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