FDA PERSONNEL GUIDE FOR THE

EVALUATION OF CBER RESEARCH AND REGULATORY

SUPPORT SCIENTISTS

AT GS-13 AND ABOVE

ISSUED SEPTEMBER 1993

FDA PERSONNEL GUIDE FOR THE EVALUATION OF CBER RESEARCH AND REGULATORY SUPPORT SCIENTISTS AT GS-13 AND ABOVE

PURPOSE:

The purpose of this Guide is to provide grade level criteria which address the specific work which research and regulatory support scientists perform in CBER at GS-13 and above. These criteria are based on those found in the various position classification standards which represent the occupational series in which CBER scientists have been classified.

COVERAGE:

The policy, procedures, responsibilities, and criteria found in this Guide will be used to evaluate all requests received from CBER managers and supervisors to establish new positions and refill vacant support and service scientist positions at GS-13 and above, and to evaluate all support and service scientists proposed for promotion to those grade levels.

CLASSIFICATION ISSUE

There are presently two types of professional scientists who function in support of or provide services to the research and regulatory scientists working within the various CBER science organizations. The difference between these types of positions needs to be clearly understood so that there may be a consistent approach to these positions by the supervisors in the expanding CBER science organizations, and because these positions are treated differently from the standpoint of career advancement and the methods of evaluation.

1. Research and Regulatory Support Scientist Positions.

The research or regulatory support scientist is a scientific professional who functions in support of, or provides service to research or regulatory scientists. Research positions which require the possession of a doctoral degree or the equivalent are defined and evaluated under the CBER Evaluation Plan for Research Scientists. In support of research scientists, this support scientist may perform limited elements of research work such as 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, biological, or chemical/data specimens. In support of regulatory scientists, this support scientist may perform work such as testing specimens and samples for conformance with established standards, modifying or establishing new methods or procedures to analyze specimens and samples, and operating sophisticated, analytical instrumentation.

2. Supervisory Positions

When support scientists are found as team leaders or as supervisors, the grade of the position may be based either on supervisory responsibilities or individual work depending on which yields the highest grade.

The grade of a team leader or supervisor of a small support unit will usually be based on the personal competence of the scientist in the performance of work for which the scientist as an individual is responsible. This Guide is designed to evaluate such work. However, some scientists who act as team leaders or who supervise small units, and nearly all who direct large support organizations, in addition to scientific competence require marked supervisory and administrative ability and qualifications. These positions are classified by the criteria found in the General Schedule Supervisory Guide.

RESOLUTION:

The attached Supplement One, Plan for the Evaluation of Research and Regulatory Support Scientist Positions in the CBER at GS-13 and Above, and Supplement Two, Research and Regulatory Support Scientist Grade Level Criteria will be used in the peer review of scientists proposed for selection and promotion into CBER support scientist positions at GS-13 and above. Whether the grade of a support scientist will be based upon individual duties or supervisory responsibilities, will be determined by CBER management based upon program needs and requirements as measured against the principles described above.

Progression of support scientists through established career ladders has traditionally been accomplished through established position classification procedures as a joint effort between CBER and DHRM. Position descriptions have been written by supervisors and evaluated by personnel generalists, support scientists proposed for promotion, and desk audited. This process will continue unchanged for promotions through the GS-12 level.

Because of the highly specialized and complex nature of support scientist work at GS-13 and above, CBER management has decided to establish an evaluation Committee composed of research and senior support scientists to assist DHRM in the classification of these positions. Such a Committee offers two advantages:

- highly technical and complex positions are evaluated by those who are similarly trained and familiar with nature of the work and;

- the support scientist community can be expected to be more accepting of, and so be more confident, in the personnel decisions which are made.

Supplement One establishes the responsibilities and procedures which will govern the conduct of the review Committee. **Supplement Two** establishes criteria which the Committee will use in evaluating proposed classification actions at GS-13 and above. **Supplement Three** offers guidance on the conduct of indepth reviews to be conducted by the various Committee members. **Supplements Four** through **Eight** address the documentation requirements for submissions.

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SUPPLEMENT TWO
RESEARCH AND REGULATORY SUPPORT SCIENTIST GRADE LEVEL CRITERIA

INTRODUCTION:

The classification criteria contained in this Supplement have been derived from the criteria published in those position classification standards which address the various biological and physical science occupations found in CBER science organizations. The classification factors, factor levels and point values, and the conversion table are identical to those required by the Office of Personnel Management, Factor Evaluation System. Positions must be evaluated on a factor by factor basis, comparing the duties of a position, the work situation, and any special competence of the scientist with the various factor level descriptions. A position must be fully equivalent to the overall intent of each factor level selected.

Specific examples of methods, procedures, or equipment described in this Supplement are for illustrative purposes only. These examples are to be used as a general frame of reference or bench mark and should not be applied mechanically. Good judgment should be used in deciding whether a position fully meets the essential requirements of a particular factor level. In order to be assigned a particular factor level, it is only necessary for the position to satisfy the overall intent of the factor level description rather than matching all of the specific examples provided.

The FES requires the use of nine factors in the evaluation of positions.

1. **Knowledge Required by the Position**- Nature and extent of information and facts which must be understood to perform acceptable work, and the kinds of skills necessary to apply this knowledge.

2. **Supervisory Controls** - The nature and extent of direct and indirect controls exercised by the supervisor, the scientist's responsibility, and the review of completed work.

3. **Guidelines** - The nature of the guidelines and the judgment needed to apply them.

4. **Complexity** - The nature, number, variety, and intricacy of the tasks, steps, processes, or methods in performing the work, and the difficulty and originality involved.

5. **Scope and Effect** - The purpose, breadth, and depth of the work assignments and the effect of the recommendation or service both within and outside the organization.

6. **Personal Contacts** - With whom and the level at which contacts are made.

7. **Purpose of Contacts** - Purpose and difficulty in communicating with those contacted.

8. **Physical Demands** - The requirements and physical demands placed on the employee by the work assignments.

9. **Work Environment** - The risks and discomforts in the scientist's physical surroundings.

These factors form a pattern which establishes the grade level of a position. Within the FES, certain factors are considered to be more important than other factors and so are more heavily weighted. These factors which control the grade of a position are Knowledge Required by the Position, Supervisory Controls, Guidelines, Complexity, and Scope and Effect. The factors for Personal Contacts, Purpose of Contacts, Physical Demands, and Work Environment will never separately or as a group control the grade of a position. While these factors are not as important as the others in terms of point scores, they must be complimentary to and be consistent with the purpose and intent of the other factors.
The critical difference between GS-12 and GS-13 will always be found in the factors for Knowledge Required by the Position, and Complexity. Factor Levels 1-8 and 4-5 must be met for a support or service scientist position to be classified at GS-13. A position must also meet the other factor level descriptions which are complimentary at GS-13: 2-4, 3-4, 5-4, 6-3, 7-3, 8-2, and 9-2. If a position fails to meet these levels which are typical of GS-13 and complimentary to the critical levels of 1-8 and 4-5, this is a strong indication that the required levels have not been met for the essential factors of Knowledge Required by the Position and Complexity. In such instances, the levels assigned to these two factors should again be carefully reviewed to make sure that these factors have been properly evaluated.

The critical difference between GS-13 and 14 will always be found in the factors for Supervisory Controls, and Guidelines. Factor levels 2-5 and 3-5 must be met for a position to be classified at GS-14. A position should also meet the other factor level descriptions which are complimentary at GS-14: 1-8, 4-5, 5-5 or 5-4, 6-3, 7-3, 8-2 and 9-2. If a position fails to meet these levels which are typical of GS-14 and are complimentary to the critical levels 2-5 and 3-5, this is usually a strong indication that the required levels have not been met for the essential factors of Supervisory Controls and Guidelines. In such cases, the levels assigned to these two factors should again be carefully reviewed to make sure that these factors have been properly evaluated.

The pattern of factors which would be typical for CBER research or regulatory support scientists at the grade levels addressed above can be seen more clearly in the following table:

GS -13	GS-14
1-8	1-8
2-4	2-5
3-4	3-5
4-5	4-5
5-4	5-4 or 5-5
6-3	6-3
7-3	7-3
8-2	8-2
9-2	9-2

The descriptions of work at the various factor levels in the following grade level criteria are stated in general terms for the purpose of illustration. These examples are to be used as a general frame of reference or bench mark and should not be applied mechanically.
In this way, the grade level criteria with the exercise of good judgment may be used to evaluate the many different kinds of support and service scientist work found in CBER.

It should be noted that neither the presence or absence of, or the number of publications attributed to a support scientist can or will be used to establish the grade level of a support scientist. None of the many position classification standards which have been established to evaluate the work of nonresearch scientists, including those which serve as the basis of the grade level criteria found in this Plan, use publications as a part of the classification grade level criteria. For support scientists, publications merely serve as evidence along with other appropriate information that a scientist has in fact performed a certain kind of work, has contributed to a project, is actually recognized for expertise in a certain area, etc.

Also, authorship, co-authorship, primary, secondary, or otherwise, as in the issue of publications has no part in establishing the grade of a CBER support scientist. As with publications, co-authorship may serve as evidence of work performed. However, this evidence may vary from scientist to scientist because of the personal habits of research scientists or research managers responsible directly or indirectly for the work of support scientists. Some research scientists generously recognize the work of other scientists by including their names as co-authors of papers, other research scientists do not. While co-

authorship may be an indicator, it may also be an inconsistent indicator. Other sources of information are important and have been demonstrated through long use to be more reliable in the Federal government. These sources include in-depth interviews with scientists and supervisors, position descriptions, functional statements, staffing charts, and other traditional evidence used to classify positions.

GRADE CONVERSION TABLE

Total points on all evaluation factors are converted to GS grades as follows:

POINT RANGE	GRADE
2755 - 3150	GS-12
3155 - 3600	GS-13
3605 - 4050	GS-14
4055 - up	GS-15

GRADE LEVEL CRITERIA

FACTOR LEVEL DESCRIPTIONS

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

This factor measures the nature, variety and intensity of knowledge, skills and ability required to perform the job successfully. How the knowledge, skill or ability is applied by the scientist, or the reason it is required must also be considered. In order to be credited, the knowledge, skill or ability must be both required by the position and actually applied, on a regular basis, by the scientist. Possession of a professional knowledge of the fundamental theories, principles and methods in a scientific discipline equivalent to that obtained through the successful completion of a bachelor's degree program, or equivalent experience or training, is the minimum requirement for positions covered by this criteria.

Level 1-7 --- 1250 Points

At this level, the scientist possesses an in-depth knowledge of the concepts, theories, principles and methods of the specialty area. This knowledge is of sufficient depth to enable the scientist to determine the most appropriate approach to be used and to recognize the need for and to adapt and modify standard methods and procedures to meet new or unprecedented requirements. For example, the scientist may have varied the standard ph or used a different gel material in an effort to improve the quality of the resolution or reduce the time required to produce pictures using electrophoresis. The scientist is skilled in the operation, calibration and minor repair of analytical instrumentation, such as the electron microscope, HPLC, and gas chromatograph, and has the ability to recognize and suggest the shapes or poor resolution. The scientist has demonstrated the ability to plan, organize and carry out projects or studies involving collaboration with other labs or branches within the Center. In recognition of the scientist's expertise in planning and carrying out the procedures associated with the specialty area, the scientist may have been requested to assist other scientists in organizing their labs, to perform the specialized procedures, or in training other labs to perform them. The scientist possesses skill in analyzing experimental results for validity and in providing preliminary interpretations as to the significance of the data to the hypothesis. Communication skills may be applied by the scientist in one or more of the following ways: to prepare the introduction or the materials and methods sections of papers; to prepare and present poster sessions at conferences; to draft technical reports; to train other members of the peer group in performing specialized procedures; to document changes to standard operating procedures in lab SOP manuals; or to explain branch operations to outside groups.

Level 1-8 --- 1550 Points

At this level, the scientist possesses a mastery of the theories, principles, and methods of a specialty area, such as molecular biology, or cytology, as evidenced by recognition as one of the Center's experts in applying the methods peculiar to the specialty area. The scientist's knowledge of the specialty area is used in recognizing the need for new and improved experimental methods and procedures in order to overcome current limitations.

For example, the scientist may have developed a new procedure for detecting the presence of bacteria and viruses in experimental animals. The scientist may have developed a new method for the computer analysis of HPLC data, or developed a users manual for the operation of a highly specialized instrument not used in any other lab, such as a mass spectrometer.

The scientist is knowledgeable of regulations, standards, and guidelines pertinent to the specialty area and applies this knowledge in recommending new experiments or changes in established methods and procedures to meet new legal or regulatory requirements. In the instrumentation area, the scientist may be skilled in the identification of new applications for and the diagnosis and repair of highly specialized equipment, such as the nuclear magnetic resonance spectroscope, electron microscope, or fluorescent activated cell sorter. The scientist at this level provides consultation to scientists throughout the Center in the use of the equipment and in the interpretation of results obtained. This consultation is sufficiently important to the outcome of studies that the scientist may be cited as co-author of publications where the equipment was used to produce data. The scientist is familiar with new methodological and technological developments in the specialty and is active in efforts to incorporate new developments into standard operating procedures. The scientist's mastery of the principles and methods of the specialty area are also applied in resolving critical, highly unusual, or unprecedented situations. The scientist may be sought out in such situations because of recognized expertise. For example, the scientist may be called upon to develop new procedures or make extensive adaptations to existing procedures in order to produce, from a limited sample, a greater quantity of data than has been produced previously. Or the scientist may be required to develop procedures for the use of new analytical instruments or for new instrument applications where there is very limited published information about the capabilities and limitations of the particular instrument. The scientist's decisions and recommendations on such matters as the validity of the data produced, the procedures to be used to produce the desired results, or the level of resources such as personnel, equipment, and time required to carry out a planned study or a new surveillance program, have a significant effect on the nature and direction of new studies and programs, and on decisions to terminate, extend, or modify existing programs or studies in progress.

Communication skills may be used in one or more of the following manners: preparing discussion or results sections of papers possibly as co-author or first author; in drafting new protocols; in presenting the results of studies at journal clubs or regional conferences; in providing advice and consultation on the applications of specialized instrumentation; or in proposing major changes in service procedures to lab chiefs.

FACTOR 2 - SUPERVISORY CONTROLS

This factor measures the degree of guidance and control exercised over the position. There are three aspects to this factor: how assignments are received, especially the

specificity of instructions or directions provided at the beginning of the assignment; the amount of responsibility entrusted to the scientist to plan and carry out the assigned work and the extent to which advice and assistance is provided to the scientist while work is in progress; and, the manner in which the work is reviewed. The kind of contact between the scientist and the supervisor should be examined closely before judgment is made on this factor, to ascertain whether the contact is actually to provide direction or guidance. Contact with the supervisor, or with other officials in the supervisory chain, is often consultative in nature, that is, to exchange information or to arrive at a mutually agreeable decision, rather than for the purpose of requesting assistance or receiving guidance.

Level 2-4 --- 450 Points

At this level, the supervisor defines the overall scope of the work, approves resources to be made available to the scientist for a particular assignment, and assists the scientist in the initial planning stages by performing such functions as negotiating agreements, or determining the supplies and equipment necessary to organize the lab for DNA cloning experiments. Priorities, deadlines and general approaches are developed cooperatively by the supervisor and the scientist in recognition of the scientist's extensive experience in the performance of established lab procedures. In the regulatory area, assignments are generated according to established surveillance program procedures; supervisory guidance is provided only when methods are changed or a new method is implemented. The scientist has typically suggested new experiments after determining the need for modification of established procedures, or the adaptation of procedures described in current literature to the lab. The scientist independently identifies and locates sources of information relevant to the assignment, including contacting scientists in other organizations, such as authors and presenters of papers, to develop more information about a new method or technique.

The scientist independently plans, organizes and carries out the work, either personally or in collaboration with other lower graded lab support workers assigned to the project. The scientist determines the need for and recommends to the supervisor changes in methods or conditions, or the extension of experiments beyond the original plans in order to ensure validity and to produce the desired results. The scientist keeps the supervisor informed through periodic discussions. The supervisor is consulted only on unusual or controversial matters such as data that may be in serious conflict with expected results, the unavailability of supplies which could affect the planning of other studies, or the lack of cooperation from service organizations.

Completed work, such as draft protocols, technical reports, papers, revised SOP's or recommendations for new areas of study, is reviewed for the accomplishment of objectives, for overall technical adequacy, and for feasibility. The scientist is responsible for the accuracy of results and for the soundness of judgments and interpretations.

The content of reports or papers prepared by the scientist are typically subject to editorial revisions only. Conclusions and recommendations made by the scientist are usually not changed by the supervisor.

Level 2-5 --- 650 Points

At this level, the supervisor defines overall scope of work, approves resources such as time, material, and assists in initial planning; priorities, deadlines, and approaches decided cooperatively; scientist locates sources of information and references, including contacts with researchers in other labs; scientist independently plans, organizes and carries out assignments; identifies need for and recommends methods changes or rerunning of experiment; supervisor consulted only on very unusual or controversial matters, such as presence of highly contagious microorganisms, lack of cooperation from support groups, major inconsistencies in data; work is reviewed for accomplishment of overall objectives, technical adequacy and feasibility of methods selected; scientist is full responsible for accuracy of results and soundness of judgments; written work reviewed for editorial purposes rather than content.

FACTOR 3 - GUIDELINES

This factor measures the availability, specificity, and applicability of guidelines, including policies and procedures, instructions, established practices, precedents, textbooks, manuals, professional journals, handbooks, and other reference materials. This factor also evaluates the degree of judgment exercised by the scientist in selecting, applying, adapting, interpreting, modifying, extending, or originating guidelines.

Level 3 - 4 --- 450 Points

At this level, guidelines include recent developments in the specialty area. The scientist obtains information about these developments through reading, attendance at conferences or workshops, or personal contact with scientists in other Center labs or in other organizations. Because newly developed methods and procedures usually have not been validated fully or contain significant gaps, the scientist must use careful judgment in applying them to the lab. In addition to adapting new methods and procedures to the lab, established methods and techniques must often be substantially modified in order to meet the requirements of the lab.

Judgment is used in determining the need for new or improved methods, and in applying new technological developments to the lab. The scientist has demonstrated initiative and resourcefulness in adapting or extending standard procedures to resolve unprecedented problems, such as using a combination of instruments not previously considered to be feasible. The scientist's investigation of trends or advances in the specialty area often results in the development of guides used by other lab workers or in proposals for new studies.

Level 3-5 --- 650 Points

At this level, guides are much broader than at the preceding level. Guidelines such as

Agency policies and regulations or legislation affecting the specialty area are applicable in only a very general sense to the work being performed by the scientist. The limited guidance that is applicable is derived more from informal means, such as discussions with prominent authorities in the specialty area, or through participation on technical or scientific committees. In the absence of applicable guidelines, the scientist develops new or substantially improved methods and procedures designed to fill gaps in knowledge or to improve understanding of a particular process or phenomenon. Judgment is exercised in identifying areas where new methods and procedures are needed and in planning projects to develop new methods. The scientist also uses judgment in explaining or defending the methods and procedures used in the lab to internal or external review groups who may challenge the validity of results contained in published reports. An integral part of the scientist's assignment is the development of guidelines, instructions, standards and procedures used by other support and service scientists throughout the Center. The methods originated by the scientist have also been adapted for use in other organizations.

FACTOR 4 - COMPLEXITY

This factor measures the nature, variety, and relative difficulty of the functions performed and the systems, methods, procedures, and instrument techniques used. Also considered under this factor is the difficulty encountered in determining what needs to be done, the nature of the problems and obstacles encountered, the degree of analysis, evaluation, and insight required, and the opportunity for creativity and ingenuity. Other complicating factors, including administrative and management issues, should also be addressed under this factor. Noteworthy professional achievements or recognition should also be included in the evaluation of this factor.

Level 4-4 --- 225 Points

At this level, the assignment involves modification of established methods and procedures to increase efficiency, such as reduce costs or time required, to improve the degree of accuracy and validity of results, to meet unusual requirements in the lab, or to take advantage of special facilities at the Center, such as highly sophisticated biophysical analytic capabilities. The scientist has demonstrated the ability to plan and carry out a wide range of moderately difficult procedures, such as SDS-PAGE, or to carry out several highly complex procedures, such as DNA sequencing. In the regulatory area, the scientist will have demonstrated competency in the performance of the most of the major analytical SOP's in the specialty area, and have developed special expertise in the analysis of specimens or samples for contaminants which are difficult to isolate and quantify. The scientist has complete logistics responsibility in the lab, including setting up the lab to implement new procedures such as establishment of tissue culture facilities in a lab formerly carrying out standard biochemical procedures. This will typically involve determining supply and equipment requirements and meeting with scientists in other labs within or outside the Center to discuss lab organization and operation. The scientist is responsible for reviewing current literature or attending workshops to identify new methods or technological advances which may have applicability to the lab. The scientist typically

will have completed an evaluation of a new method, procedure or instrument, resulting in the approval and introduction of the procedure or instrument into the lab or approval pending the availability of funds or facilities.

The scientist is responsible for not only recognizing inconsistencies in the data produced, as is characteristic of the preceding level, but also for determining the source of the inconsistency and for recommending corrective action. The scientist is also responsible for reconciling conflicting data, often by identifying possible validity problems in previous studies. The scientist is responsible for analyzing experimental data and for drawing tentative conclusions about the significance of the data to the hypothesis. The scientist prepares tables, charts and graphs which are typically used intact in published papers. At this level, the scientist may have co-authored publications, prepared one or more abstracts, written in-house technical reports, prepared a new SOP, or prepared or presented information in other forms which clearly demonstrated the scientist's ability to communicate results to other professionals. Creativity and originality is required to modify and adapt established methods to meet unique or unusual requirements in the lab and to evaluate the applicability of newly developed analytical methods and procedures and to make recommendations for implementation where feasible.

Level 4-5 --- 325 Points

At this level, the assignment involves the development of new or significantly improved procedures or techniques, or the establishment of new analytical capabilities to meet highly specialized requirements. Much of the scientist's effort is devoted to the implementation, refinement, and documentation of new procedures, and the training of Center personnel in the performance of the procedures. Analytical assignments involve the isolation and characterization of compounds on which a limited amount of information or conflicting data has been published. The scientist's most significant contributions have been the origination and validation of new procedures. Accomplishments may also have included the development and implementation of new analytical applications for highly specialized instrumentation. In the regulatory area, the scientist has responsibility for providing a complete range of services in the specialty area, such as chemical or microbiological surveillance. In the research area, the scientist has responsibility for determining the resources, such as funding, supplies, equipment, personnel, required to meet the short and long range needs of the lab. The scientist's responsibilities in this regard may include such administrative functions as drafting the budget for the lab, presenting proposals for the purchase of new equipment, or justifying lower graded support staff. The scientist continually reviews current literature, including unpublished manuscripts, and initiates discussions with other scientists carrying out related studies to maintain an awareness of new developments in the field. The scientist also may have coordinated or participated in workshops held at the Center to explain new procedures to other scientists. The scientist may have served as first author on a published paper, presented papers or poster sessions at local or regional conferences, or communicated the results of assigned projects to other scientists in a comparable fashion. The scientist may have received recognition for professional expertise or accomplishments in a number of different ways, such as being

invited to serve on committees to discuss new procedures or to share similar information with other scientists, earning professional certification in the specialty, nomination for more than one special achievement award, or other comparable means of professional recognition. The number of new or improved methods, procedures and instrumental techniques developed and/or implemented are evidence of the high level of creativity and originality applied by the scientist. The scientist will typically have served as a project leader, team leader, or supervisor over other support or service scientists, or had responsibility for monitoring work performed under contract.

FACTOR 5 - SCOPE AND EFFECT

This factor measures the purpose of the work and the impact, influence, and importance of the scientist's efforts to the accomplishment of the organizational mission and to the advancement of scientific principles, methods, and procedures. This factor is also designed to recognize those situations where the unusual initiative and exceptional abilities of the scientist have resulted in the expansion of the job beyond its standard dimensions.

Level 5-4 --- 225 Points

At this level, the purpose of the work is to modify and adapt established methods and to develop new procedures designed to meet unusual requirements or to enhance the current capabilities of the lab. The scientist provides expertise in the performance of specialized procedures, including advising other labs on applying and implementing such procedures. The scientist may have developed exceptional skill in a highly specialized assay or procedure, such as newborn mouse assay or gel autoradiography, to the point where other scientists, including scientists in other government or private labs, request the scientist's advice and guidance. Responsibilities also include the evaluation of new methods, procedures and instrumentation for the lab, and communicating results of the scientist's work to scientists outside the immediate lab. The scientist's efforts have resulted in new and improved methods which have enhanced the accuracy and validity of results or substantially increased the efficiency with which analytical services are provided.

The documentation and/or publication of refinements or other modifications to standard procedures made by the scientist extends the impact of the scientist's contributions beyond the immediate lab and, in some cases, the Center.

Level 5-5 --- 325 Points

At this level, the purpose of the work is to provide expert advice and guidance to other scientists throughout the Center in the specialty area. The specialty area may be the application of highly specialized instrumental techniques, such as the NMR spectroscopy, mass spectrometry, or fluorescence activated cell sorters, development of new analytical or diagnostic services, or the adaptation of microcomputers to standard analytical procedures. The scientist's expertise is also applied in the resolution of long standing problems, such as inability to isolate specific compounds of interest which have resisted the efforts of other

specialists. The scientist's recognition extends outside the Center; the scientist's reputation in the specialty area may have been an important factor in the receipt of contracts from other agencies to perform analytical services. Another aspect of the scientist's responsibility is the recognition of future requirements and the implementation of new or significantly improved procedures or new services in response to projected future needs. The scientist's advice affects decisions made by Center management officials on such matters as the initiation of new services or the expansion or curtailment of current services, whether or not to approve new protocols involving the use of relatively new, untested procedures, or in determining the regulatory or policy impact of analytical results. The presentation of information about procedures developed or substantially improved by the scientist, whether in journals or through conferences and workshops, has the potential for advancing the state-of-art in biochemical or biophysical analysis.

FACTOR 6 - PERSONAL CONTACTS

This factor measures the kind, level, role, and authority, of people contacted and the conditions and circumstances surrounding the contacts. Careful consideration should be given to the frequency of contacts to avoid crediting contacts made on an occasional basis only.

Level 6-2 --- 25 Points

At this level, contacts are primarily with other Center scientists and lab technicians, both within the immediate lab and in other labs, with Center service workers, with the Office of Management and computer specialists, and with administrative specialists at the Center and at FDA headquarters. Occasional contact may be made with equipment sales personnel or repair technicians and with professionals from other organizations when attending workshops or conferences. Most contacts are made at the work site.

Level 6-3 --- 60 Points

At this level, contacts are maintained with top Center management officials including Division Directors and Office Directors, with scientists in other organizations, such as NIH and at universities, medical schools, and private laboratories, with policy, planning and administrative management officials at FDA headquarters, with representatives of the biotechnology industry, such as scientists or attorneys, with management consultants, and with sales and technical representatives from biological supply companies and equipment manufacturers and suppliers. Many of these contacts are initiated by the scientist. Contacts are frequently made away from the work site.

FACTOR 7 - PURPOSE OF CONTACTS

This factor measures the reason for making contacts addressed in Factor 6 - Personal Contacts and the difficulty involved in justifying, defending or persuading others to accept the information presented.

Level 7-2 --- 50 Points

At this level, contacts are to plan and coordinate the work, to explain and advise on the use of new methods and procedures, to solve problems, to train others in lab procedures, to defend proposals for new studies or study extensions, to keep informed about new developments, and to present the results of experiments to Center officials. Contacts are initiated both by the scientist and by others seeking the scientist's advice or guidance. Most of the information presented by the scientist is not controversial. However, the scientist is required to persuade others to accept the scientist's decision or recommendation to implement new methods and to initiate new projects, where there may be some resistance because of unwillingness to change methods or because of a scarcity of resources to support new projects.

Level 7-3 -- 120 Points

At this level, contacts are principally to convince other scientists or scientific management officials to accept the scientist's judgment or recommendation where there is serious disagreement or conflicting opinions about the information presented by the scientist. Recommendations may concern such matters at the implementation of new programs at the Center, such as a new animal genetics facility, or the purchase of highly sophisticated, costly instrumentation. Contacts may also be made to motivate others to cooperate on an important study or to submit additional information where the information may lead to unfavorable findings. Contacts may be made to provide expert advice to other organizations in the application of new procedures or instruments designed to solve critical problems or to improve the overall quality of experimental results. The scientist may present testimony as an expert witness in court or in an administrative hearing on an issue that is contested by two opposing parties.

FACTOR 8 - PHYSICAL DEMANDS

This factor measures the intensity and regularity of physical demands, imposed on the scientist and the requirement for possession of unusual physical characteristics or special abilities.

Level 8-1 --- 5 Points

At this level, the work is primarily sedentary and involves only occasional walking, standing, bending, and carrying of light objects.

Level 8-2 --- 20 Points

At this level, the work requires moderate to heavy physical exertion including standing for prolonged periods at the laboratory bench, working under biological hoods for several hours in succession, or lifting of moderately heavy objects (less than 50 pounds) such as animal cages or lab supplies and equipment.

The work may also require possession of above average manual dexterity to perform delicate surgical manipulations on lab animals, such as removal of small organs, or implantation of electrodes in fetuses, possession of acute visual perception to make precise observations, and above average resistance to fatigue.

FACTOR 9 - WORK ENVIRONMENT

This factor measures the physical surroundings in which the scientist works including the need to take precautionary measures to avoid exposure to hazardous materials or other physical risks.

Level 9-1 --- 5 Points

At this level, work is performed in an office setting with adequate light, heat and ventilation. The scientist is occasionally exposed to the hazards typical of a biochemical laboratory.

Level 9-2 --- 20 Points

At this level, the scientist is regularly exposed to toxic, carcinogenic, and infectious compounds, to radioactive materials, or to excessive noise and heat. The assignment may also require working in proximity to high voltage equipment creating the potential for electric shock. There is also the possibility of painful animal bites. The work requires the exercise of special precautions such as working under hoods, wearing badges indicating radioactive exposure, or wearing protective clothing.

ABBREVIATED GRADE LEVEL CRITERIA

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

Level 1-7: 1250 Points

Intensive knowledge of principles and methods in specialty area; ability to recognize need for and adapt/modify established procedures; skill in operation, calibration, and minor repair of STEM, HPLC, GC and the like, and ability to pinpoint basic instrumentation problems; ability to plan, organize and carry out projects involving other lab workers; skill in validating results and making preliminary interpretations; communication skill to prepare sections of manuscripts, draft technical reports, document changes to SOP's, and train others in

specialized procedures.

Level 1-8: 1550 Points

Mastery of theories, principles and methods of specialty area to serve as expert in application of specialized methods; ability to recognize need for and develop new procedures to solve critical or novel problems or to perform more refined analyses; knowledge of legal and regulatory issues affecting the specialty area; ability to advise others in application of highly sophisticated instrumentation, such as NMR, MS, or innovative microcomputer applications; skill in diagnosis and repair of specialized lab equipment; ability to apply state-of-the-art in methods and technology to biotechnology research; communication skills to draft papers for publication, provide advice to other scientists, or propose major changes in lab organization or service procedures.

FACTOR 2 - SUPERVISORY CONTROLS

Level 2-4: 450 Points

Supervisor defines overall scope of work, approves resources such as time, material, and assists in initial planning; priorities, deadlines, and approaches decided cooperatively; scientist locates sources of information and references, including contacts with researchers in other labs; scientist independently plans, organizes and carries out assignments; identifies need for and recommends methods changes or rerunning of experiment; supervisor consulted only on very unusual or controversial matters, such as presence of highly contagious microorganisms, lack of cooperation from support groups, major inconsistencies in data; work is reviewed for accomplishment of overall objectives, technical adequacy and feasibility of methods selected; scientist is fully responsible for accuracy of results and soundness of judgments; written work reviewed for editorial purposes rather than content.

Level 2-5: 650 Points

Supervisor provides administrative direction only with assignments which are made within the terms of broadly defined national programs, missions, of functions; the scientist is a recognized expert in field of scientific specialization and is responsible for independently planning, designing, and carrying out projects, assignments, studies or other work independently; the scientist is the one to whom other Center scientists regularly turn and rely upon to resolve issues of exceptional complexity and scope within the field of specialization where little policy or scientific guidance exists, these decisions are accepted as authoritative, and serve as precedents for future analogous situations often forming the basis for formal written statements of scientific policy, procedures, and processes; results of work are accepted as scientifically and technically authoritative and are normally accepted without significant change; recommendations for new projects and alteration of

objectives are usually evaluated for such considerations as availability of funds and other resources, broad program goals, or national priorities.

FACTOR 3 - GUIDELINES

Level 3-4: 450 Points

Guides include recent discoveries and advances in the specialty area; scientist must research new developments through personal contact with other scientists; judgment is required in adapting new methods and procedures to the lab; judgment also exercised in determining the need for new or substantially modified procedures to solve problems or meet unique requirements, isolation of unknown compounds, and in applying new procedures in the lab; initiative demonstrated by successful incorporation of new procedures in the lab; has developed SOP's or instructions used by other scientists in the lab.

Level 3-5: 650 Points

Guides include agency policies, regulations and legislation affecting biological products; scientist must assess impact of new policies and regulations and pending legislation on the assignment area, such as effect of new directions in food and drug regulation on current or planned research or established procedures; guidance is often derived through discussions with scientists in other organizations who are pursuing related research problems; scientist recognizes need for new procedures in the specialty area to close gaps in knowledge or increase understanding about critical processes; judgment required in identifying areas where new or improved procedures are needed and in implementing and providing training on new or significantly improved procedures; judgment also applied in defending and explaining methods used to outside review groups; procedures and guides originated by scientist are applied throughout the Center and may have been adapted for use in other government and private labs as well.

FACTOR 4 - COMPLEXITY

Level 4-4: 225 Points

Assignments involve modifying established procedures to improve accuracy and validity of data, increase efficiency or respond to unusual requirements; scientist has demonstrated ability to carry out a wide range of moderately difficult procedures or most of major analytical/surveillance SOP's and has developed recognized expertise in applying a highly specialized assay or test; scientist has complete lab logistics responsibility including determining supply and equipment requirements; researches literature and other sources of information to discover promising new developments; determines sources of inconsistencies in results and recommends correction; analyzes data and draws tentative conclusions regarding significance of data to hypothesis; prepares tabular material for publications; scientist may have co-authored papers, written technical reports, documented

new SOP's or, communicated results similarly; exercises creativity in modifying established methods and evaluating applicability of new methods developed in other labs.

Level 4-5: 325 Points

Assignments involve development of new or significantly improved procedures or introduction of new analytical capabilities; primary function is implementing, refining, documenting and training other scientists in applying new methods; analytical efforts concentrate on characterizing highly complex or controversial biological products; responsibilities may include development/implementation of new instrumentation techniques for highly specialized equipment, or planning and directing major services; scientist typically shares administrative responsibilities with lab chief, such as budget administration, personnel management, procurement; evaluates new developments in the specialty area for the Center; may have authored papers, presented papers or posters at conferences, or served on technical panels or committees; scientist has attained significant professional recognition, such as achievement awards, professional certification; creativity and originality is evident in impressive numbers of new or improved procedures or new instrumentation techniques introduced.

FACTOR 5 - SCOPE AND EFFECT

Level 5-4: 225 Points

Purpose of work is to modify established procedures and develop new methods to meet unique requirements or upgrade current capabilities; scientist provides expertise in performing specialized procedures and advises other labs in their application; scope of assignment includes evaluating new methods and communicating results of work to scientists outside the immediate lab; scientist's efforts enhance ability of lab to produce and analyze valid data or increase efficiency of service delivery; documentation of new or improved methods has salutary impact on other labs including those in other government and non-government organizations.

Level 5-5: 325 Points

Purpose of work is to provide expert advisory services to other scientists on new or improved application of highly specialized instrumental techniques or implementation of new analytical or diagnostic services; scientist is often called upon to resolve unusually difficult or long standing problems involving the specialty; recognition extends to other labs outside the Agency as evidenced by requests for consultation/collaboration; scope of work includes assessing and planning for future requirements, such as, initiating new services or new procedures; advice influences decisions to expand or contract current services, or to approve new protocols; scientist's counsel is also solicited in formulating long range plans for the lab or division; results of scientist's efforts have potential for advancing procedural state-of-the-art in the specialty area.

FACTOR 6 - PERSONAL CONTACTS

Level 6-2: 25 Points

Personal contacts are made with scientists and experiences technicians in different scientific occupations in the Center and/or Agency outside of the immediate and related work units in the same parent organization.

Level 6-3: 60 Points

Personal contacts are made with scientists, administrative representatives and others outside the Agency such as scientists from other Federal agencies, state and local governments and technical representatives from private industry or other countries. These contacts are in addition to those described at the next lower level.

FACTOR 7 - PURPOSE OF CONTACTS

Level 7-2: 50 Points

The purpose of the personal contacts, in addition to exchanging information, is to plan and coordinate work with others, discuss problems concerning scientific methods and possible solutions, interpret data which has been gathered and explain its significance, or clarify the information requested, resolve operating problems, and agree on schedules and plans. Those contacted are cooperative because they are working toward mutual goals.

Level 7-3: 120 Points

The purpose of the personal contacts is to persuade, influence, or motivate others who are skeptical, uncooperative, or have different and conflicting opinions such as persuading other scientists to accept changes in procedures and methods about which there is technical disagreement.

Level 7-4: 220 Points

The purpose of the contacts is to justify, defend, or settle matters involving significant or controversial issues. Occasionally serves as the Center representative at meetings, hearings, conferences concerning national programs, controversial policies or regulations, or the development of Agency wide standards and guides.

Those contacted typically have widely differing viewpoints, objectives, or goals which require the scientist to convince those contacted to accept the Agency position or to develop suitable compromises or alternatives.

FACTOR 8 - PHYSICAL DEMANDS

Level 8-1: 5 Points

Work does not impose any unusual physical demands.

Level 8-2: 20 Points

Work requires moderate to heavy physical effort, including prolonged standing, lifting and moving moderately heavy objects; above average manual dexterity and visual acuity is also required.

FACTOR 9 - WORK ENVIRONMENT

Level 9-1: 5 Points

Work is performed in office setting with occasional performance in lab.

Level 9-2: 20 Points

Work involves frequent exposure to hazardous materials, or to excessive noise and heat, or, working in proximity to high voltage equipment, special precautions such as working under hoods, wearing protective clothing, and periodic physical exams may be required.

SUPPLEMENT THREE
GUIDELINES FOR IN-DEPTH REVIEWS

Prior to a scheduled Committee meeting, the Committee Chair will assign cases to the various Committee members and alternates for in-depth reviews. Objectivity is critical to this process. The reviewer is expected to read both the case and any material which has been submitted to enhance the case such as commendations, letters of appreciation, etc. This review should be conducted in enough detail to allow the reviewer to critically evaluate and intelligently discuss the assigned case with the whole Committee. The reviewer should also go beyond the written case material in an attempt to clarify and check the significance of scientist's accomplishments, sort contributions from those of other scientists, and bring any additional information to the Committee meeting for discussion which was not available in the case material.

Each in-depth review will ideally involve at least two interviews, the scientist being reviewed and the immediate supervisor. The supervisor usually is the best source for points of clarification and of additional information pertinent to the case. The reviewer may also find

it necessary to interview others as well, depending upon the reviewer's familiarity with the scientist and the position, and the mission of the organization.

Preparation before conducting interviews is important because it will save time for both the reviewer and the one interviewed. In addition to reading and being familiar with the case material, the reviewer should also read and be familiar with the grade level criteria for CBER support and service scientists found as Supplement Two, the memorandum of recommendation, and the position description submitted with the case. It should be remembered that the position description is an official document which the supervisor certifies as containing both an adequate and accurate description of the work assigned to scientist. Both the grade level criteria and the position description are presented in the nine factor FES format. Supplement Three, Position Description Format offers questions related to each of these nine factors which can help the reviewer prepare for an interview and suggests questions which can be asked in order to gather the kind of information necessary to evaluate a case.

Interviews should be scheduled at a mutually convenient time. To conduct a successful interview, the reviewer should make sure the questions are understood, let the one being interviewed take the lead whenever possible, ask open-ended questions and be sure to understand the answers, restate the important points during the interview, take notes, look at work samples and collect any that might be relevant to a better understanding of the work, summarize the main points at the end of an interview, and let the one being interviewed know that the reviewer is available if there is any additional information.

SUPPLEMENT FOUR
LIST OF ACCOMPLISHMENTS

This list should be restricted to actual accomplishments, not future plans or problems. The list may begin with a brief paragraph summarizing the scientist's career by indicating total years in research and regulatory support scientist work, and a general statement about the scientist's reputation and recognition.

Following the introductory paragraph, the most significant accomplishments over the scientist's total career should be selected and listed in chronological order. **Accomplishments since the last review should be identified with an asterisk**. There is no limit on the number of accomplishments which may be listed.

Each accomplishment should be described as concisely as possible with the primary emphasis on **what was accomplished** and **why the accomplishment** was significant. In the case of a team effort, it will be necessary to explain exactly what the scientist contributed to the total accomplishment. Since the significance of an actual

accomplishment sometimes changes with time, these statements should be carefully written.

Each selected accomplishment may be documented by memoranda, final technical reports, manuscripts, publications, etc. Documentation should be chosen with the following in mind:

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

Publications should be referenced to the particular accomplishments as appropriate. When more than one publication is used to document an accomplishment, all the publications must support the single accomplishment. Many research and regulatory support scientist positions include duties and responsibilities that are not specifically support oriented. This kind of work which is performed on a regular and recurring basis should be documented in the position description. This includes work such as special assignments and projects. Accomplishments of this kind that are extensions of research and regulatory science work may help to support the significance and impact of the scientist's overall responsibilities. These accomplishments may be seen as activities similar to research and regulatory science work which assures maintenance of scientific competence.

SUPPLEMENT FIVE
POSITION DESCRIPTION FORMAT

DUTIES:

The object of this part of the position description is to present major duties of the position in their order of importance. Major duties are those which usually occupy more than ten percent of a scientist's time, and are performed on a regular and recurring basis. Regular and recurring duties are those which are performed on a day-to-day basis or even seasonably, such as once a year, but every year. The duties are not one time duties such as special projects, or of a temporary nature such as acting for a supervisor or filling in for another scientist. Major duties are the primary reason for the existence of a position, all other duties are minor or peripheral.

These duties are best described in simple, straight forward language. Sentences should be in the active voice, using action verbs, and made up of words with as few syllables as possible. Enough information should be presented so that the Committee can readily understand what is going on. Do not use words and phrases like; assists, executes, coordinates, participates, facilitates, or serves as the focal point. The Committee wants to know what the employee actually does.

In addressing each one of the following nine factors, it would be well not only to consider the questions, but also to carefully consider the grade level criteria presented under each factor in Supplement Two, Research and Regulatory Support Scientist Grade Level Criteria.

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

What knowledge is required to do the work of the position such as the scientific discipline, the categories of products, functional specialties, other Agency programs, the regulated industry, programs of State, local, and foreign governments, programs of national, international organizations etc.?

What knowledge is required by Agency enabling legislation, policy, rules, regulations, court decisions and precedents, past decisions and practices, the way in which industry and others approach the Agency, the wishes and desires of the Congress, etc.?

What kinds and levels of skill are necessary to perform the work of the position such as identifying problems, gathering and analyzing information, drawing conclusions, recommending solutions, writing reports and papers, organizing and delivering briefings, negotiating acceptance and implementation of recommendations, planning, organizing, and directing the work of others?

FACTOR 2 - SUPERVISORY CONTROLS

How does the supervisor assign work (with detailed or general instructions, with instructions for new, difficult, or unusual aspects of the work only, with general suggestions on approaches to work, etc.)?

What responsibility does the scientist have for carrying out the work (within general guidelines establishes approach to assignments, handles all work independently according to accepted policies and practices, resolves, conflicts, determines approach to be taken, etc.)?

How is the work reviewed (for appropriateness, accuracy, adequacy, and compliance with instructions, is it expected to be technically accurate, accepted as authoritative, etc.)?

Is the scientist involved in team or collaborative efforts? Is it a formal team? Does the scientist function in a lead role?

FACTOR 3 - GUIDELINES

What guides are used in performing the work, such as laws, rules, regulations, manuals, precedents, established guidelines?

How are the guidelines used, how applicable are they, are they lacking, are precedents available, is judgment needed to follow established guidelines, in deviating from or interpreting guidelines, in adapting or developing new guidelines, etc.?

If new or modified guidelines are developed as a result of the scientist's work, who must use them, does the employee continue to be the source of information on and the intent of the guidelines, etc.?

FACTOR 4 - COMPLEXITY

What is the nature of the work and assignments (related, sequential steps, different processes, independent assignments with varying duties, etc.)?

What kind of variations exist in the work? Is the scientist concerned with factual situations, with identifying interrelationships or deviations, with originating new approaches or techniques, with establishing new standards, etc.?

FACTOR 5 - SCOPE AND EFFECT

Does the scientist's work impact others and the way in which they work?

Does the scientist's work affect the accuracy, reliability, or acceptability of other work processes?

Does the scientist's work affect the programs, objectives, and goals of the organization in which employed, other organizations? Which ones?

What impact does the work have on regulated industry, State, local and foreign governments, other agencies, national or international organizations, etc.?

FACTOR 6 - PERSONAL CONTACTS

What kind of people and which organizations does the scientist come into contact with, such as co-workers, various supervisors and managers in the Agency, representatives of industry, State, local and foreign governments, trade organizations, national and international organizations, Congress, etc.?

What positions do these contacts hold and at what levels in the organizations which they represent?

FACTOR 7 - PURPOSE OF CONTACTS

What is the purpose of the scientist's contacts, to give and receive information, to resolve problems, to motivate and influence others, to justify, defend, negotiate, or settle matters,etc.?

Does the scientist deal with people who are skeptical, uncooperative, unreceptive, hostile?

Does the scientist settle controversial issues or arrive at compromise solutions with persons who have different viewpoints, goals or objectives?

What kind or level of commitment authority does the scientist have in representing the office, Center, or Agency?

FACTOR 8 - PHYSICAL DEMANDS

What is the nature of the scientist's physical activity, sedentary, walking, standing, etc.?

FACTOR 9 - WORK ENVIRONMENT

What is the nature of the environment in which the scientist works, office, laboratory?

SUPPLEMENT SIX
CURRICULUM VITAE

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

Name -

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

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

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

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

Special Invitations - These are usually specific invitations to present a paper before scientific or industry groups, prepare a paper or a chapter for a book, conduct a seminar, etc. Be selective since the stature of the group 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. Provide sufficient information for the reader to determine scientific significance. If a paper was subsequently published, cross reference it to the publication list.

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

Membership in Professional or Honorary Societies - List each and show dates of membership and whether invited or elected.

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

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

Outside Professional Advisory and Consulting Activities - List each, give dates, name and type of organization or situation, and type or significance of contribution. Generally, these should be activities outside of FDA which are not a part of the regular work assignment. If there are numerous activities summarize information or list activities in recent years only.

SUPPLEMENT SEVEN
BIBLIOGRAPHY

It should be noted that the information provided in this Supplement cannot and will not be used to establish the grade level of a scientist's position. None of the many position classification standards which have been established to evaluate the work of nonresearch scientists, including those which serve as the basis of the grade level criteria found in the Plan, use publications as a part of the classification grade level criteria. For nonresearch scientists, publications merely serve as evidence along with other appropriate information that a scientist has in fact performed a certain kind of work, has contributed to a project, and is actually recognized for expertise in a certain area.

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

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

- Thesis.

- Abstract.

° Review Article.

° Book.

° Book Chapter.

° Conference or Society Proceedings.

° Patent.

° Popular Publication.

° Technical Research Report (a written report that requires clearance for public release).

° Others, such as SOP's, Manuals, etc.

SUPPLEMENT EIGHT
LETTERS OF RECOMMENDATION

Letters of recommendation must accompany each case submitted to the Panel. At least four letters must accompany a request to promote a CBER research and regulatory support scientist. Letters must be solicited from scientists in the field of scientific interest who are capable of objectively evaluating the accomplishments of the scientist. Letters of recommendation should speak to:

-how the respondent is acquainted with the scientist,

-the adequacy of the scientist's education, training, and experience in relation to the work being conducted or to be conducted in CBER,

-why the scientist is truly exceptional, and how the scientist's projects and contributions prove that point in terms of the significance of the problems addressed and the impact of the solutions reached, and

-the scientist's ability and interest in working with and, when appropriate, leading others.