SERVICE FELLOWSHIP PROGRAM for the
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
(December 2009)

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SERVICE FELLOWSHIP PROGRAM AT THE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

I. INTRODUCTION

The mission of the Center for Biologics Evaluation and Research (CBER) is to ensure the safety, purity, potency, and effectiveness of biological products, including vaccines, blood and blood products, and cells, tissues and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Most of the products that CBER regulates are complicated biological products including vaccines, tissues, blood and blood products, cellular and gene therapies. Many involve novel technologies, and are in constant states of evolution. In order to regulate such products, it is important to have staff with appropriate scientific and technological expertise. CBER staff conducts mission-related research to resolve regulatory challenges, where needed. In-house scientific research maintains and expands our knowledge of biologics-related manufacturing, nonclinical studies necessary to support development of new products and new technologies applicable to regulated products. CBER research is conducted by permanent and temporary scientists, who also participate directly in product regulation and review. These scientists are referred to here, as research-regulators.

This document describes CBER policies, roles, responsibilities and procedures for the CBER Service Fellowship Program, including positions for both US and non-US citizens.

For research-regulator Service Fellow Track individuals this "Service Fellowship Program for CBER, dated November 2009, is a revision of and replaces the previous addition, dated April 2004.

This document describes two CBER Service Fellowship tracks. The first is a four year training track for Staff Fellows and Visiting Associates (equivalent to a post-doctoral fellowship,), hereafter referred to as the "Staff Fellow/Visiting Associate (SF/VA) Track". This track offers the potential to extend the fellowship for an additional three years in order for the Fellow to obtain research and regulatory experience required for possible conversion to a permanent position, as a Staff Scientist. The second is a seven year track for Senior Staff Fellows and Visiting Scientists, created to provide an opportunity for outstanding doctoral level scientists to develop an independent research/regulatory program as a Principal Investigator, in order to be considered for possible conversion to a permanent Senior Investigator position., , Hereafter this program will be referred to as the "Senior Staff Fellow/Visiting Scientist (SSF/VS) Track". For more information regarding the conversion process through CBER's Promotion and Conversion Evaluation (PCE) Committee refer: http://research.cber.fda.gov/PCEcommittee/main.html.

II. PURPOSE, OBJECTIVE, and GENERAL INFORMATION

The primary purpose of CBER's Service Fellowship Program is to provide a flexible mechanism for the temporary employment, training, and professional development of promising postdoctoral scientists, as well as an alternative employment means to secure the services of proven talented scientists for a period of limited duration. Service Fellows are appointed and extended under Title 42, U.S.C. 210(f).

The objective of the fellowship is to provide an unambiguous, uniform, and equitable mechanism to advance the Service Fellow's career in close association with leading authorities in biologics and public health-related research and regulation. The goal of the fellowship program is to offer

all necessary resources and encouragement to these fellows, thus giving them a fair opportunity to demonstrate their scientific potential and productivity that subsequently may lead to permanent research-regulator positions at CBER.

Service Fellows may perform any function directly related to conducting and supporting research, regulatory review, and scientific studies and investigations incidental to their research. They may provide technical direction and supervision to other researchers, exercise leadership in defining conceptual problems in a particular field of research, organize conferences and workshops to clarify those problems and promote the interchange of research ideas and information, consult others about ongoing research/regulatory projects, provide education on recent advances in research, attend professional meetings, publish scientific articles and review contract and grant proposals designed to support their research projects. The Service Fellows' work may include bench research, computational-based research, or other research-related activities.

Eligibility Requirements

1. Staff Fellow and Senior Staff Fellow applicants must be U.S. citizens. Visiting Associate and Visiting Scientist applicants are non-US citizens holding valid U.S. employment visa status (O-1, H1B1, or permanent resident status). If at any time a Visiting Associate or Visiting Scientist loses his/her visa status, his/her Service Fellow appointment will immediately terminate.

2. Must possess a Ph.D. or equivalent doctoral degree (e.g., M.D., D.V.M., Sc.D. or D.D.M.), awarded by a U.S. science program or a foreign science program certified by national or regional accrediting institutions in the U.S. as meeting all the appropriate requirements leading to a doctorate. However, a lower level of education and/or experience may be acceptable depending on the needs of the particular fellowship, but must have prior approval through the Center Associate Director for Research or designee.

3. Staff Fellows/Visiting Associates may be hired with less that two years post-doctoral experience. Senior Staff Fellows and Visiting Scientists must have at least two years of post-doctoral experience.

Service Fellow Appointments

Appointments to CBER's Service Fellowship Program should be initiated based on demonstration of research excellence, existence of a programmatic role in support of CBER's mission, and availability of resources (e.g., FTE positions, suitable financial resources and space) are available. The appointments are temporary and, unless extended, expire at the end of the initial appointment. These appointments do not confer permanent civil service status, nor is conversion to permanent civil service status guaranteed.

Initial Service Fellow appointments may be for up to **four years**, with extensions thereafter possible for up to a maximum of seven years depending on visa status (if non-US citizen), quality of performance, programmatic needs, available funds, and FTE positions.

If the candidate is coming from outside of CBER and the salary that the Office/Division intends to offer is equivalent to a GS-14 or GS-15, the candidate must undergo peer review by CBER's

PCE Committee; receive a positive PCE recommendation, and receive approval from the Center Associate Director for Research (ADR) **prior to final selection**. This is to ensure that the candidate's qualifications meet those required for either the GS-14 or GS-15 levels. In the same manner, if the salary that the Office/Division intends to offer an incumbent Service Fellow is equivalent to GS-13, GS-14, or GS-15, the incumbent must undergo peer review by the PCE Committee; receive a positive recommendation and approval from the Center ADR before the promotion can be processed. Refer to the *CBER Guide for the Evaluation of Research-Regulatory Scientist from GS-13 through GS-15*, Section VI for instructions on preparing a package for the PCE Committee's review (http://research.cber.fda.gov/PCEcommittee/main.html).

In order to obtain expert assessment of scientific program merit, mission relevance, and productivity, site visits of research-regulator Service Fellows are conducted by a Site Visit Committee scheduled on a rotating basis every four years. The Committee for a particular laboratory is chosen to include experts in the relevant research fields of the laboratory under review and is chaired by a member of the appropriate CBER scientific Advisory Committee. The Committee evaluates the Service Fellows for the quality, relevance, and productivity of their research accomplishments, and makes recommendations for whether the Service Fellow is ready for conversion to permanent status. For further information see "Site Visit Guidelines, for Review of Intramural Research in the Center for Biologics Evaluation and Research, Food and Drug Administration": http://research.cber.fda.gov/SiteVisits/main.html.

In keeping with CBER's aim of fostering diversity in the workplace, efforts should be made to encourage women and minority groups to apply for positions, and the candidates should be evaluated using the same criteria applied to all applicants.

Annual Performance Evaluations

Although Service Fellows are not included in the official FDA Performance Management Appraisal Program (PMAP), the Service Fellow's immediate supervisors must prepare an annual written evaluation using the PMAP document and accompanying research elements: http://inside.fda.gov:9003/downloads/EmployeeResources/PMAP/FDAPMAP/UCM124766.pdf. Supervisors shall discuss the Service Fellow's current research and regulatory performance and future expectations of performance. The appraisal period begins when the PMAP has been approved by the supervisor and communicated to the Service Fellow in writing.

Extension of Appointments

After the initial **four year** appointment, a Service Fellow may be given an extension of appointment up to the maximum term of seven years. Extension requests are signed by the Division Director and Office Director, approved by the Center Associate Director for Research or designee and forwarded to the Office of Management (OM)/Division of Program Services (DPS)/Program Operations Branch (POB) for processing at least **120 days prior** to the appointment termination date.

Exceptional extension requests beyond the maximum appointment will require written justification, from the Division and Office Directors, indicating the necessity for the extension, and must be approved by the Center Associate Director for Research.

Documents Required for Extension of Appointment

1. Request for Personnel Action (SF-52);

2. Acknowledgement of Temporary Appointment Status, signed by the candidate (**Attachment 1**);

3. Updated Curriculum Vitae (CV) of the candidate, to include: (1) bibliography listing (a) published original research, (b) original research articles "in press", (c) reviews, and (d) chapters/books; (2) additional training completed; and (3) invited presentations at national and international meetings;

4. Updated Statement of Duties; indicate specific allocation of time for research and regulatory activities;

5. Extension of appointment memorandum, from the immediate supervisor, through the Division and Office Directors addressing: to include length of stay at CBER; length of proposed extension; current research and regulatory work accomplishments; and the Division's intent for the future of candidate;

6. Non-U.S. citizens must provide a copy of appropriate documents as proof of legal U.S. visa status (i.e., O-1 visa, H1B1 visa, or permanent resident status).

Stop-the-Clock with Extension Provisions

In an effort to promote a more family-friendly environment, a **Stop-the-Clock** provision may be granted to a Service Fellow. This provision is to allow the Fellow time off for reasons such as childbirth, adoption, major illness, or a family emergency. If the Fellow should require this provision an extension of his/her appointment beyond the allowed seven years may be granted for up to one year. A written request detailing the reason and length of time needed must go through the immediate supervisor, Division and Office Director, and must be approved by the Center Associate Director for Research (ADR). The clock will not stop for accrued annual or sick leave. Once the request is approved by the Center ADR, the Office should forward a copy of the approved request to OM/DPS/POB and keep the original for their records.

Termination of Appointments

One year prior to the expiration of a Service Fellowship appointment, the Service Fellow will receive written notification of termination from the Center Associate Director for Research. Appointments may also be terminated prior to their expiration date for a number of reasons, including but not limited to: the services of the Service Fellow are no longer needed; budget constraints, realignment or loss of resources or research priorities; concerns about the quality or productivity of Service Fellow's research or regulatory review, or any other performance deficiency, and/or inappropriate conduct.

Documents Required for Termination

Termination letters are initiated by the OM/DPS/POB (**Attachment 2)**. The Center Associate Director for Research or designee will sign all termination letters for research-regulator Service Fellows. Once the termination letter is signed by the Center Associate Director for Research or

designee it will be returned to the employing Office/Division to be presented to the Service Fellow, who will sign and date, where indicated, to acknowledge receipt. A fully executed, signed copy of this letter must be forwarded to the OM/DPS/POB for their records.

Conversion to a Permanent Civil Service Appointment

In order to be converted to a permanent civil service appointment, a Service Fellow must be a citizen of the United States, undergo a site visit and evaluation by CBER's Promotion and Conversion Evaluation (PCE) Committee.

Non-U.S. citizen Fellows should expect U.S. citizenship within one to two years prior to being peer reviewed for a permanent civil service appointment. If this is not possible, due to the substantial delays in processing citizenship applications through the U.S. Citizenship and Immigration Services/U.S. Department of Homeland Services or for any other reason beyond the individual's or Center's control, Office senior management, having strong evidence that the Fellow could meet requirements for conversion to a permanent civil service appointment, should prepare a package for the Fellow to undergo PCE Committee review. If the PCE Committee recommendation is positive and approved by the Center Associate Director for Research, then exceptional extensions to the Fellow's appointment beyond the seven year term will be granted to allow the Fellow the needed time to obtain U.S. citizenship and finally a permanent civil service appointment. Any Fellow not receiving their U.S. citizenship within four years from the time of the initial PCE recommendation must undergo an additional site visit and PCE review prior to any final conversion action.

After meeting all the qualifications for a civil service appointment, the Service Fellow must apply for the permanent position through an external vacancy announcement. Applicants should consult with their nominating Office in preparing for a site visit, PCE Committee review, and application for permanent civil service employment.

Contacts

Questions pertaining to salaries and other information related to Service Fellow and civil service employment through CBER's PCE Committee should be directed to the Special Assistant to the Center Associate Director for Research at (301) 827-0833.

APPENDIX I

STAFF FELLOW/VISITING ASSOCIATE (SF/VA) TRACK

A. Background

This track is a four year support position, equivalent to a post-doctoral fellowship, with the potential of extension for an additional three years in order that the Fellow obtains research and regulatory experience required for possible conversion to a permanent Staff Scientist position.

Service Fellows in the SF/VA Track are doctoral level individuals, who perform research and regulatory activities under the supervision of a Senior Investigator. In order to obtain expert assessment of the SF/VA Fellow's research project(s), mission relevance, and productivity, site visits of their Senior Investigator supervisor's research program are conducted by a Site Visit Committee composed of experts from outside the Center, which are scheduled on a rotating basis every four years. SF/VA Fellows are not eligible for reappointment beyond the fourth year without supervisory concurrence and strong evidence that the Fellow could meet requirements for conversion to a Staff Scientist position within the next three years (**see sections D, E, F, & G**).

B. Responsibilities and Procedures for Appointing a SF/VA Track Service Fellow

1. The need to appoint a SF/VA Track Service Fellow is identified by the immediate Supervisor, who receives concurrence from the Division and Office Directors;

2. Once the candidate is identified, the Office Program Manager together with the Office of Management (OM)/Division of Program Services (DPS)/Program Operations Branch (POB) compiles an appointment package and submits it to the Division Director and Office Director for signatures. Note: **If the salary that the Division/Office intends to offer is equivalent to a GS-14 or higher the candidate must undergo peer review by CBER's Promotion and Conversion Evaluation (PCE) Committee prior to final selection. Refer to the *CBER Guide for the Evaluation of Research-Regulator Scientists from GS-13 through GS-15* (http://research.cber.fda.gov/PCEcommittee/Section0.html) for instruction on preparing a package for the PCE Committee's review.**

3. The candidate's nominating Office forwards the appointment package to the OM/DPS/POB for review of format and completeness;

4. The OM/DPS/POB forwards the completed package to the Center Associate Director for Research or designee for review and final approval;

5. Once approved, the Center Associate Director for Research or designee forwards back to the OM/DPS/POB;

6. The OM/DPS/POB forwards the appointment package to the Rockville Human Resources Center (RHRC) for final processing.

7. The RHRC informs the candidate that he/she has been approved for appointment to a SF/VA Track Position.

C. Documents Required for Appointment to the SF/VA Track

1. Request for Personnel Action (SF-52);

2. Staff Fellows: Application for Staff Fellow Program (PHS-3997) or
Visiting Associates: Request for Appointment to the International Visiting Scientists Program (FDA 2688);

3. Memo from the CBER Supervisor hiring the candidate, through the Division and Office Directors, to the Center Associate Director for Research, giving details regarding the programmatic need to hire the candidate, a summary of the candidate's education, experience, and mission relevance;

4. Statement of Duties; indicate specific allocation of time for research and regulatory activities;

5. Acknowledgement of Temporary Appointment Status, signed by the candidate (**Attachment 1**);

6. Curriculum Vitae (CV) of the candidate, to include a (1) a bibliography listing: (a) published original research, (b) original research articles "in press", (c) reviews, and (d) chapters/books; (2) additional training completed; and (3) invited presentations at national and international meetings;

7. Copy of doctoral degree and graduate transcripts (if in a foreign language, include a certified translation in English);

8. Proof that foreign education has been evaluated by a national or regional accrediting institution in the U.S., if applicable;

9. Educational Commission for Foreign Medical Graduates (ECFMG) certification for graduates of non-U.S. medical school programs, if applicable;

10. Two (2) to three (3) recent publications authored by the applicant;

11. Two (2) letters of professional reference (in English);

12. For non-U.S. citizens: provide copies of appropriate documents as proof of legal U.S. visa status (e.g., O-1 visa, H1B1 visa, or permanent resident status).

D. Criteria for extending a SF/VA Fellow for an additional three years beyond the initial four year track appointment

SF/VA track appointments are generally limited to four year terms. If there is strong evidence that a Fellow shows the potential to meet requirements for conversion to a permanent Staff Scientist position within the next few years and the Division Director supports the need, then

extensions of the initial appointment can be granted for an additional three years or for a period not to exceed a total of seven years. In this case appropriate benchmarks and expectations that must be met, as described below, should be clearly communicated to the Fellow. The extended SF/VA appointment constitutes a career track leading to potential conversion to a permanent Staff Scientist, contingent on a positive review from a site visit of the immediate supervisor (although CBER prefers if the SF/VA candidate is also actively reviewed during the same site visit), a positive PCE recommendation, and final approval by the Center Associate Director for Research.

The immediate supervisor, using the outline below, sends a memo to the Division and Office Directors providing a brief summary of the Fellow's career during the past four years that would support extending the Fellow's appointment up to three years beyond the initial SF/VA four year track program, in order to prepare him/her for possible conversion to a permanent Staff Scientist position (**see section E for further responsibilities and procedures)**. For more information on preparing for conversion to a permanent Staff Scientist position refer to the CBER Guide for the Evaluation of Research-Regulator Scientists from GS-13 through GS-15 at: http://research.cber.fda.gov/PCEcommittee/main.html.

RESEARCH ACCOMPLISHMENTS

- Specific research projects in which the Fellow plays a significant role
- Productivity as indicated by the quality and relevance impact of peer reviewed publications, including acknowledgments in publications
- Significance and impact on the Fellow's field of expertise both locally and nationally
- Level of supervisory input into the Fellow's research efforts
- Role the Fellow's research has had in supporting CBER's mission and regulatory process
- Any other pertinent research achievements (e.g., participation on committees and working groups, meeting presentations, awards, etc.)

REGULATORY ACCOMPLISHMENTS

- Specific product responsibilities
- Key regulatory accomplishments, including productivity as evidenced by number and quality of reviews of new INDs and amendments and new BLAs and supplements
- Guidance and other CBER/FDA policy documents written or contributed to, if applicable
- Published papers on regulatory subjects, if applicable
- Participation and/or leadership roles in committee meetings, workshops, and working groups
- Inspections performed, if applicable
- Any other pertinent regulatory achievements

E. Responsibilities and Procedures for extending a SF/VA for an additional three years beyond the initial four year track appointment

1. The need to extend a SF/VA Track Fellow beyond the initial four year track is identified by the immediate supervisor, who receives concurrence from the Division and Office Directors;

2. The nominating Office assembles an ad hoc Extension Evaluation Committee to review the scientific qualifications and contributions of the candidate (**see Glossary for details on Committee's composition**).

3. The potential candidate is required to present a scientific seminar to the appropriate CBER staff, including members of the Extension Evaluation Committee;

4. Interviews with the candidate are conducted by at least two members of the Extension Evaluation Committee;

5. The Extension Evaluation Committee meets to determine if the candidate possesses the experience and scientific qualifications that could meet requirements for conversion to a permanent Staff Scientist position within the next few years; and develops a consensus recommendation memo addressing their findings to the Center ADR;

6. The Office Program Manager, together with the OM/DPS/POB compiles an appointment package (**see section F**) and submits it to the Division and Office Director for approval;

7. The nominating Office forwards the package to the OM/DPS/POB to review format and completeness;

8. The OM/DPS/POB forwards the completed package to the Center Associate Director for Research or designee for review and final approval;

9. Once approved, the Center Associate Director for Research or designee forwards back to the OM/DPS/POB;

10. OM/DPS/POB forwards the appointment package to the RHRC for final processing.

F. Documents Required for the extension of SF/VA Track beyond the four year track appointment

1. Request for Personnel Action (SF-52) (**extension dates may be for up to three years**);

2. Statement of Duties; indicate specific allocation of time for research and regulatory activities;

3. Immediate supervisor memo outlining the reasons to support the extension (**see section D), and** future plans (i.e., conversion to a permanent Staff Scientist position upon a positive site visit review of their immediate supervisor and recommendation from the PCE Committee);

4. Curriculum Vitae (CV) of the candidate, to include (1) updated bibliography listing: (a) published original research, (b) original research articles "in press", (c) reviews, and (d) chapters/books, if applicable; (2) additional training completed; and (3) invited presentations at national and/or international meetings;

5. Acknowledgement of Temporary Appointment Status, signed by the candidate (**Attachment 1**);

6. Extension Evaluation Committee member's roster and consensus recommendation memo;

7. For non-U.S. citizens: proof of legal residency (e.g., O-1 visa, H1B1 visa, or permanent resident status).

APPENDIX II

SENIOR STAFF FELLOW/VISITING SCIENTIST (SSF/VS) TRACK

A. Background

The Senior Staff Fellow/Visiting Scientist (SSF/VS) Track is a seven (7) year program, created to provide an opportunity for outstanding doctoral level Service Fellows to develop their skills as independent research-regulators, while leading a research program, in order to be considered for conversion to a permanent Senior Investigator position. SSF/VS Track Service Fellows are provided with independent laboratory space, personnel resources [e.g., Support Scientists, Contract Post-doctoral Fellows (see glossary)] and funding for laboratory supplies.

SSF/VS Track Service Fellows perform research and regulatory activities including: performing and leading an independent research program that results in peer-reviewed original scientific publications; providing technical advice and guidance to other researchers and consulting with others about ongoing research/regulator projects; leadership activities; organizing conferences and workshops; teaching; attending professional meetings; applying for and receiving contracts, grants, interagency agreements, and, if applicable, developing Cooperative Research and Development Agreements (CRADAs), and leveraging other resources to support their research projects. In order to obtain expert assessment of the SSF/VS Track Service Fellow's program mission relevance, and productivity, site visits of their research program are conducted by a site visit committee composed of expert scientists from outside the Center, that are scheduled on a rotating basis every four (4) years.

B. Responsibilities and Procedures for Appointing a SSF/VS Track Service Fellow

To begin the process of appointing an SSF/VS (as a Principal Investigator (PI)) to direct a new research program, the Division identifies the need for a new research program in consultation with the Office Director and Associate Director for Research (ADR) and submits a *Memo of Intent* (**Attachment 3)** to the Center ADR for approval. Once approval is granted by the Center ADR, the Office/Division should work with the OM/DPS/POB to advertise the new Service Fellowship PI position in an open, public manner, such as relevant scientific journals or websites. Applicants within or outside CBER/FDA must submit their applications to the address indicated in the public advertisement.

The recruiting Office/Division must also assemble an ad hoc Search Committee (**see Glossary of Terms for details on the Committee's composition)** to assist in the review/hiring process, as follows**:**

1. The OM/DPS/POB forwards the applications to the Division Director, who forwards them to the immediate supervisor for review;

2. The candidate(s) deemed to have the highest scientific qualifications by the Search Committee are required to present a scientific seminar to the appropriate CBER staff, including members of the Search Committee;

3. Interviews with the candidate(s) are conducted by at least two members of the Search Committee;

4. The Search Committee meets to discuss each candidate's scientific qualifications and develops a consensus recommendation of the top and one alternate candidate for the position;

5. The Search Committee Chairperson will forward a summary memo to the Division and Office Director for approval. **The summary memo must document the members of the Search Committee, how many applications to the announcement were received and reviewed by the Search Committee, and the names and qualifications of the candidates who presented scientific seminars and were interviewed by two or more members of the Committee. Most importantly, the final summary should explain the rationale for choosing the recommended first choice and alternate candidates for the position. All of the documents associated with the search should be retained, at least until the candidate is converted to permanent status, to document the process and to support the eventual conversion package in the case of a Service Fellow, since the PCE committee will need to be able to verify that recruitment was competitive.**;

6. Once appropriate Office/Division approval is obtained, the Division Director should submit a candidate recommendation summary memo to the Center ADR through the Office ADR for final approval. The Division Director memo should include all the same information as the Chair's memo with the additional information of the final candidate chosen, suggested salary request, and whether the intended pathway is to hire the candidate into the Service Fellowship program (PI/conversion-track) or directly into a permanent SI position (details regarding these pathways are provided below). The memo should be accompanied by a description of the proposed research program, to include the program name, public health importance, regulatory contribution, relevance to FDA mission, and research approach (see http://research.cber.fda.gov:591/ResearchPrograms for examples);

7. Once the Center ADR approves the requested hire and the salary, the Office Program Manager, together with OM/DPS/POB will compile an appointment package and submits it to the Division Director and Office Director for signatures. Note: **If the salary that the Division/Office intends to offer is equivalent to a GS-14 or higher the candidate must undergo peer review through CBER's PCE Committee prior to final selection. Refer to the *CBER Guide for the Evaluation of Research-Regulator Scientists from GS-13 through GS-15* (http://research.cber.fda.gov/PCEcommittee/Section0.html) for instruction on preparing a package for the PCE Committee's review.**

8. The OM/DPS/POB forwards the completed package to the Center ADR or designee for review and final approval;

9. Upon approval by the Center ADR, the package is forwarded back to OM/DPS/POB to enter personnel information into the appropriate personnel systems. If the package is not approved by the Center ADR, it will be returned to the hiring Office with explanation;

10. The OM/DPS/POB forwards the package to the Rockville Human Resources Center (RHRC) for final processing and notification to the candidate that he/she is approved for appointment into the SSF/VS track position.

C. Documents Required for Appointment to the SSF/VS Track:

1. Request for Personnel Action (SF-52);

2. Senior Staff Fellows: Application for Staff Fellow Program (PHS-3997) or Visiting Scientists: Request for Appointment to the International Visiting Scientists Program (FDA 2688);

3. Search Committee members roster and Search Committee individual and summary recommendations;

4. Statement of Duties; indicate specific allocation of time for research and regulatory activities;

5. National recruitment advertisement (copy of advertisement in scientific journal or internet advertisement printout)

6. Curriculum Vitae (CV) of the candidate, to include a (1) a bibliography listing: (a) published original research, (b) original research articles "in press", (c) reviews, and (d) chapters/books; (2) additional training completed; and (3) invited presentations at national and international meetings

7. Acknowledgement of Temporary Appointment Status, signed by the candidate (**Attachment 1**);

8. Copy of doctoral degree and graduate transcripts (if in a foreign language, a certified translation in English);

9. Proof that foreign education has been evaluated by a national or regional accrediting institution in the U.S, if non-US citizen;

10. Educational Commission for Foreign Medical Graduates (ECFMG) certification (for graduates of non-U.S. medical school programs), if applicable;

11. Four (4) to five (5) examples of publications authored by the applicant;

12. Four (4) letters of professional reference (in English) from scientists **outside** of CBER who are <u>not</u> collaborators and who are experts in the candidate's field;

13. For non-U.S. citizens: proof of legal residency (e.g., O-1 visa, H1B1 visa, permanent resident status).

ATTACHMENT 1

ACKNOWLEDGEMENT OF TEMPORARY APPOINTMENT STATUS

I. I fully understand that:

- My Service Fellowship position with the Center for Biologics Evaluation and Research is temporary;

- I may be terminated at any time prior to my expiration date for a number of reasons, including but not limited to: my services are no longer needed; concerns about the pace or progress of my research and/or regulatory work; budget constraints, including the realignment or loss of resources to other research endeavors; or any other reasons relating to my performance and/or conduct:

- Participation in the Service Fellowship Program does not guarantee or imply any right or expectation for conversion to a permanent appointment anytime during or after the term of employment.

II. I further understand that my appointment in the:

- Staff Fellow/Visiting Associate Track is generally limited to a four year term. However, if there is strong evidence that I could meet requirements for conversion to a permanent Staff Scientist position within the next few years, extensions of my appointment can be granted for an additional three years or for a period not to exceed a total of seven years. In this case, I acknowledge that appropriate benchmarks and expectations must be met as described by my supervisor, and that I must have approval by my Division, Office and the Center Associate Director for Research: or

- Senior Staff Fellow/Visiting Scientist Track is for up to seven years, and that any exceptional extensions beyond the maximum will require written justification from the Division and Office indicating the necessity for the extension, and must be approved by the Center Associate Director for Research.

As of _____ I will have completed ___ year(s) under the:
(date last yr. completed)

☐ Staff Fellow/Visiting Associate Track Program
☐ Senior Staff Fellow/Visiting Scientist Track Program

Visiting Associates/Scientists: I further understand my appointment will be terminated automatically if at any time my employment visa and/or valid work authorization expires or is cancelled for any reason.

_____ _____
Service Fellow Date

* Staff Fellow, Visiting Associate, Senior Staff Fellow, or Visiting Scientist

ATTACHMENT 2

TERMINATION LETTER EXAMPLE

Date

Candidate's Name
Laboratory of _____
Division of _____
Office of _____
Center for Biologics Evaluation and Research
Bethesda, MD 20892

Dear Dr. _____:

As you are aware, the program under which you are appointed is a temporary program that may allow for periodic extensions. Under the program, the research and regulatory contributions of the candidate are reviewed yearly and decisions are made regarding the continuance of appointments.

As of _____, you will have completed _____ years in the [insert track program (e.g., Staff Fellow/Visiting Associate Track Program)]. This letter is to inform you that your appointment will expire on _____. Your employment with CBER will end at the close of business on that day.

Sincerely,

Carolyn A. Wilson, Ph.D.
Associate Director for Research,
Center for Biologics Evaluation and Research

Candidate's signature of receipt_____ Date_____

ATTACHMENT 3
(Use official letterhead)

Memo of Intent to Hire a Principal Investigator to Direct a New Research Program

Date:

From: Immediate Supervisor

Subject: Request to hire a Principal Investigator (PI) to direct a new research program in the Office of _____, Division of _____

To: CBER Associate Director for Research

Through: Division Director, Office Director, and Office Associate Director for Research

It is our intention to hire a PI to direct a new research program in the Laboratory of _____.

**Describe the new research program here. Please identify the reasons the new program is needed and provide defining characteristics that distinguish it from existing research programs

We understand the following:

- The PI selection process must include selection through an open competition advertised outside the Agency.

- The candidate must undergo peer review through the Promotion, Conversion, and Evaluation committee prior to final selection when:

    - Hiring a PI within CBER into the Service Fellowship Program as a Senior Staff Fellow or Visiting Scientist at an equivalent salary to the GS-13, GS-14, or GS-15 levels;

    or

    - Hiring a candidate from outside of CBER at the equivalent salary to the GS-14 or GS-15 levels.

We acknowledge that according to policies set forth by the Center we must provide the PI independent laboratory space, a budget for personnel resources (e.g., ORISE/IRTA fellow), and funding for laboratory equipment and supplies, as well as the opportunity to apply for and receive outside funding with Office and Center approval.

_____ _____

Approved Date **Not Approved Date**

Reason for non-approval:

_____

CBER Associate Director for Research

GLOSSARY OF TERMS

Contract Post-doctoral Fellows – Fellows hired through a contract mechanism, such as Oak Ridge Institute for Science Education (ORISE), Intramural Research Training Award (IRTA), or Interagency Oncology Task Force (IOTF).

Conversion - changes an employee from a temporary appointment to permanent status, in the same agency, with no break in service or with a break of three (3) days or less.

Educational Commission for Foreign Medical Graduates (ECFMG) - an accredited institution, which provides required certification for candidates who are graduates of non-U.S. medical school programs applying to a permanent position.

Extension - continues a time-limited appointment up to the maximum allowed by the authority under which it was affected.

Extension Evaluation Committee: is an ad hoc Committee convened to evaluate a Staff Fellow or Visiting Associate (SF/VA) for an additional three years beyond the initial four year track appointment. This Committee must consist of at least four permanent Senior Investigators*. The members should include: 1) Chairperson (NOT the immediate supervisor); 2) at least three additional Senior Investigators (one member must be from outside the nominating Office/Division), who are scientific experts, to the extent feasible, in the scientific area for which the SF/VA is being evaluated. Exceptions to the proposed composition of the Committee may be made with review and approval by the Center ADR.

Foreign national - a person owing permanent allegiance to a foreign country (alien).

Permanent Resident – a non-US citizen admitted to the U.S. as a legal permanent resident (LPR) with an immigrant visa or permanent resident card.

Permanent Resident Card - A card commonly referred to as a Green Card; allowing the permanent resident gainful employment in the U.S.

Promotion and Conversion Evaluation (PCE) Committee - a CBER review committee chartered by the Center Director to evaluate the scientific qualifications and contributions of (1) Research-regulator scientists considered for promotion to GS-13 and above; (2) Service Fellows considered for conversion to a permanent research-regulator position at GS-13 and above; (3) Permanent Staff Scientists considered for reassignment as permanent Senior Investigator positions at GS-13 and above; (4) Outside candidates considered for employment as permanent Staff Scientists/Senior Investigators at GS-13 and above. In addition, PCE performs mandatory four year cyclical review of Research-regulator scientists (GS-13 to GS-15). The PCE Committee will also review such candidates from other FDA Centers as requested by that Center's leadership.

Request for Personnel Action (SF-52) – Office of Personnel Management's (OPM) official form used to request and process various civilian personnel actions.

Permanent Resident – a non-US citizen admitted to the U.S. as a legal permanent resident (LPR) with an immigrant visa or resident alien card.

Search Committee: is an ad hoc Committee, formed by the nominating Office/Division, convened to evaluate a candidate for a Principal or Senior Investigator position. This Committee must consist of at least four permanent Senior Investigators*. These members should include: 1) Chairperson (NOT the immediate supervisor); 2) at least three additional Senior Investigators (one member must be from outside the nominating Office/Division), who are scientific experts, to the extent feasible, in the area for which the candidate(s) are being evaluated. Exceptions to the proposed composition of the Search Committee may be made with review and approval by the Center ADR.

Senior Investigator – an independent doctoral level research-regulator, GS-13 and above, who is a permanent employee performing research and regulatory activities leading their own scientific research program; appointed after being selected in an open competition on the basis of candidate's independent scientific research and regulatory accomplishments. Senior Investigators are expected to perform regulatory activities, with research allocation no less than 50%.

Site Visit - is an evaluation by a group of qualified outside experts of the quality of the scientific achievements, productivity and mission relevance of the research programs. The experts base their review on a combination of detailed written reports provided in advance by the scientists under review, and oral presentations and interviews on the day of an in-person visit to CBER.

Staff Scientist - a doctoral or non-doctoral research-regulator, GS-13 and above, who is a permanent employee possessing exceptional technical skills or unique scientific expertise; performs important collaborative work within an existing research/regulatory program; does not receive independent resources, but is supported by and carries out research and regulatory activities under the supervision of a Senior Investigator. Staff Scientists are expected to spend no more than 50% of their time performing regulatory activities.

Support Scientist – a non-doctoral research-regulator, who is a permanent employee up to and including GS-12, functioning in support of a Senior Investigator's research program. Support scientists may engage in regulatory activities.

Visa – certificate issued or a stamp marked on the applicant's passport by the immigration authorities of a country to indicate that the applicant's credentials have been verified and he/she has been granted permission to enter the country for a temporary stay within a specified period.

> **H1B1 Visa**: Issued to a temporary worker to perform services that require practical application of a highly specialized knowledge. Time limitation is a maximum of six (6) years, and is sponsor specific.
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> **O-1 Visa**: Issued to an alien having extraordinary ability in science. Extensions of stay may be granted in increments of no more than one year at a time. Time limitation is for the duration of the specific activity, and is sponsor specific.