III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in Guidance for Industry #170. These collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been approved under OMB Control No. 0910–0540.

IV. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either CVM home page (*http://www.fda.gov/cvm*) or the Division of Dockets Management Web site *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: March 1, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4322 Filed 3–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submissions for OMB Review; Comment Request; Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability to Recruit and Retain Staff

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Human Resources (OHR), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. The purpose of this notice is to allow 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Evaluation of the Impact of the New Conflicts of Interest regulations on the National Institutes of Health's Ability To Recruit and Retain Staff.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: To assess the impact of new Department of Health and Human Services (HHS) conflicts of interest regulations on the NIH's ability to continue to attract and recruit highly qualified scientific personnel. Gauging both the immediate and long-term impact of these new rules is crucial to NIH's ability to develop and maintain a world-class staff. This project will produce data that will help NIH and HHS leaders determine the impact of the regulations and how to minimize the effect of the regulations on NIH's ability to recruit and retain staff. NIH intends to survey potential applications for NIH employment from scientific organizations from which NIH has traditionally drawn leading scientific personnel, and those senior scientists and administrators who have voluntarily left NIH since February 2005. This will allow NIH to determine whether the regulations impact individuals' attitudes about employment at NIH and the likelihood of their joining and/or leaving the agency. This proposed one-time survey is part of a larger study that will provide OHR with the high-quality data needed to evaluate the impact of the new rules. Data will be collected on respondents' understanding of the new regulations, how they believe the regulations could impact them, and on their feelings about working at NIH in light of the regulations. Data will also be collected from current NIH employees and the combined data will be used in the review of the rules. The survey is planned to launch in early 2007 and to be in the field for eight weeks.

Frequency of Response: Once.

Affected Public: Individuals or households.

Type of Respondents: Potential applicants for NIH positions and senior scientists and administrators who have voluntarily left NIH since February 2005.

The annual reporting burden is as follows:

Type of respondent	Number of respondents	Frequency of response	Average time per response (minutes)	Estimated total annual hour burden (hours)
Potential Applicants	400	1	15	100
Former NIH Employees	100	1	10	16.67
TOTAL	500			116.67

Total Number of Respondents: 500.

Total Number of Responses: 500.

Total Hours: 116.67 hours.

The annualized cost to respondents is estimated at: $3,850.

There are no capital costs, operating costs, and/or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comment to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive

Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mr. Richard M. Taffet, Director, Client Services Division; Office of Human Resources, Office of the Director, National Institutes of Health, Room 2–D234, East Jefferson Street, Bethesda, MD 20892–8503, or call the non-toll-free number 301–402–6627, or e-mail your comments or request, including your address, to: *Taffetr@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of this publication.

Dated: February 26, 2007.

Richard M. Taffet,

Director, Client Services Division, OHR, OD, National Institutes of Health.

[FR Doc. 07–1087 Filed 3–8–07; 8:45 am]

BILLING CODE 4140–10–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods of Treating Conditions Characterized by Unwanted or Excessive Presynaptic Neuronal Activity or Secretion

Description of Technology: Botulinum toxins are highly potent neurotoxins produced by the spore-forming bacterium, *Clostridium botulinum.* Poisoning by any of the seven known botulinum toxin serotypes, designated A to G, results in impaired communication between nerve and muscle that causes paralysis in patients and possible death by respiratory failure. Injections of botulinum toxins A and B have been approved for treating disorders associated with uncontrollable muscle contractions. However, the use of approved botulinum toxins is limited by their temporary duration of action, the development of neutralizing antibodies after repeated injections, and cross-reactivity with autonomic neurons. Thus, an interest exists in finding new ways to achieve longer-lasting effects using botulinum toxins.

This technology describes a novel method for treating diseases by combining two botulinum toxins, botulinum toxin A and B. Researchers at the FDA have shown that the combination of the A and B toxins is synergistic, improves muscle paralysis characteristics compared to individually administered serotypes, and produces a longer duration of action and a faster onset of paralysis. The synergistic effect allows lower doses compared to single use of either toxin and should help reduce resistance after repeated use. This technology is beneficial for the treatment of diseases already known to be treatable with botulinum toxins, such as facial wrinkles, headaches, muscle spasms, and cervical dystonia. This technology is also suitable to treat other diseases, such as strabismus, hemifacial spasms, facial nerve damage, and hyperhidrosis (excessive sweating).

Available for licensing are methods and pharmaceutical compositions for administering a combination of botulinum toxin A and B to treat unwanted or excessive presynaptic neuronal activity or secretion.

Application: Alternative therapy for diseases treatable with individual botulinum toxins; such therapies include Botox®, Botox Cosmetic®, and Myobloc®.

Market: Patients who are currently prescribed individual toxins for treatment of diseases such as strabismus, blepharospasm, cervical dystonia, and cosmetic wrinkle reduction.

Development Status: Pre-clinical data is available.

Inventors: James E. Keller (CBER/FDA).

Publications: JE Keller. Recovery from botulinum neurotoxin poisoning in vivo. Neuroscience 2006 May 12;139(2):629–637.

Patent Status: U.S. Provisional Application No. 60/773,412 filed 15 Feb 2006 (HHS Reference No. E–172–2005/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Norbert Pontzer, PhD, J.D.; 301/435–5502; *pontzern@mail.nih.gov.*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research, Laboratory of Respiratory and Special Pathogens, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact James E. Keller, PhD, at 301/ for more information.

Synergistic Effect of TGF-Beta Blockade and Immunogenic Agents on Tumors

Description of Technology: Overcoming immune suppression in cancer patients is a major challenge for the success of cancer immunotherapy. TGF–β and its receptors are expressed in essentially all tissues, and they have been found to be important in many cellular processes including cell growth inhibition. The inhibition of TGF–β signaling has been shown to have an inhibitory effect on tumor growth. However, TGF–β also has immunosuppressive properties.

Cancer vaccines are one of many therapies available for treatment and prevention. In particular, vaccines that elicit immune responses have been used to treat or control tumor growth that has evaded immunosurveillance. However, these vaccines have demonstrated limited success.

Available for licensing is a method for synergistically affecting tumor growth involving the administration of an agent that blocks the TGF–β signaling pathway, in combination with an immunogenic agent. The agent that blocks the TGF–β signaling pathway may inhibit the immunosuppressive effects of TGF–β, while the immunogenic agent is believed to enhance an immune response. Surprisingly, the combination of such elements produces a synergistic effect. The administration of the 1D11.16 anti-TGF–β antibody in combination with the human papilloma virus E7(49–57) peptide enhances tumor regression in an animal model. The administration of the 1D11.16 anti-TGF–β antibody in