CENTER MANAGEMENT AND ADMINISTRATION

CDER Expert Regulatory Scientist Peer Review Committee

CONTENTS

PURPOSE This MAPP describes:

- The role and responsibilities of the Expert Regulatory Scientist Peer Review Committee (ERSPRC) in the Center for Drug Evaluation and Research (CDER).
- The procedures to be used for CDER expert regulatory scientist peer review in preparing for Agency peer review.
- The structure of the CDER committee.
- The procedures to be used in designating members to serve on the CDER committee, as well as the responsibilities of those members designated to serve on the committee.

BACKGROUND

The CDER Expert Regulatory Scientist Peer Review Committee has been established to assist potential applicants, evaluate nomination packages, and recommend applicants to the Center Director for consideration by the FDA Regulatory Review

Scientist Peer Review Committee. The CDER committee is responsible for reviewing the format and general content of nomination packets included to support a recommendation by the Center Director. Nomination packets that are signed off by the Center Director are then forwarded to the FDA Committee for final action. Self-nominated expert applications are sent directly to the FDA Committee. The FDA Committee operates under a guide that complements the Office of Personnel Management position classification standards.

ORGANIZATION

The following descriptions and explanations should be applied on a general basis. There may be some fluctuation in implementation due to workload demands.

- **Chairperson** - The ERSPRC Chairperson is appointed by the Center Director.

- **Executive Secretary** - The Chairperson may act as the Executive Secretary or appoint a full-time or part-time Executive Secretary to the ERSPRC.

- **Members** - ERSPRC membership is comprised of GS-15 and above representatives from a balance of scientific disciplines. CDER staff may apply for membership through their supervisory chain or be nominated by CDER Office Directors for membership, and all members shall be appointed by the Center Director.

RESPONSIBILITIES

- **The ERSPRC will:**

  1. As consultant to the Center Director, evaluate nomination packets using Attachment A and criteria outlined in Attachment B for CDER expert regulatory scientists.

     a. Develop policies and procedure for preparing and evaluating packets.

     b. Provide guidance to applicants on draft packets.

  2. Serve as repository for committee recommendations, decisions, and actions and maintain the CDER database of expert regulatory scientists.

3. Receive input from the FDA Committee on its findings and review.

4. Maintain confidentiality of the nomination packets.

! **The Chair will:**

1. Provide overall direction and decision-making of the ERSPRC and facilitate proceedings.

2. Appoint a member to serve as a champion for each applicant and the applicant's nomination packet.

3. Serve as liaison between the ERSPRC and Center staff.

! **The Executive Secretary (ES) will:**

1. Arrange and organize meetings of the committee. Issues to be brought before the ERSPRC should be directed to the attention of the ES who will attempt to schedule the issues, in consultation with the Chairperson of the ERSPRC.

2. Distribute documents.

3. Maintain files of ERSPRC activities.

4. Assure all components of a nomination packet are present before forwarding to the Center Director.

! **Members of the committee will:**

1. Regularly attend the committee meetings or provide written comments and recommendation if unable to attend.

2. Be lead reviewers on applicants' nomination packets and assist applicants when assigned as champions.

3. Be objective and impartial.

PROCEDURES

- **Meetings** of the ERSPRC are held on an as needed basis. Meeting dates and due dates are established in coordination with the meeting schedule of the FDA Regulatory Review Scientist Peer Review Committee.

- **Records** of proceedings will be kept and maintained confidentially in accordance with the provisions of the Privacy Act, the Freedom of Information Act, and the Agency position classification practices and policies.

- **Consensus** - At least 51 percent of the members of the ERSPRC must be present with a majority determining the recommendation. The members not present shall provide written comments and recommendation that will be used in determining the majority.

- **Recommendations** - Recommendations and nomination packets, upon approval by the committee, will be forwarded to the Center Director for signature and transmitted to the FDA Regulatory Review Scientist Peer Review Committee. The packets not recommended will be returned to the nominator.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT A

FDA Regulatory Review Scientist Peer Review
List of Required Documents

The candidate prepares an original packet for the CDER Expert Regulatory Scientist Peer Review Committee and the FDA Regulatory Review Scientist Peer Review Committee with the following items in sequential order:

1. **Transmittal Memorandum** from the Center Director to the Chair, FDA Regulatory Review Scientist Peer Review Committee, for promotion to either regulatory review scientist position at GS-14 or GS-15. The memorandum should explain why the scientist merits promotion to the higher grade by highlighting how his or her regulatory role and activities represent a vital and important contribution to the Center's needs in regulating drugs. The memorandum should contain the following information:

    a. Brief description of the candidate's work at CDER.

    b. Career summary (education, prior employment, FDA career and outside activities related to work).

    c. Accomplishments and contributions to the Agency, regulated industry, scientific and health community, and/or the regulatory review process (e.g., specific major reviews, scientific contributions, guidance).

    d. Special expertise of the candidate (knowledge required, supervisory controls, guidelines, complexity, scope and effect, and personal contacts).

2. **Memoranda of Recommendation.** One memorandum should be written by the immediate supervisor or the immediate past supervisor if that official is more familiar with the work of the candidate. Additional memoranda may be written by a supervisor, team leader, or senior regulatory review scientist, other than the current supervisor, who has a good knowledge of the candidate's career and work. This individual may have supervised the candidate in the past or may currently work within the same or another organization closely associated with the organization to which the candidate is officially assigned. Memoranda must address the following points:

    a. The name, title, series, and current grade of the scientist and the nature of the action requested.

    b. A brief summary of the candidate's career. This summary may address the candidate's educational background, the area in which the candidate is considered to be specially

qualified, the reputation that the candidate has built, related and pertinent FDA experience in other program areas, and recognition that the candidate has earned and received, such as honors, awards, invitations, or any other appropriate information.

c. A list of accomplishments to the Agency, regulated industry, scientific community, and the regulatory process. The substance and impact of the contributions are of the greatest interest to the committee. Volume and numbers are not critical and may present an image that a case lacks focus and relevance.

d. A description of special expertise. Briefly describe the kind and level of expertise that enables the candidate to function at the senior level being proposed. Recommendations should focus particularly on the following:

- knowledge required
- supervisory controls
- guidelines
- complexity
- scope and effect
- personal contacts

3. **Curriculum Vita**.

4. **OF-8 Position Description**. The proposed position description must follow the nine-factor format required by the Factor Evaluation System.

ATTACHMENT B

CDER Expert Regulatory Scientist
Peer Review Criteria
(Comparison GS 13-14-15)

- Knowledge
- Personal Contacts
  - Nature of contacts
  - Purpose of contacts
- Supervisory Controls
  - Description of controls
  - Responsibility
  - Review
- Guidelines
  - Availability of guidelines
  - Utility of guidelines
  - Judgmental demands
- Complexity
  - Assignment
  - Potential for discretionary judgment
- Scope and Effect
  - Criticality
  - Scope and level of assignments
  - Impact of position and assignments

KNOWLEDGE REQUIRED

This factor measures the nature and extent of information that must be understood and the skills needed to apply that knowledge.

13	14	15
Same as for GS-14.	The scientist must have mastery of a specialty area or program field. This enables the incumbent to apply new scientific and technological developments to novel and critical problems that cannot be solved using conventional methods. Alternately, some scientists at this level make decisions or recommendations that significantly change, interpret, or develop important scientific policies or programs. At this level, scientists extend and modify approaches, precedents, and methods to resolve (or prevent) obscure and unprecedented problems. The scientist is a recognized technical expert in a scientific area, a product class, or a functional area.	Grade 15 regulatory scientists are assigned to significant, mission-oriented programs having national priority. Generally, these positions fall within one of the following situations: a. The scientist must have mastery of a specialized program of major importance to FDA. He or she is the leading authority in the program in the Agency and is a nationally recognized expert in the program. b. The scientist must have mastery of a broad area or program field and must provide leadership and guidance to a number of scientists in specialty areas or program fields. The scientist is a nationally recognized authority in the broad area.

KNOWLEDGE REQUIRED – continued

13	14	15
		In either case, the scientist must have knowledge of management and administrative principles to evaluate extensive, long-range scientific programs. This program leadership requires resolution of extraordinarily complex issues and requires knowledge of advanced scientific concepts and state-of-the-art technology. The grade 15 regulatory scientist participates fully in formulating policy, planning and evaluating programs of the Center and/or Agency, and overseeing those programs. The scientist develops programs to solve or prevent far-reaching and previously unresolvable public health problems. Because of the visibility and criticality of the programs, there is intense interest by Congress, the press, and the general public.

PERSONAL CONTACTS

This factor considers the level and frequency of the incumbent's interaction with other professionals, officials, or executives (not in the supervisory chain) within and outside the Agency. It weighs the significance of these contacts, their purpose, and the impact of the incumbent's influence.

13	14	15
Nature of Contacts Contacts are principally with other scientists within the Office or Center; from industry, other agencies, and academia; and with others concerned primarily with technical matters.	Nature of Contacts Contacts extend into broader areas outside incumbent's primary discipline. These include meetings with Agency program managers, administrators, and attorneys. Contacts often are with high-ranking officials from both inside and outside the Agency, including those at the national or international level.	Nature of Contacts Same as for GS-14
Purpose of Contacts Primarily to present FDA's requirements and responses during the approval process. Incumbent may also explain data requirements to nontechnical industry representatives. While he or she primarily exchanges information, there is some degree of influencing or persuading professionals to accept Office or Center position. The major skills required are an adequate knowledge of the field; scientific objectivity; and tact, courtesy, and thoroughness.	Purpose of Contacts In addition to GS-13 level purposes, the incumbent frequently is relied upon to ultimately justify, defend, or negotiate the Office and/or Center technical position in assigned area. The subject matter is often discussed in more depth, and it is frequently more controversial or delicate. More skill at negotiation and problem resolution is required, as the incumbent is expected to use his or her tact and special skills and knowledge to persuade others to accept the Office and/or Center viewpoint.	Purpose of Contacts Same as for GS-14

SUPERVISORY CONTROLS

This factor covers the nature and extent of direct or indirect control exercised by the supervisor, the level of the scientist's responsibility, and the degree to which the completed work is subject to review.

13	14	15
Controls The supervisor sets the objectives, workload, and resources available. The scientist and supervisor together develop projects, deadlines, and work to be done. Responsibility As a technical expert in the field, the incumbent is responsible for planning and carrying out the assignments, resolving technical conflicts, coordinating with others, and applying established policy and guidelines to achieve objectives. He or she may participate in projects as a member of a team.	Controls The supervisor provides only administrative direction and support. Assignments are given in terms of broad program objectives. Responsibility The incumbent is a recognized technical expert in a scientific area, a product class, or a functional area. The incumbent is responsible for planning, designing, and carrying out programs, projects, studies, or other work independently. The Center regularly turns to and relies upon this person to resolve technical issues of exceptional complexity and scope that are within the specialty field. The scientist's expertise is relied upon and used throughout the Center's functional areas (e.g., research, review, compliance). The incumbent makes decisions in areas where little	Essentially, similar to GS-14 under the subheadings, "Controls" and "Review." Under "Responsibility" the work assignment is at a higher level of responsibility due to the increased scope and breadth of assigned work as described under "Knowledge Required" at the grade 15 level. Further, the GS-15 scientist has national recognition as an expert in the assigned area, and as such is the FDA's senior expert within the area.

SUPERVISORY CONTROLS – continued

13	14	15
	policy guidance exists; these decisions are accepted as authoritative and serve as precedents for future analogous situations, and often form the basis for formal policy statements. The incumbent exercises a controlling influence on the development of new policy within own area of responsibility. Assignments frequently involve potentially controversial matters or those with far-reaching implications. He or she may lead team projects.	
Review Completed work is reviewed by the supervisor from an overall standpoint for quality, completeness, and effectiveness in meeting assigned objectives. The incumbent is considered as technically authoritative and major changes are not expected.	Review Completed work is considered as technically authoritative and is accepted without significant change. Review typically concerns broader issues not within incumbent's responsibility (e.g., impact on overall program, resource constraints, and broad Center priorities).	

GUIDELINES

This factor considers the degree of professional judgment required of the incumbent in those areas where existing guides, standard practices, precedents, and procedures may be of limited value or may require interpretation, modification, or development.

13	14	15
Availability of Guidelines General guidelines are available in the form of Agency policies, written manuals and procedures, regulations, technical literature, and a general scientific consensus.	Availability of Guidelines Few guidelines apply. Applicable guidelines are chiefly pertinent legislation and broad or general Agency policy statements.	Availability of Guidelines Same as for GS-14
Utility of Guidelines Assignments are typically of such a nature that guides are available but are not directly applicable, and the scientist must deviate from traditional methodology or develop new methods or criteria.	Utility of Guidelines Assignments generally are without guidelines and precedents except as noted above. The guidelines require extensive interpretation of the intent of basic Agency policy, as well as major and untested deviations from or adaptations to currently accepted methodology.	Utility of Guidelines Same as for GS-14
Judgmental Demands Independent judgment is required to select, interpret, and apply available guidelines. The incumbent is required to extend or adapt these guidelines to meet novel or difficult situations.	Judgmental Demands Considerable independent judgment and ingenuity are required to interpret and adapt the few existing guidelines and to develop new ones.	Judgmental Demands Same as for GS-14

COMPLEXITY

This factor covers the difficulty and intricacy of the work performed. It includes the difficulty in identifying what needs be done and measures the extent to which discretionary professional judgment is required or expected.

13	14	15
Assignment Consists principally of interpreting scientific information in terms of existing standards for regulated substances. Requires comprehensive critique of data, recommendations for additional studies, gathering of pertinent scientific information, and written evaluations and professional conclusions. Assignments anticipate full capability in applying skills and knowledge to the range of problems occurring within incumbent's subject matter area. Problems are usually limited to those delegated to the organization's element to which assigned.	Assignment While of a similar nature to the GS-13 level, the incumbent's assignments are typically more difficult, controversial, or novel. He or she is involved in developing guidelines, science policy, and Agency requirements. Based on functional area of expertise, the incumbent is expected to integrate knowledge and experience to resolve problems, modify procedures, and develop and interpret policy to meet new and novel conditions. Actions taken and solutions devised cut across other functional areas within the Office or Centers.	Assignment Deals with broad and extensive scientific programs or with scientific problems of extraordinary emergency, public interest, or economic significance. Previous work in the area has failed to yield satisfactory solutions; issues are currently unknown or undefined and require the development of new scientific and regulatory methodologies.
Potential for Discretionary Judgment Generally limited to interpreting scientific data within area of expertise. May set limited precedents that affect internal and industry program activities and the marketing of regulated products. Approaches ordinarily involve	Potential for Discretionary Judgment In the resolution of more difficult problems and precedent-setting issues, considerable ingenuity and professional judgment are required, notably in the selection and evaluation of methods and the modification of	Potential for Discretionary Judgment In carrying out assigned projects or programs, the scientist develops alternative courses of action that become national or international standards for the regulated industry and for future regulatory activity. This requires judgment in the selection,

COMPLEXITY – continued

13	14	15
technically complex issues but fairly well-established methods and procedures. Assignments usually are not of international scope, but if they are, the impact of the assignments is limited.	previously formulated requirements. Incumbent frequently becomes the Office and/or Center representative or liaison with outside professional groups. He or she is depended upon to assume responsibility for the product of group efforts. Negotiating skills and skills in resolving scientific and regulatory problems play an important role in assignments. Incumbent is regarded as the Office and/or Center expert in a particular area and is depended upon and held accountable for timely expertise. Some assignments address continuing international health problems. Because of international visibility, knowledge of worldwide problems and technological advances must be employed. The scientist participates in the development of technical solutions to these problems and is recognized as a technical expert.	evaluation, and modification of methods, objectives, and criteria applicable to problems encountered. As at GS-14, some assignments may be international in scope. Unlike GS-14, the health problems may be addressed dif-ferently in other parts of the world. Therefore, the scientist must be exceptionally sensitive and resourceful to build a scientific consensus for the most practical solution.

SCOPE AND EFFECT

This factor considers the impact of the incumbent's position and assignment on policies, programs, and activities both within and outside the organization.

13	14	15
Criticality Work involves providing essential, but standard and defined, expertise in a particular field.	Criticality Incumbent is relied upon to represent the Agency and to resolve controversial and sensitive issues. Incumbent typically is a crucial resource and able to integrate his or her special skills, experience, and knowledge in effective ways to solve problems.	Criticality Essentially, similar to GS-14 level but may involve complex matters of more critical or urgent nature. These matters frequently are of exceptional importance to the Agency (e.g., a nationwide medical emergency or a matter of great economic significance to the regulated industry). Some cases may be of national or even international scope.
Scope and Level of Assignments Incumbent is regarded as *journeyman level* (i.e., complete professional within subject-matter area). Incumbent only infrequently becomes involved with issues outside of immediate work environment and assigned area of responsibility.	Scope and Level of Assignments Incumbent is typically given more difficult and significant assignments. May represent Office, Center, or Agency on intercenter, interagency, national, or international committees or forums. Incumbent frequently acts as principal liaison with such groups. Frequently works with other professionals and is relied upon to assume responsibility for team or group efforts.	Scope and Level of Assignments The incumbent resolves critical problems, isolates and defines unknown conditions, or develops new methodology for the use of other scientists. He or she provides expert advice and direction to others on professional issues within the assigned area of responsibility. Represents the FDA in decision-making conferences and has authority to decide that Agency resources will be applied to a course of action.

SCOPE AND EFFECT – continued

13	14	15
Impact of Position and Assignments The impact of the incumbent's work is usually confined to the particular team, branch, or division where signed. However, incumbent's findings may establish limited precedents that affect internal programs or individual company program activities and the availability of some regulated products.	Impact of Position and Assignments Incumbent's work affects Office, Center, or Agency policies and may affect broad segments of the regulated industry. The professional skills and stature of the incumbent `play a significant role in getting recommendations approved and accepted. The incumbent's assignments and area of responsibility are regarded as particularly important or critical by Office and/or Center management.	Impact of Position and Assignments Essentially, similar to GS-14. In some cases, the work may have the effect of modifying previously accepted regulatory concepts to deal with new and changed circumstances.