PEER REVIEW GUIDE FOR THE EVALUATION OF

FDA MEDICAL OFFICERS

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PURPOSE:

The purpose of this Guide is to establish written grade level criteria for the evaluation of FDA, Medical Officers at the GS-15 grade level, and to establish the responsibilities and procedures to be followed in an Agency-wide peer review classification system.

COVERAGE:

The policy, responsibilities, procedures, and criteria found in this Guide will be applied to all requests received form FDA management to establish new medical officer positions, and/or to promote medical officers to the GS-15 grade level. All medical officers at the GS-15 level are to be reviewed periodically on a cyclical review basis.

CLASSIFICATION ISSUE:

The CDER is organized into a number of pre and post-market regulatory review offices which are staffed by medical officers and scientists in a variety of scientific disciplines engaged in the review of New Drug Applications, Investigative New Drug Applications, Abbreviated New Drug Applications, and related documents and functions. The recruitment, retention, and development of an accomplished staff of medical officers is of critical importance to carrying out the regulatory mission of the CDER.

Progression to GS-14, which has traditionally been accepted as the full performance level, is accomplished through conventional personnel procedures. Promotions to GS-15 have been accomplished through the requirements of the Evaluation Plan for Nonsupervisory GS-15 Level Medical Officer Positions in Regulatory Review Activities. Since the establishment of that Plan, the regulatory mission of the CDER has grown both in size and sophistication with the passage of new legislation and the progress of the sciences supporting the products regulated by the Center. Consequently, the number of medical officers and regulatory review organizations have grown to meet increased volume, variety, and complexity in the regulated products. Also, passage by the Congress of Title 38 has enabled the CDER compensate medical officers at levels beyond that allowed under the General Schedule.

To consistently and fairly evaluate the work of Center medical officers, CDER management has decided that criteria for GS-15, and compensation under Title 38 which speak to the current work of medical officers involved in regulatory review work are necessary. Promotions to the GS-14 level and the filling of vacant GS-14 medical officer positions will continue to be subject to normal personnel merit promotion practices, and will not be a part of this peer review process**.**

RESOLUTION:

To address the concern of CDER management for the appropriate and consistent evaluation of medical officers, the CDER has decided to establish the CDER, Medical Officer Review Committee composed of senior medical officers and managers to assist in the evaluation and classification of medical officers. A review committee offers two advantages. Highly scientific and technical positions are evaluated by medical officers familiar with the nature of the work being performed and evaluated, and the medical officer community can be expected to have greater confidence in the decisions made by peer medical officers, and so more readily accept those decisions.

GS-14 is the accepted full-performance level for medical officers in the CDER regulatory review offices and divisions. Therefore, promotions of medical officers to and the establishment and filling of medical officers at the GS-14 grade level will continue to be made through accepted personnel merit promotion procedures, and will not be a part of this peer review process**.**

Medical officers may also be found as team leaders or supervisors. The grade of a team leader is based on the personal competence of the medical officer in the performance of the work for which the medical officer is personally responsible. The grade of a supervisor may be based on supervisory responsibilities or on the work performed as an individual depending on whichever situation yields the highest grade. This Guide can only be used to evaluate the work performed by a supervisor as an individual.

The Guide is augmented by a number of supplements which are designed to assist and meet the needs of the principle users. The following matches the three principle users with the supplements.

- The Review Committee - Supplements 1, 6, and 7.
- Recommending supervisors - Supplements 2, 3, 4, and 5.
- Candidates - Supplements 2, 3, 4, and 5.

Supplement One, Plan for the Evaluation of CDER, Medical Officer Positions at GS-15 Title 38 Medical Officer Positions establishes the responsibilities and procedures which will govern the conduct of the Committee.

Supplement Two, Documentation Requirements, Memorandum of Recommendation, Supplement Three, Position Description Format, Supplement Four, Sample Position Description, and Supplement Five, Curriculum Vitae address and set the requirements which must be met for cases submitted to the Committee.

Supplement Six, Guidelines for Conducting Indepth Reviews offers guidance to Committee members.

Supplement Seven, Criteria for the Evaluation of GS-15 General Schedule and Title 38 Medical Officers establishes the criteria based on written grade level criteria found in

the Medical Officer Series, GS-602 of the U.S. Office of Personnel Management position classification standards which the CDER, Medical Officer Review Committee will use in evaluating proposed positions proposed by CDER management for classification at GS-15 and for coverage under Title 38.

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SUPPLEMENT ONE

EVALUATION PLAN FOR CDER REGULATORY REVIEW MEDICAL OFFICERS

1. PURPOSE

This Evaluation Plan establishes the responsibilities and procedures which will be followed in evaluating (1) CDER Medical Officers for promotion to and selection at the GS-15 grade level, and compensation under Title 38, and (2) the mandatory, three year cyclical review of Title 38 medical officers promoted under this Plan.

2. THE MEDICAL OFFICER REVIEW COMMITTEE

A. Members.

1. The Medical Officer Review Committee will consist of ten members.

2. A Center review division or office director appointed by the Center Director will serve as the Chair of the Committee. A position classification specialist made available by OHRMS will serve as a permanent member of the Committee.

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3. Medical officers from the Center drug evaluation offices at the senior level will be selected by the Deputy Director (Review Management) to serve on the Committee. A Committee member will be appointed as the Vice Chair by the Deputy Director (Review Management). Committee members will serve three year terms with one third of the membership rotating off the Committee each calendar year.

4. Alternates, as agreed on by the Committee Chair and the drug review office directors will be appointed to serve when necessary.

5. The position classification specialist will serve as a full member of the Committee and offer guidance in the review and evaluation of cases which come before the Committee.

6. A Project Officer who will not be a voting member of a committee will be provided for the Committee, and will report to the Committee Chair.

7. Seven members present at a meeting including the Chair or Vice Chair of the Committee and the OHRMS position classification specialist will constitute a quorum.

B. Advisory Participants. The Committee has the authority, when seen fit, to call on candidates, recommending officials, other medical officers, and any other appropriate individuals who may be of assistance in the review of a case.

3. RESPONSIBILITIES

A. Center Director. Selects the Committee Chair in consultation with the Deputy Center Director (Review Management).

B. Deputy Director (Review Management).

1. Recommend the Committee Chair to the Center Director.

2. Review and sign transmittal memoranda for cases to be submitted to the Committee.

C. Drug Evaluation Office Directors.

1. Nominate senior medical officers and medical officer management officials with appropriate background to the Deputy Director (Review Management) for membership on the Committee.

2. Review cases submitted by supervisors within the Office for completeness and scientific merit.

3. Sign transmittal memoranda for cases to be submitted to the Committee.

D. Committee Chair.

1. Schedule, call, and chair stated meetings of the Committee, and notify drug review Office Directors of those dates. Special meetings may be called at the discretion of the Chair for such purposes as orienting and training new Committee members, and handling unexpectedly large numbers of cases.

2. Establish the required three year mandatory review cycles for all Title 38 medical officers, and insure that concerned supervisors are notified when reviews are scheduled.

3. Conduct orientation meetings with the Committee to establish guidelines or the review and evaluation of cases, and provide guidance in instances which are not specifically covered by this Plan.

4. Receive all case material. With the OHRMS member, decide whether cases have been submitted in the proper format, are adequate and complete, and all appropriate supervisory signatures are present.

5. Assign cases to Committee members for indepth review prior to scheduled committee meetings.

6. Insure the confidentially of Committee meetings and proceedings.

7. Prepare Committee recommendations on the disposition of cases.

8. Speak for the Committee in communications with the Center Director, drug evaluation Office Directors, review Division Directors, sponsors, candidates, and any others having business with the Committee.

E. Committee.

1. Meets on a regular schedule established by the Chair, and when called by the Chair due to special circumstances.

2. Review and evaluate case material.

a. Each case will be carefully reviewed, and evaluated on scientific merit. All appropriate information such as memoranda of recommendation, reports and evaluations by supervisors, and work examples will be used.

b. The Committee may schedule interviews with the recommending supervisors or persons with knowledge of a candidate's achievements and contributions. Representatives of disciplines not represented on the Committee may be invited to provide information on the role and impact of the candidate on the review process.

c. Any Committee member who is also the recommending supervisor may discuss, but not participate in deciding on the disposition of a case.

d. A consensus of those present at a Committee meeting will determine the recommended disposition of a case.

e. The Chair or a member designated by the Chair will summarize the findings and final recommendation of the Committee in writing. On acceptance of the recommendation, the Chair will notify the recommending supervisor through the appropriate recommending officials.

f. The activities of the Committee including both written and verbal communications and actual Committee deliberations, discussions, and decisions are considered to be confidential.

F. Position Classification Specialist.

1. Works with the Chair and Committee in all aspects of the evaluation process.

2. Serves as a full member of the Committee.

3. Applies the appropriate OPM position classification standard and criteria to cases being considered by the Committee, and prepares evaluation statements relating the written grade level criteria to a candidate's contributions.

4. Informs the Committee of any modifications or changes in the Medical Officer Series, GS-602 and any other criteria used in the review and evaluation of Center medical officers.

G. Project Officers.

1. Keeps track of the terms of Committee members and alerts the Chair when terms will expire so that replacements can be nominated and selected.

2. Coordinates and schedules meeting dates with the Chair, and confirms dates with Committee members.

3. Receives cases from the Deputy Director (Review Management), and distributes case material to the Chair and Committee members.

4. Establishes mandatory review schedules, and notifies supervisors of this requirement when necessary.

4. PROCEDURAL STEPS

A. The Chair establishes the dates for stated and any necessary special Committee meetings, and notifies drug evaluation managers.

B. Candidates are responsible for preparing required case material. The immediate supervisor is responsible for certifying the completeness and accuracy of the case material. This supervisor is responsible for submitting the original and ten copies of case through appropriate management channels to the Committee, Project Officer.

C. Cases must be received by the Project Officer at least four weeks before the date on which a Committee meeting is scheduled.

D. The Chair and the position classification specialist review all cases and make an initial evaluation of the documentation and recommendations. Cases which are accepted will be given to the Project Officer for distribution to the Committee members. If it is decided that a case does not contain sufficient documentation, the case material will be returned to the recommending supervisor for the collection of pertinent information and resubmission. Failure to respond with relevant material, or in a timely fashion, may result in the deferral of a case until the next scheduled

meeting of the Committee.

E. The Chair assigns each case to a Committee member as an indepth reviewer. The indepth reviewer will obtain any additional information which will help the Committee to better understand a case. At a minimum, the indepth review will consist of a personal interview with both the recommending supervisor and the candidate. When the work of the candidate is directly related to or impacts the program of another distinct organizational entity, an effort should be made to interview the manager or scientist responsible for or associated with the program. See Supplement Six, Guidelines for Conducting Indepth Interviews.

F. Prior to a scheduled Committee meeting, each Committee member will review each case and reach a tentative conclusion based on the criteria found in Supplement Seven, Criteria for the Evaluation of CDER GS-15 Medical Officers and Title 38 Medical Officers.

G. Committee meetings will be conducted in accordance with accepted Committee guidelines. Discussions are considered to be absolutely confidential, and Committee recommendations and decisions will be distributed through official channels only.

H. After completing the review of a case, the Chair will prepare a written recommendation in behalf of the Committee which will be sent to the recommending supervisor through appropriate Center management.

I. The position classification specialist will prepare an evaluation statement for each case which has been found acceptable by the Committee, and insure that necessary personnel action is taken.

J. Cases which do not meet the necessary criteria will be returned to the recommending supervisor through appropriate Center management with a written explanation prepared by the Chair detailing the reasons for the decision. Any subsequent resubmission must clearly address the points raised by the Committee decision.

K. All medical officers covered by this Guide may appeal the final classification of their positions through established Agency and OPM classification appeal procedures.

5. DOCUMENTATION REQUIREMENTS

A. The supervisor in conjunction with the candidate prepares an original package and ten copies for submission to the Committee Chair through appropriate Center management channels.

B. The original package will contain the following in sequential order:

1. Transmittal Memorandum from a drug evaluation Office Director through the Deputy Director (Review Management) to the Committee Chair.

2. Two Memoranda of Recommendation. The first memorandum should come from the immediate supervisor, or from the immediate past supervisor, if that official is more familiar with the work of the candidate. The second memorandum may come from a supervisor, team leader, or senior medical officer 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 currently work within the same or another organization closely associated with the organization to which the candidate is officially assigned. Both memoranda must be signed or countersigned by the candidate's current supervisor.

Both memoranda must address the following points:

a. The name, title, series, and current grade of the candidate, 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 which the candidate has built, related and pertinent FDA experience in other program areas, and recognition which the candidate has earned and received such as honors, awards, invitations, or any other appropriate information.

c. 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 topics addressed in Supplement Seven, CDER, Criteria of the Evaluation of CDER GS-15 Medical Officers and Title 38 Medical Officers. Also of interest to the Committee, is the skill and ability of the candidate to express both verbally and in writing those opinions, conclusions, and positions which the candidate has reached.

3. Candidate's Memorandum. This memorandum must address the following points, and within that format should address the criteria set out in Supplement Seven. Special emphasis should be given to those activities which the candidate considers to have exceeded those expected of a full performance level GS-14 medical officer, and how those activities have impacted the candidate's work situation.

a. The name, title, series, and current grade of the candidate, 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 which the candidate has built, related and pertinent FDA experience in other program areas, and recognition which the candidate has earned and received such as honors, awards, invitations, or any other appropriate information.

c. List of accomplishments to the Agency, regulated industry, scientific community, and the regulatory process. See Supplement Two, Documentation Requirements, Memorandum of Recommendation. Each accomplishment should be described as completely as possible with primary emphasis on what was accomplished and why the accomplishment was significant to Center and Agency enforcement and consumer protection efforts. Care should be taken in selecting the most significant contributions, and in clearly explaining how those contributions have impacted the review mission of the Center. 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. 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 criteria found in Supplement Seven, Criteria for the Evaluation of CDER GS-15 Medical Officers and Title 38 Medical Officers. Also of interest to the Committee is the skill and ability of the candidate to express both verbally and in writing those opinions, conclusions, and positions which the candidate has reached.

4. Curriculum Vitae. See Supplement Five, Curriculum Vitae.

5. OF-8 and Position Description. The proposed position description must follow the nine factor format required by the Factor Evaluation System. See Supplement Three, Position Description Format, and Supplement Four, Sample Position Description.

SUPPLEMENT TWO
DOCUMENTATION REQUIREMENTS

MEMORANDA OF RECOMMENDATION AND CANDIDATE'S MEMORANDUM

The Memoranda of Recommendation should be restricted to actual accomplishments within the recent past such as two to three years, not future plans or problems or accomplishments which are long past. Each memoranda should begin with a brief paragraph summarizing the medical officer's career by giving the total time which has been devoted to regulatory review work and the various organizations and locations in which that work has been performed, and a general statement about the medical officer's reputation and recognition which has been earned and received.

Following the introductory paragraph, the medical officer's area or areas of expertise and the most significant accomplishments over the medical officer's career should be addressed in chronological order. There is no particular limit to the number of accomplishments which may be addressed.

Each accomplishment should be described as concisely as possible with primary emphasis placed 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 medical officer contributed to the total effort. Since the significance of an actual accomplishment sometimes changes with time, these statement should be carefully written.

The medical officer's memorandum may document accomplishments by the inclusion or attachment of memoranda, final technical reports, manuscripts, publications, or any other pertinent document. Good judgment should be used concerning the quality and numbers of such documents. Any 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.

If publications are offered, they should be referenced to the particular accomplishment which they accompany. When more than one publication is used to document an accomplishment, all the publications must support the single accomplishment.

A medical officer's position may include duties and responsibilities which are not specifically oriented to regulatory review. If this kind of work is performed on a regular and recurring basis, it should be documented in the position description.

SUPPLEMENT THREE

POSITION DESCRIPTION FORMAT

DUTIES:

The object of the "Duties" section of the position description is to present the major duties of the position in the order of their importance. Major duties are those which usually occupy more than ten percent of a medical officer'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 seasonally, such as once a year, but every year. Major 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. Major duties are the primary reason for the existence of a position. All other duties are minor or peripheral, and do not enhance the grade.

The duties of a position 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 indepth reviewer and other members of a committee can understand what is going on. Do not use words and phrases such as assists, executes, coordinates, participates, facilitates, or serves as a focal point. The Committee wants to know what the medical officer 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 corresponding factor description in Supplement Seven, Criteria for the Evaluation of CDER GS-15 Medical Officers and Title 38 Medical Officers.

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION.

What knowledge is required to perform the work of the position, such as the professional and scientific discipline or disciplines, the categories of products and samples, functional specialties, other Agency programs, the regulated industry or industries, programs of State, local, and foreign governments, programs of national and international organizations?

What knowledge is required of Agency enabling legislation, policies, 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?

What kinds and levels of skills are necessary to perform the work 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, and leading 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 only general suggestions on approaches to work?

What responsibility does the medical officer have for carrying out the work? Within general guidelines, establishes the approach to assignments, handles all work independently according to accepted policies and practices, resolves conflicts, determines approaches to be taken?

How is the work reviewed? For appropriateness, accuracy, adequacy, and compliance with instructions; or is it expected to be technically accurate, accepted as authoritative?

FACTOR 3 - GUIDELINES.

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

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

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

FACTOR 4 - COMPLEXITY.

What is the nature of the work and assignments? Are they made up of related, sequential steps; different processes; independent assignments with varying duties?

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

FACTOR 5 - SCOPE AND EFFECT.

Does the medical officer’s work impact others and the way in which they work?

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

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

FACTOR 6 - PERSONAL CONTACTS.

With what kind of people and organizations does the medical officer come into contact? Coworkers, various supervisors and managers in the Agency, representatives of industry, other Federal agencies, State, local, and foreign governments, trade organizations, national and international organizations?

What positions do those contacted hold and what levels do they occupy in their organizations?

FACTOR 7 - PURPOSE OF CONTACTS.

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

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

Does the medical officer 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 medical officer have in representing the Agency?

FACTOR 8 - PHYSICAL DEMANDS.

What is the nature of the medical officer's physical activity? Sedentary, walking, standing?

FACTOR 9 - WORK ENVIRONMENT.

What is the nature of the environment in which the medical officer works?

SUPPLEMENT FOUR

SAMPLE POSITION DESCRIPTION

This sample position description is intended to be used as a general frame of reference, and should not be applied mechanically. Good judgment should be used in deciding whether any part of this sample meets the specific situation work situation being described. It is expected however, that each medical officer position description will be unique because of those functions which are peculiar to the organization to which the medical officer is assigned, the areas of responsibility in which the medical officer has become recognized as an authority, and the way in which the medical officer has uniquely impacted the position.

Medical Officer, GS-15, Title 38 Medical Officer.

DUTIES:

Serves as a medical officer in a Center regulatory review organization with responsibility for the review of a variety of proposed scientifically complex human drugs. Assignments include reviewing of New Drug Applications, Investigations Drug Exemptions, and/or Abbreviated New Drug Applications; providing recommendations and guidance to Center review organizations, medical officers and review scientists, and the regulated industry; and representing the Center at local, State, and national meeting on matters concerning regulated products. Assignments cover such work as:

Analyzing and determining the adequacy of data and tests submitted by a manufacturer regarding the safety and efficacy of a regulated product or products.

Determining if additional data or other information is necessary within the context of applicable laws, policies, regulations, and guidelines.

Providing verbal and written conclusions to other Federal agencies, industry, universities, and State, local, and foreign governments.

Developing and recommending new and revised research treatises and guidelines for regulated products, and proposing areas of study for in-house and contract research projects.

Recognizing the need for and initiating new and amended regulations, policies, and procedures.

Maintaining comprehensive surveillance of the impact and significance of complex periodic reports of clinical experiences, studies, and tests submitted by sponsors of important products including scientific information on unexpected side effects, injuries, toxicity, or sensitivity reactions associated with the product and similar products.

Advises on difficult issues associated with product development, technological changes, environmental impact, industrial changes, and toxicity assessment in advance of or during

the early stages of product development.

FACTOR 1 - KNOWLEDGE REQUIRED BY THE POSITION

Mastery of a professional discipline and associated disciplines sufficient enough to allow the medical officer to review a variety of complex New Drug Applications, Investigational Drug Exemptions, and/or Abbreviated New Drug Applications, master files, supplements and amendments from manufacturers of products intended for use nationally in the diagnosis, treatment, and prevention of specific diseases in humans.

This mastery includes a thorough knowledge of recent developments in the professional discipline and associated disciplines; applicable FDA laws, regulations, policies, and guidelines; the regulated industry; scientific information on unexpected side effects, injury, toxicity, or scientific reactions associated with the products and any related products.

Skill in identifying problems, gathering information, drawing conclusions, recommending solutions, preparing reports, and negotiating acceptance and implementation of recommendations.

Ability and skill in accomplishing work through others when necessary at all necessary levels within the Center and with all other organizations which the Center impacts.

Ability to present findings and recommendation in scientific terms both verbally and in writing.

FACTOR 2 - SUPERVISORY CONTROLS

The supervisor provides only administrative direction making assignments in terms of broad program objectives. The medical officer independently plans, designs, and carries out work, functions, projects, and studies which may also come from sources other than the supervisor.

The results of the work are considered to be professionally and technically authoritative, and are normally accepted without significant change. Recommendations for new work and projects, and altering of objectives are usually evaluated only for such considerations as availability of funds and other resources, broad program goals, and national priorities.

FACTOR 3 - GUIDELINES

Guidelines are mostly broad and general policy statements, professional, scientific, and trade literature, Agency and Center regulations, and pertinent legislation which are either inadequate or unavailable for most of the questions and issues encountered. Considerable judgement and ingenuity must therefore be used in interpreting and modifying the available guidelines. As an authority, the medical officer is responsible for initiating and developing policies, instructions, and guidelines which must by used by other Center medical officers scientists, and the regulated industry.

FACTOR 4 - COMPLEXITY

The work involves a combination of professional, scientific, and regulatory responsibilities which are difficult because of the advanced scientific and technical complexity surrounding the wide variety of products reviewed, and which call for a number of unique scientific and regulatory approaches. The work requires the medical officer to deal with such matters as new products, industrial changes, technological changes in the production of regulated products, and new scientific knowledge. The medical officer's approaches are influenced by precedents drawn from ongoing improvement in the regulatory review process, advances in the applicable sciences and the regulated industry, new product problems, and disagreements in the application of science and regulatory review procedures.

FACTOR 5 - SCOPE AND EFFECT

The work involves resolving critical problems and developing new approaches to problems which are difficult because of the advanced scientific and technical complexity surrounding the products reviewed, and which affect the work of other Center medical officers and scientists, and the regulated industry. The medical officer provides authoritative advice to officials and scientists in the Agency and Center, other Federal agencies, and the regulated industry. Findings and conclusions affect the Agency and Center regulatory missions and the safety and health of those affected by the regulated products .

FACTOR 6 - PERSONAL CONTACTS

The medical officer makes contacts with a variety of key and top officials, managers, scientific professionals, and executives both within and outside the Agency such as directors and scientists in public and private laboratories, corporate officials and representatives of regulated firms, official representatives of other Federal agencies and foreign governments, and representatives of professional and trade associations.

FACTOR 7 - PURPOSE OF CONTACTS

The purpose of the medical officer's contacts is to discuss, justify, defend, resolve, negotiate, and achieve common understanding and satisfactory solutions of controversial scientific and technical issues and regulatory requirements and policies. Because contacts are made with individuals of widely differing viewpoints, goals, and objectives, the medical officer must use tact, expert professional, scientific, and product knowledge, and authoritative knowledge of Agency and Center policy and regulations to persuade others to accept the Agency point of view or in the development of suitable alternatives.

FACTOR 8 - PHYSICAL DEMANDS The work is primarily sedentary with occasional walking, standing, bending, and carrying of light items.

FACTOR 9 - WORK ENVIRONMENT The work is usually performed in an office setting.

SUPPLEMENT FIVE

CURRICULUM VITAE

Each of the following headings should be listed and addressed. Even if there is nothing to report under a heading, include the heading and say “none” or “nothing to report.” The Committee will then know that the heading was not overlooked or inadvertently omitted.

Name -

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

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

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

Honors and Awards - List titles and dates and give a brief, but sufficient enough description, so that the Committee may be able to determine the significance and prestige. If cash was involved, give the amount.

Special Invitations - These are usually specific invitations to present papers or make other presentations before professional, scientific, or industry groups, to 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 invitation. For each invitation, list the title of the presentation, date, location, and organization or purpose of the gathering. Provide sufficient information for the Committee to determine professional and 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, whether current or expired, and a 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, and any offices held. List and give dates of any offices held, and of any committee assignments or special assignments undertaken.

Participation in National Scientific Meetings, Technical Conferences, Workshops, Seminar, etc. - List each, give date, location, type of meeting, title of talk or paper if one was presented, or a brief description of role or reason for attendance if no presentation was made. 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 each individually.

Outside professional Advisory and Consulting Activities - List each, give dates, name and type of organization or situation, and type or significance of contributions. These should be activities outside the 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.

FDA Special Assignments and Advisory Activities - These should be of a technical and professional nature within FDA, but outside of the immediate work assignment or organization. Include items such as participation in hearings or testimony preparation; science advisor to the Office of the General Counsel, Agency, or Center level; task force assignments; or similar activities. List each, give dates, and briefly describe the role and significance.

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

Publications other than refereed articles in scientific journals or bulletins should be identified as one of the following: thesis, abstract, review article, book, book chapter, conference or society proceeding, patent, popular publication, technical research report (a written report that requires clearance for public release), or other (identify specifically).

SUPPLEMENT SIX

GUIDELINES FOR CONDUCTING INDEPTH INTERVIEWS

Prior to a scheduled meeting, the Committee Chair will assign cases to appropriate Committee members for the conduct of indepth reviews. Objectivity in the reviewer is critical to this process. The reviewer will be expected to read both the case and any material which has been submitted to enhance the case such as recommendations letters or appreciation. The 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 will be expected go beyond the written case material in an attempt to clarify and check the significance of the medical officer's accomplishments, sort contributions from those of other professionals, and bring any additional information to the Committee meeting for discussion which may not have been made available in the case material.

The indepth review will involve a interview with the medical officer under consideration. An interview with the immediate supervisor is also expected. The supervisor usually is the best source on points that need to be clarified and any additional information which may be pertinent to the case. The reviewer may also find it necessary to interview others as well, depending on the reviewer's familiarity with the medical officer and the position, the impact of the medical officer outside the organization, the mission of the organization, and any other aspects which may be relevant to the case.

Preparation before interviews are conducted is essential in order to save the time of both the reviewer and those being 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 and those assignments which are characteristic of the grade level being requested as found in Supplement Seven, Criteria for the Evaluation of CDER GS-15 Medical Officers and Title 38 Medical Officers, the memoranda of recommendation and list of accomplishments, and the position description submitted with the case. It should be remembered that the position description is an official document which the requesting supervisor certifies as containing both an adequate and accurate description of the work assigned to the medical officer. Both the grade level criteria and the position description are presented in the Factor Evaluation System format. Supplement Three, Position Description Format offers suggested questions for each of the major factors which can help the reviewer prepare for the interviews in order to gather the information which will be necessary to evaluate the request.

Interviews should be scheduled at a time which is mutually convenient to the reviewer and those being interviewed. To conduct a successful interview, the reviewer should make sure that 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, summarize the main points at the end of the interview, and let the one being interviewed know that the reviewer is available if there is any additional information which may come to mind at a later time.

SUPPLEMENT SEVEN

CRITERIA FOR THE EVALUATION OF CDER GS-15 MEDICAL OFFICERS AND TITLE

38 MEDICAL OFFICERS.

INTRODUCTION:

The accepted full-performance level for medical officers in CDER drug review organizations is GS-14. This level has been established through long experience with and application of the Medical Officer Series, GS-602 position classification standard which is used to evaluate CDER medical officers. The full performance level may be defined as the highest grade level of work in an occupation which involves the independent performance of the full range of duties found in an organization. An established career ladder allows all who enter the ladder to rise to the top grade, or full performance level, without being subject to merit promotion procedures when the employee satisfactorily demonstrates the knowledges, skills, and abilities to perform at the next higher grade level. This Supplement speaks to those unique medical officers who because of the combination of the work which they perform and the personal qualifications which they bring to that work are performing at either at the GS-15 grade level or as Title 38 medical officers.

OCCUPATIONAL INFORMATION:

Medical officers apply their skills in the context of the regulatory framework of the consumer protection responsibilities of the CDER. They review a variety of applications submitted by the regulated industry to ensure the safety and efficacy of human drugs. Medical officers must have considerable knowledge of current professional and scientific methods and procedures, the ability to interpret data, and the ability to explain decisions by means of written and verbal presentations. They must be able to demonstrate the capability to conduct and bring to proper conclusion, appropriate scientifically based review activities solving novel situations that involve complex scientific data and methodology, and related issues.

It must be stressed that the GS-15 and Title 38 levels represent exceptional levels of responsibility combined with exceptional degrees of scientific and technical complexity. To justify classification at these levels, a medical officer is required to possess expertise in an area of **on-going** functional importance to the CDER. This responsibility should not be fragmented beyond that which is necessary for effective management control. Ideally the work which controls the compensation of a position should occupy a majority, at least 50 percent or more, of a medical officer's time. It is understood that GS-15 and Title 38 medical officers hold their positions on an incumbency basis only, and that those positions will be abolished when vacated.

Medical officers who have been successfully promoted to GS-15 or compensated under Title 38 level by means of this peer review process will be subject to a review every three years from the date of promotion to insure that they are still performing at the appropriate level of compensation.

POSITION CLASSIFICATION SYSTEM

The criteria in this Supplement have been derived from the published, written grade level criteria in the Medical Officer Series, GS-602 which must be used as required by the U.S. Office of Personnel Management to classify the various medical officer positions in the CDER. By agreement with CDER management, this position classification standard has served as the basis for developing criteria to evaluate medical officers proposed for promotion to GS-15 and for compensation under Title 38. A position must be fully equivalent to the overall intent of the criteria at a particular level before a proposed position may be placed at that level.

Examples of work 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 must be used in deciding whether a position fully meets the essential requirements of a particular factor. In order to be assigned to a particular grade level described in a factor, it is necessary for the position to satisfy the overall intent of the factor description rather than just matching the specific examples provided.

The Medical Officer Series, GS-602 requires that the following **two factors** be used in the evaluation of General Schedule medical officer positions.

1. Level of Assignment. As applied to the medical officer, this factor measures the complexity of the problems dealt with, the variety of types of problems, the degree of responsibility for recommendations and the extent to which decisions and opinions are accepted, and the extent of ingenuity and insight required in making decisions.

2. Level of Professional Development. This Factor speaks to the qualification requirements, the various stages of training or experience, and reflects the level of professional knowledge, ability, and competence of the medical officer and the confidence placed in the medical officer as demonstrated by the acceptance of recommendations by supervisor and colleagues. As professional competence increases, supervision from others decreases and greater insights, more mature judgment, higher skills, etc., are used in the work. The accumulation of both advanced knowledge and experience provides a background for greater understanding of problems and greater ingenuity in the resolution of problems.

It should be noted that the presence or absence of, or the number of publications attributed to a medical officer may not be used to establish a grade level. None of the many established position classification standards which have been established to evaluate the work of medical officers and scientists in the Federal government, including the one which serves as the basis of the grade level criteria found in this Plan, use publications as a part of the classification grade level criteria. For medical officers, as is the case with all other nonresearch professionals, publications serve as evidence along with other appropriate information that a medical officer 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

presence and number of publications cannot be considered in establishing the level of compensation of a medical officer position. As with publications in general, authorship serves as evidence of work performed. However, this evidence may vary from researcher to researcher because of the habits of research scientists and managers with whom a medical officer may have been working. Some researchers generously recognize the work of others by including their names as co-authors of papers, other researchers do not. While 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 indepth interviews with workers and their supervisors, position descriptions, staffing charts, and other traditional sources used to classify positions.

GENERAL SCHEDULE MEDICAL OFFICER GRADE LEVEL CRITERIA

LEVEL OF PROFESSIONAL DEVELOPMENT

> This Factor reflects the level of professional knowledge, ability, and competence of the medical officer and the confidence placed in the medical officer as demonstrated by the acceptance of the medical officer's recommendations by supervisors and colleagues. As professional competence increases, supervision from others decreases and greater insights, mor mature judgment, higher skills, etc., are used by the medical officer in the performance of the work. The accumulation of both advanced knowledge and experience provides a background for greater understanding of problems and greater ingenuity in the resolution and treatment of problems.

In the experience of the CDER, the requirements of this Factor should be found equally in the GS-15 and Title 38 medical officers which are both considered to be senior positions within the Center responsible for dealing with the most complex and novel cases and problems. Ideally, a medical officer should meet all of the aspects of this Factor listed below. However, the Committee may, at the discretion of the Committee, allow particularly outstanding or exceptional achievements or attributes in one aspect of this Factor to offset a weakness in another part.

1. A GS-15 or Title 38 medical officer is by training and experience a senior professional in a medical specialty. Typically, the medical officer has completed an approved residency program and possesses additional clinical or research experience. The medical officer must be board eligible or must have gained progressive experience equivalent in breadth or intensity to board eligibility. Or, in addition to the medical degree, the medical officer may possess a Ph.D. or equivalent combination of experience, education, and training in a medical related field.

2. A GS-15 or Title 38 review medical officer possesses a working knowledge of applicable Food and Drug Laws, regulations, and policies; and knowledge of the principles of clinical pharmacology, statistics, and/or other disciplines appropriate to the work performed.

3. A GS-15 or Title 38 review medical officer is an expert and authority in one or more regulatory review programs of new drugs, the evaluation, monitoring, and investigation of research and/or research facilities, or the evaluation of or conduct of major compliance efforts. The review medical officer is cognizant of current literature, regulations, and research related to assigned and closely related program areas and work.

4. The GS-15 and Title 38 review medical officer engages in professional development activities designed to maintain and enhance the medical officer's capability in the assigned functional area of regulatory review work. Professional development activity may be defined as involvement in, but not necessarily limited to, one or more of the following:

> a. Association with a teaching hospital or research institution when there is opportunity to discuss problems with and/or work with physicians, scientists,

and students.

b. Participation in a regularly continuing program of graduate education.

c. Participation in educational programs, classes, seminars, etc., for regulators sponsored by the Agency. These include the various Food and Drug Law courses, statistics courses, and scientific seminars.

d. Attendance at bona fide meetings, symposia, seminars, post-graduate course, etc., or recognized medical societies, specialty colleges and/or boards, and other scientific groups dealing with clinical medicine, drug research, or regulatory law and policies or other fields related to the assignments of the medical officer.

LEVEL OF ASSIGNMENT

This Factor measures such elements as the complexity of the work and problems dealt with; the variety of types of problems; the degree of responsibility for recommendations, and the extent to which decisions or opinions are accepted; the extent of ingenuity and insight required in the development of solutions to problems, and the professional judgment and required by the work. Difficulty and responsibility will increase as precedents become fewer, less routine or well established courses of action, unknowns become more frequent, combinations and overlapping make problems difficult to discern and uncover, and new and unknown entities are introduced the the program and work of the review medical officer.

Complexity. The medical officer is recognized as a Center authority in the area of assigned functional responsibility, and as such develops guidelines, science policy, and Agency and Center requirements for application to the regulated industry. It is expected that the medical officer integrates personal knowledge and experience in the resolution of problems, the modification of procedures, and in the development and interpretation of policy to meet difficult, controversial, and new and novel situations and conditions. Creativity and originality are evident in such areas as the introduction of new and novel approaches to the problems and issues encountered. Actions taken and solutions devised cut across other functional areas within the Office and Center. The medical officer frequently represents the Office and Center, or acts as liaison, with outside professional groups.

Some assignments may address continuing international health problems. Because of the visibility of such problems, the medical officer must employ a knowledge of worldwide problems and technological advances. The medical officer participates in the development of technical solutions to these kinds of problems, and is recognized as the authority in the area of functional responsibility.

The medical officer has attained significant professional recognition which may be reflected by achievement awards and professional certification.

When appropriate, the medical officer may assume responsibility for work groups.

Impact. The purpose of the work is to provide authoritative expertise in the resolution of especially critical, sensitive, and controversial issues related to the area of assigned functional responsibility. The issues and problems are especially critical because of their broad significance and scope, and because they involve extremely broad, long-term, and far-reaching studies addressing extremely broad and varied health issues.

Based on established and widely recognized expertise, knowledges, skills, abilities, and experience, the medical officer isolates and defines unknown conditions and develops new approaches and methodology for use by other medical officers and review scientists, and provides expert guidance to others on professional issues within the area of functional responsibility. The medical officer represents the Agency in decision-making conferences and has the authority to decide which Agency resources will be devoted to chosen courses of action.

The medical officer's work affects the Office, Center, Agency, and the regulated industry as well as similar programs in other countries. Guidance and direction are given to others on scientific and regulatory issues in the area of functional responsibility; findings and conclusions are of considerable significance in altering and modifying Agency science and regulatory concepts on a long-term and continuing basis, and influence the science and programs of other Federal agencies, State, local, and foreign governments, and the regulated industry, and decisions are frequently questioned and challenged at the highest levels, by the established and recognized professional stature of the medical officer is such that results of the work are proven and accepted.

Supervisory Controls. The supervisor provides administrative direction only, and makes assignments only in terms of broadly defined national programs, mission, and functions. As a recognized authority in an assigned functional area, the medical officer is responsible for independently planning, designing, and carrying out project, assignment, studies, or other work.

The results of the work, conclusions, and decisions are considered to be scientifically authoritative, and are accepted without significant change. Any review of the medical officer's work typically concerns broader issues which are not the medical officer's responsibility such as the impact on overall Center programs and goals, resource constraints, or national priorities and authorities.

Judgment Exercised. In the resolution of difficult problems and precedent-setting issues, considerable ingenuity and professional judgment are required, notably in the selection and evaluation of approaches and methods and in the modification of previously formulated requirements. Negotiating skills and skill in the resolution of scientific and regulatory problems play an important role in the work assignments.

Guidelines. Few guidelines apply to the work being performed, and those that do are very general and therefore inadequate such as broad legisltion and general Agency policy. These guidelines require extensive interpretation of the intent of basic Agency policy, as well as major and untested deviation from or adaptations to currently accepted procedures and practices.

As a recognized authority, the medical officer must assess the impact of new policies, regulations, and pending legislation on the area of fucntional reponsibility, recognize the need for new procedures in the area of functional reponsibility to close gaps in knowledge or increase understanding about critical processes, indentify areas where new or improved policies and procedures are needed, and develop new policies and procedures which must be applied and followed by other medical officers and regulatory review scientists and by the regulated industry.

Personal Contacts. Contacts are made with top management in the Agency such as Agency program managers and administrators, and high ranking officials in other Federal agencies, State, local, and foreign governments, and the regulated industry. Contacts often

extend beyond the boundaries of the medical officers area of functional responsibility.

Contacts are made to justify, defend, or settle matters involving significant, delicate, or controversial issues. Those contacted typically have widely differing viewpoints, objectives, or goals which require the medical officer to convince those contacted to accept the Agency position or to develop suitable compromises or alternatives. Negotiations are conducted in behalf of the Agency for the purpose of resolving divergent viewpoints by achieving common understanding and satisfactory solutions, enlisting support on key matter, and insuring concerted action by all involved. The medical officer represents the Agency at meeting, hearings, conferences, which deal with such issues as controversial scientific and regulatory policies or the development of Center and Agency-wide standards and guidelines.

TITLE 38 MEDICAL OFFICER CRITERIA

In addition to the requirements which the Medical Officer has met to achieve the GS-15

grade level, the following are characteristic of the two primary kinds of Title 38, Medical Officers found in the CDER. On occasion, both types may be found in the same position depending on the needs and requirements of management.

TYPE 1 - WORK PERFORMED BY AN INDIVIDUAL

The Medical Officer is responsible for attacking basic drug review, evaluation, and regulatory problems of such fundamental interest, extraordinary difficulty, and resistance to solution that:

there have been numerous attempts by highly competent Medical Officers and scientists to explore the field and to gain a fundamental understanding of the processes and phenomena,

new concepts and techniques must be developed for approach and interpretation, and

the successful performance of the work will lead to the creation, major modification, and/or important extension of current approaches and programs.

The assignment and leadership exercised by the Medical Officer influence the shaping of Center and Agency program goals, advancement of programs and understanding in the field, and the planned activities of numerous other Medical Officers and scientists in the Center and Agency, other Government agencies, the regulated industry, and national and international health organizations.

Center and Agency management is confident in and relies on the Medical Officer's productivity, competence, and judgment so that there is an unusual degree of confidence in and support of the Medical Officer's recommendations and pursuit of novel and unique problems. The supervision which the Medical Officer receives is further characterized by a confidence that interpretations, recommendations, and conclusions will have major impact on matters of great urgency and significance, and that such interpretations, recommendations, and conclusions will be accepted by other Federal agencies, foreign governments, the regulated industry, and national and international health organizations without reference to or knowledge of higher authority in the Center or the Agency. The supervisory relationship fully reflects the recognition of the Medical Officer as both a top authority in a field of major interest to the Center and Agency and as a distinguished and brilliant representative of the Center and the Agency.

The work of the Medical Officer is characterized by the application of unusual productivity, creativity, and depth of insight toward fundamental problems facing the Center and Agency so that a substantial number and variety of new methods and techniques , new approaches to formerly intractable problems, the identification of new problems to be attacked, and the creation of important new concepts are the result. These results of the work have widespread applicability in the Center and Agency and serve as a major stimulus to the mission and programs of the Center and Agency.

The Medical Officer is a nationally and internationally recognized authority and leader in a field of major endeavor and importance and interest to the Center and the Agency. The Medical officer will typically have received honors and awards from the Center and the Agency as well as national and international organizations for the Medical Officer's accomplishments. The Medical Officer is sought as an advisor and consultant on problems and programs which extend well beyond the field in which the Medical Officer is the authority. The Medical Officer's reputation as a leader is such that the Medical Officer serves a representative of the Center and Agency with the ability and authority to commit the Center and Agency to courses of action without referral to higher authority.

TYPE 2 - RESPONSIBILITY FOR A PROGRAM

The Medical Officer possesses extraordinary program, scientific, and technical knowledges, skills, and abilities and has used those knowledges, skills, and abilities to develop and/or materially redefine or redesign broad, complex national and/or international programs. Possession and use of such knowledges, skills, and abilities is well known not only to those officials to whom the Medical Officer is responsible, but also to those other officials in the Agency, other Federal agencies, State, local, and foreign governments, the regulated industry, and/or professional, trade, and citizen organizations, who are directly affected by the program for which the Medical Officer is responsible. These relationships and subsequent impact of the Medical Officer can be documented upon request.

Based on the demonstrated use of these knowledges, skills, and abilities, the Medical Officer will typically have primary responsibility for a broad and complex program which has been recognized by high level Center and Agency management as being nationally and/or internationally significant and important to the Center and Agency, and to which substantial resources may have been committed in terms of positions and/or public funds. Such positions may actually be present or found in authority delegated to the Medical Officer to coopt other medical officers and scientists when necessary to accomplish the mission of the program..

Primary responsibility for a program means that the Medical Officer has recognized a need, developed or modified a program to meet that need, and convinced high level Center and Agency management of the continuing need for such a program within the Center and Agency. The Medical Officer is solely responsible to those high level officials for the success or failure of the program.

When authority is delegated to the Medical Officer to coopt other medical officers and scientists, that authority extends throughout the Center, and outside the Center when considered appropriate and on agreement with other officials at the same or higher levels within the Agency, other Federal agencies, foreign governments, and national and international health organizations.

For all practical purposes, the Medical Officer is recognized as the "final word" in the area of program responsibility, and is therefore, the primary and essentially the only individual in

the Agency to whom high level officials both within and outside the Agency go for authoritative advice and guidance which will establish or change basic Center and Agency drug review, investigation, and regulation policy. In short, the Medical Officer is a nationally and internationally recognized authority and leader in a field of widespread interest and activity.

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