. Patent 789,187. Adams, J.R. (July 27, 1982) No-Waste On-Demand Rabbit Feeder.

D. Abstracts

1. Adams, J.R. (1980) Studies on coccidiosis in the pocket gopher. *Proc. Am. Soc. Protozool.*, 2:16.

(Published Since Last Peer Review) _____

2. Adams, J.R. (1985) Identification of the *Hanta* virus in pocket gophers. *Proc. Fed. Am. Soc. Exp. Biol.*, 89:25.

SUPPLEMENT 6

POSITION DESCRIPTION FORMAT

The following format must 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. Research Assignment

1. Identify the field of research.
2. Outline in specific terms:
 - a. the objectives and scope of the research;
 - b. the research approach and methodology;
 - c. the extent and complexity of the research required to validate hypotheses or expected conclusions;
 - d. the necessity to convert abstract concepts to hardware and/or easily understood statements of theories;
 - e. the variety and intensity of the knowledge which must be brought to bear on the solution of problems;
 - f. the expected end results. (These results do not refer to the specific outcome of individual experiments, but to the potential impact on scientific theory or problem solutions.)
3. If the assignment included particulars as a member/leader of a research team, indicate the broad objective of the research group, but be specific in describing your participation.
4. If the assignment includes regulatory review functions, the area(s) of recognized "Technical Expertise" must be given.

B. Supervisory and Team Leadership

1. 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 scientists.
2. Indicate the number, titles, range of grades, and location of the scientists and other employees supervised.
3. Outline the scientist's supervisory responsibilities of an administrative nature, including those involving EEO.
4. If appropriate, describe how the team leader caused a significant or extensive increase in the quantity or quality of productivity of the research team led.

C. Guidelines and Originality

1. Describe the extent and nature of the written guides available.
2. Describe the intrinsic difficulty encountered by the scientist in applying guides, in terms of their ready adaptability to current situations.
3. Describe the degree of judgment required in selecting, interpreting, and adapting guides.
4. Describe the position's requirements for original and independent creativity, analysis, reasoning, evaluating, judging, and choosing between alternative methodologies.
5. Describe the position's requirements for interpreting findings, translating findings into a problem solution, and recording findings and interpretations in a form usable by others, as well as in the application to specific end products.
6. Describe the impact of theories, principles, concepts, techniques, and approaches developed by the scientist upon the scientific field.

D. Other Duties

Many research positions include duties and responsibilities which 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 description when performed on a regular and recurring basis. This includes work such as preparation of handbooks, special assignments, technical review for applications, technical consultation on compliance cases, etc. These accomplishments may also, but not necessarily, support the significance and impact of the research.

III. Supervision Received

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

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

(Revised version)

POSITION DESCRIPTION FORMAT

The following format must be followed.

I. **Introduction**

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

II. **Duties and Responsibilities**

- List duties here.
- **Other Non-Research Duties**
Many research positions include duties and responsibilities, which 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 description when performed on a regular and recurring basis. This includes work such as preparation of handbooks, special assignments, technical review for applications, technical consultation on compliance cases, etc. These accomplishments may also, but not necessarily, support the significance and impact of the research.

Research Grade Evaluation Factors

Factor 1 - Research Assignment

This factor deals with the nature, scope, and characteristics of the researcher's current assignment.

Projects and Teams – For project and team members, describe only the specific projects or portion of projects for which the researcher is responsible. For project managers, describe this factor in terms of the scope and character of the total project.

Primary Considerations:

- assignment scope and complexity, objectives, and means of accomplishment;
- problem breadth and depth;
- availability of related research studies;
- extent to which objectives can be defined;
- number of unknowns and critical obstacles;
- variety and depth of knowledge and expertise required to solve problems;
- extent and complexity of the required validation process;
- necessity to translate abstract concepts into easily understood statements of theory or models, and to determine how best to disseminate information or transfer research findings;

- utility of the end product in solving the initial problem and in opening new areas of investigation; and
- expected impact of results, products, or outcomes.

Factor 2 - Supervisory Controls

This factor deals with the researcher's current level of independent performance and the technical and administrative guidance and control the supervisor exercises over research work.

Researchers may consult frequently with colleagues and collaborators. Use caution in distinguishing between consultation and supervisory control and guidance.

Primary Considerations – In evaluating this factor, consider the following:

- manner in which the supervisor assigns work;
- researcher's freedom to determine a course of action;
- researcher's opportunity for procedural innovation; and
- degree of the supervisor's acceptance of the researcher's recommendations, decisions, and final products.

Researchers working on complex team projects not divided into smaller components exercise independent performance when they:

- participate fully as a professionally responsible team member in substantive aspects of the work; and
- make contributions equivalent to independently performing more limited research projects.

Factor 3 - Guidelines and Originality

This factor deals with the creative thinking, analysis, synthesis, evaluation, judgment, resourcefulness, and insight characterizing the work currently performed.

Guidelines usually consist of literature in the field, procedures, instructions, or precedents and may be adapted or modified to meet the requirements of the current assignment.

Features to be considered are:

- the extent and nature of available written guides;
- intrinsic difficulty encountered in applying guides in terms of their ready adaptability to the current assignment; and
- the degree of judgment required in selecting, interpreting, and adapting guidelines.

In assessing the impact of creativity in the position, consider the requirement for:

- original and independent creation, analysis, reasoning, evaluation, and judgment; and
- originality in interpreting findings and translating findings into a form usable by others.

Factor 4 - Contributions, Impact, and Stature

This factor focuses on the researcher's total contributions, impact, and stature as they bear on the current research assignment. It is not restricted to present and immediate past accomplishments and achievements. However, recency of accomplishment is important. Recent research or similar activity is essential to receiving full credit.

Security regulations, proprietary agreements, or other circumstances may prevent publishing research results and make it difficult to evaluate the work based on its impact on the larger professional community. Agencies should develop alternative processes to evaluate the impact of this work. In such cases, the work will have to be evaluated by means of the best possible judgment of its importance and the impact it would have if it could be published.

Contributions – The researcher's contributions reflect the knowledge, skills, and experience the incumbent brings to the position. Professional journal articles are an important product of research results for communicating scientific findings to the broader research community; however, they are not the only outlet for communicating information. Journal articles should be balanced with other forms of communication to ensure broad impact from the results of the work. Indicators of the researcher's contributions may include:

- research publications (for example, journal articles, monographs, books, reviews, agency and customer reports, models, maps, and novel interpretative materials); and
- innovations and technology transfer.

While the quantity of publications, research contributions, and professional activities represent one measurement of impact on a field, do not give undue weight to this metric. Consider primarily the quality, impact, and relevance of the researcher's contributions on the scientific community or field.

Impact – Consider whether the researcher:

- has an impact on scientific and/or societal issues;
- sets new research directions;
- develops new methods, techniques, or tools to be used by other researchers; and
- drives management and policy outcomes.

Stature – Stature is established when the researcher is recognized by the scientific field and/or society, as indicated by:

- requests for expert advice/consultation by other professionals and managers;
- requests to exercise leadership on research teams or projects;
- invitations to serve on advisory boards;
- requests to organize or chair committees, workshops, or symposia;
- invitations to address scientific or professional organizations;
- invitations to write synthesis papers;
- recognition by professional societies and external groups; or
- honors and awards.

EXAMPLE, SUPPLEMENT 6
POSITION DESCRIPTION

I. Introduction

This position is located in the Research Evaluation Branch, Division of Research. The mission of the Branch is to develop new and improved methods for assessing developmental abnormalities resulting from prenatal chemical exposure.

II. Duties and Responsibilities

A. Research Assignment

The incumbent works as a Junior Staff Fellow in the Research Evaluation Branch of the Division of Research. The incumbent has two major areas of responsibility: 1) developing and maintaining the laboratory for behavioral teratology testing (50%), and 2) improving and/or developing new methods for assessing behavioral dysfunctions resulting from developmental exposures (50%). The first of these responsibilities involves the setting up of the behavioral teratology laboratory within CFSAN, which consists of equipment purchase and verification of test functions. The laboratory is controlled by two microprocessor systems, which are being developed under contract, for which the incumbent serves as project officer. This laboratory is used solely for conducting pilot work to verify and further specify the protocol being used by five collaborative laboratories participating in the National Toxicology Program-sponsored Collaborative Behavioral Teratology Study (CBTS). The incumbent serves as principal investigator for the pilot study.

The incumbent is involved in a team approach with members of the Project Advisory Group (PAG) for the CBTS, and with Dr. Carole A. Kimmel and Judy Buelke-Sam, the project officers on the collaborative study contracts. In the early stages of planning and designing the CBTS, the incumbent is to serve as a member of the PAG and play a critical role in developing the Memorandum of Need (MON) and schedule of work for the study. Upon the enactment of the contracts to the participating laboratories, the incumbent is responsible for organizing and conducting a workshop at CFSAN to train the technicians at each laboratory. The incumbent functions as a "liaison" to the labs in regard to answering questions about equipment function or clarifying the experimental protocols.

The incumbent's second area of responsibility includes research development and validation of behavioral approaches to the study of postnatal dysfunction. These studies involve the treatment of pregnant animals and evaluation of offspring, including routine teratology, growth and development of the young, and in particular, behavioral assessment of the offspring. The latter includes the assessment of the developmental behavior of the animals at postnatal, juvenile, and adult ages using a life span, longitudinal approach.

The incumbent is responsible for designing and carrying out these studies, often in collaboration with other members of a project team. Only limited inspection and supervision is provided by a senior staff member. The incumbent must keep abreast of new areas of research related to teratology and developmental psychobiology, psychology, and toxicology. She must maintain contact with her scientific colleagues and societies, and present to her colleagues well-prepared oral and written reports of her scientific work.

The incumbent must respond to the needs and requests of CFSAN and other government agencies for review of manuscripts, technical reports, and protocols.

B. Supervisory and Team Leadership

The incumbent provides technical supervision to two behavioral technicians who work on the pilot study for the CBTS. She must be able to effectively direct the efforts of these individuals toward implementing the collection and synthesis of data attained from both the pilot study and from the participating laboratories. The incumbent must also collaborate with personnel in chemistry, biometry, and animal care to effectively conduct the pilot study. The incumbent is responsible for monitoring the performance of the laboratories involved in the CBTS. This role primarily concerns interacting with the principal investigators and technicians at each laboratory by answering questions regarding equipment function and details of conducting the behavioral tests. She is also responsible for directing the shipments of necessary equipment and supplies to each of the laboratories. This role requires successful collaboration with personnel in the procurement and property divisions of CFSAN.

C. Guidelines and Originality

The incumbent's guidelines consist of behavioral evaluation studies, Z-80 and S-100 computer manuals, BASIC and FORTRAN programming guides, and technical reports relevant to biopsychology and developmental psychology. These guidelines are generally applicable to the work to be performed and require only minor adaptations; however, they do require an extensive amount of judgment relative to their proper selection. An extensive amount of originality, creativity, analysis, reasoning, and judgment is also required in choosing between alternative methodologies. In addition, the incumbent is required to interpret findings, translate them into solutions, and record these solutions in a manner for others in CFSAN to follow. The incumbent's end products are used solely for conducting pilot work to verify and further specify protocols being used at the Center.

D. OTHER DUTIES

Nothing to report.

III. Supervision Received

The incumbent is directly responsible to the Chief, Research Evaluation Branch, Division

of Research. She is solely responsible for overseeing the conduct of the pilot study for the CBTS, and for other research projects for which she serves as principal investigator. The incumbent independently develops the theoretical basis for her work in methods development and evaluation; determines the methods and protocols needed to explore a particular problem; and defines the resources needed to carry out the research effort. The incumbent is responsible for obtaining, analyzing, interpreting, and communicating results and has complete authority to speak on matters that relate to her area of professional expertise and research.

Revised EXAMPLE, SUPPLEMENT 6
POSITION DESCRIPTION

I. Introduction

This position is located in the Research Evaluation Branch, Division of Research. The mission of the Branch is to develop new and improved methods for assessing developmental abnormalities resulting from prenatal chemical exposure. The incumbent serves as principal investigator for a pilot study.

II. Duties and Responsibilities

- Duty A
- Duty B
- Duty C
- Etc.
- Other Non-Research Duties

- The incumbent provides technical supervision to two behavioral technicians who work on the pilot study for the CBTS. She must be able to effectively direct the efforts of these individuals toward implementing the collection and synthesis of data attained from both the pilot study and from the participating laboratories.
- The incumbent must also collaborate with personnel in chemistry, biometry, and animal care to effectively conduct the pilot study.
- The incumbent is responsible for monitoring the performance of the laboratories involved in the CBTS. This role primarily concerns interacting with the principal investigators and technicians at each laboratory by answering questions regarding equipment function and details of conducting the behavioral tests.
- She is also responsible for directing the shipments of necessary equipment and supplies to each of the laboratories. This role requires successful collaboration with personnel in the procurement and property divisions of CFSAN.

III. Research Grade Evaluation Factors

Factor 1 - Research Assignment

The incumbent works as a Junior Staff Fellow in the Research Evaluation Branch of the Division of Research. The incumbent has two major areas of responsibility: 1) developing and maintaining the laboratory for behavioral teratology testing (50%), and 2) improving and/or developing new methods for

assessing behavioral dysfunctions resulting from developmental exposures (50%). The first of these responsibilities involves the setting up of the behavioral teratology laboratory within CFSAN, which consists of equipment purchase and verification of test functions. The laboratory is controlled by two microprocessor systems, which are being developed under contract, for which the incumbent serves as project officer. This laboratory is used solely for conducting pilot work to verify and further specify the protocol being used by five collaborative laboratories participating in the National Toxicology Program-sponsored Collaborative Behavioral Teratology Study (CBTS).

The incumbent is involved in a team approach with members of the Project Advisory Group (PAG) for the CBTS, and with Dr. Carole A. Kimmel and Judy Buelke-Sam, the project officers on the collaborative study contracts. In the early stages of planning and designing the CBTS, the incumbent is to serve as a member of the PAG and play a critical role in developing the Memorandum of Need (MON) and schedule of work for the study. Upon the enactment of the contracts to the participating laboratories, the incumbent is responsible for organizing and conducting a workshop at CFSAN to train the technicians at each laboratory. The incumbent functions as a "liaison" to the labs in regard to answering questions about equipment function or clarifying the experimental protocols.

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The incumbent is responsible for designing and carrying out these studies, often in collaboration with other members of a project team. Only limited inspection and supervision is provided by a senior staff member. The incumbent must keep abreast of new areas of research related to teratology and developmental psychobiology, psychology, and toxicology. She must maintain contact with her scientific colleagues and societies, and present to her colleagues well-prepared oral and written reports of her scientific work.

The incumbent must respond to the needs and requests of CFSAN and other government agencies for review of manuscripts, technical reports, and protocols.

Factor 2 - Supervisory Controls

The incumbent is directly responsible to the Chief, Research Evaluation Branch, Division of Research. She is solely responsible for overseeing the conduct of the pilot study for the CBTS, and for other research projects for which she serves as principal investigator. The incumbent independently develops the theoretical basis for her work in methods development and evaluation; determines the methods and protocols needed to explore a particular problem; and defines the resources needed to carry out the research effort. The incumbent is responsible

for obtaining, analyzing, interpreting, and communicating results and has complete authority to speak on matters that relate to her area of professional expertise and research.

Factor 3 - Guidelines And Originality

The incumbent's guidelines consist of behavioral evaluation studies, Z-80 and S-100 computer manuals, BASIC and FORTRAN programming guides, and technical reports relevant to biopsychology and developmental psychology. These guidelines are generally applicable to the work to be performed and require only minor adaptations; however, they do require an extensive amount of judgment relative to their proper selection. An extensive amount of originality, creativity, analysis, reasoning, and judgment is also required in choosing between alternative methodologies. In addition, the incumbent is required to interpret findings, translate them into solutions, and record these solutions in a manner for others in CFSAN to follow. The incumbent's products are used solely for conducting pilot work to verify and further specify protocols being used at the Center.

Factor 4 - Contributions, Impact, and Stature

(A description of the position's contributions, impact, and stature needs to be added.)

SUPPLEMENT 7
REGULATORY REVIEW WORK PERFORMED BY RESEARCH SCIENTISTS

[Copies of the Research Grade Evaluation Guide (RGEG) and the Factor Evaluation System Guide (FES) are available from the Human Resources staff.]

APPROACH: Criteria in Factor IV, Qualifications and Contributions, of the RGEG have been expanded to recognize the several publications which a CFSAN research scientist may produce. That part of Factor IV which addresses a research scientist's demonstrated research and technical accomplishments has been expanded to cover both research publications and regulatory review reports and papers which impact on the "Agency mission." As a result, those reports are measured against the applicable FES standards and the results are equated to Factor IV of the RGEG. (This paragraph should be reviewed in light of the current RGER.)

RGEG: Research papers make the results of research known to the scientific community at large through professional scientific journals. These papers are subjected to an intense review and approval process to insure a high level of quality. Journal advisory boards and committees review proposed papers to determine whether or not the research work being reported will expand and promote the state-of-the-art of the science involved. At the GS-14 level, the CFSAN research scientist is expected to be a recognized contributor to a chosen scientific field and to have been the author of a number of research publications which have had a significant impact on the field of interest and to be regularly sought for consultation. The CFSAN Research Scientist Peer Review Committee was established to evaluate the significance of these kinds of publications in relation to RGEG criteria.

FES: Regulatory review reports and papers establish CFSAN/Agency scientific and regulatory policy which applies to and must be followed by the regulated industry. These kinds of publications are measured by Factor 3 (Guidelines in FES standards) as they relate to regulatory guidance applicable to both internal and external organizations (i.e., CFSAN, FDA, and the regulated industry). Within the context of their significance/impact, these papers and reports can be equivalent to either FES level 3-4 (GS-13) or Level 3-5. Those which are equivalent to the GS-14 level, when measured against both RGEG and FES criteria, establish that a scientist is the CFSAN authoritative source of information in an area of regulatory review responsibility and, as such, develops broad policy, guidelines, and instructions which must be followed by others in the Agency and in the regulated industry. Normally, the FDA Regulatory Review Scientist Review Committee would evaluate regulatory review work to determine if FES Level 3-5 (GS-14) was met. However, because of the mixed responsibilities of some CFSAN research positions, that approach is not considered to be the best mechanism for handling these situations.