## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0275]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Application for Participation in the Medical Device Fellowship Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application for Participation in the Medical Device Fellowship Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 9, 2004 (69 FR 41508), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0551. The approval expires on February 28, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–21074 Filed 9–17–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0395]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an application for participation in the Medical Device Fellowship Program (MDFP). Elsewhere in this issue of the **Federal Register** FDA published a notice announcing the Office of Management and Budget's (OMB's) approval of this collection of information (OMB control number 0910–0551). Since this was an emergency approval that expires on February 28, 2005, FDA is following the normal PRA clearance procedures by issuing this notice.

**DATES:** Submit written or electronic comments on the collection of information by November 19, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Application for Participation in the Medical Device Fellowship Program (OMB Control Number 0910–0551)—Extension**

Collecting applications for the MDFP will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| FDA Form No. | No. of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| FDA Form 3608 | 100 | 1 | 100 | 1 | 100 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of inquiries that have been received about the program and requests for application forms over the past year. We anticipate the number of interested individuals and universities, and subsequent number of applications, to increase as we continue to develop an outreach program and an alumni base.

In addition, we would expect applicants who are not selected for their preferred term of employment to reapply at a later date. For these reasons we would expect that the number of applications submitted in the second and third years would increase substantially. During the first year, we expect to receive 100 applications. We believe that we will receive approximately 100 applications the second year and 100 applications the third year. FDA believes it will take individuals 1 hour to complete the application. This is based on similar applications submitted to FDA.

Dated: September 9, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–21075 Filed 9–17–04; 8:45 am]

**BILLING CODE 4160–01–S**

## 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 invention listed below is owned by an agency of the U.S. Government and is 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 listed below may be obtained by contacting Marlene Shinn-Astor, J.D., Technology Licensing Specialist, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/435–4426; fax: 301/402–0220; e-mail: *shinnm@mail.nih.gov*.

**Evaluative Means for Detecting Inflammatory Reactivity**

*Esther M. Sternberg et al. (NIMH)*

U.S. Patent 5,209,920 issued 11 May 1993 (DHHS Reference No. E–289–1988/2–US–01)

Dysregulations of neuroendocrine stress responses have profound effects on the immune system that are associated with various autoimmune/inflammatory disorders such as rheumatoid arthritis (RA) and psychiatric conditions such as depression and post traumatic stress disorder (PTSD). Inventors from NIMH had previously found that the hypothalamic pituitary adrenal (HPA) hormonal axis, which acts as a regulatory checkpoint between the neuroendocrine and the immune system, is dysregulated in such disorders. Further research now shows that in particular, dysregulation in the secretion of corticotropin releasing hormone (CRH) from the hypothalamus contributes to these conditions. Therefore, the HPA axis, CRH and CRH receptors can serve as major targets for drug development and diagnosis of these diseases.

This patent covers the development of therapeutics and diagnostics for autoimmune/inflammatory diseases that affect millions of people. The patent proposes the use of a wide variety of classes of HPA axis active agents to treat inflammatory illnesses. The patent claims specifically predict that an HPA agonist can be used to treat arthritis. The usefulness and applicability of the patent also extends to the CRH receptor antagonists (*e.g.*, CRH R1 antagonist, Antalarmin) that are now being developed for the treatment of depression and PTSD. Diagnostically, this invention can be used to identify individual susceptibility to autoimmune/inflammatory diseases. Testing of the HPA axis to predict and select responders and non-responders to HPA agonists and CRH receptor antagonists could provide an approach for safe application of such therapeutic agents to a larger proportion of the target population. For example a subject found to have a low HPA axis responsiveness based upon the methods as described in the patent, would be predicted to have a greater risk of developing adrenal insufficiency while being treated with this new class of drugs. Such individuals could then be treated accordingly to prevent adverse events while on CRH antagonist therapy.

Currently, such predictive approaches are not used routinely in clinical settings. The potential of this invention to diagnose and treat certain diseases in a predictive fashion makes it an excellent candidate for simultaneously developing therapeutics and the associated diagnostics. Antalarmin—which is being developed through an NIH initiative—has passed preliminary assessment at the FDA and will soon be in phase I human trials. The inventors found Antalarmin to be effective in reducing clinical arthritis score in rats by 50%, possibly through its blockade of CRH's peripheral pro-inflammatory effects.

Given that an estimated 43 million people in the United States alone have arthritis or other rheumatic conditions, and that this number is expected to reach 60 million by 2020, this patent holds great potential in further development of therapeutics and diagnostics for autoimmune/inflammatory diseases.

Dated: September 14, 2004.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 04–21120 Filed 9–17–04; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer