DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Cancer Institute Science Enrichment Program Surveys

SUMMARY: In compliance with the requirement of section 44 U.S.C. 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: National Cancer Institute Science Enrichment Program Evaluation: Follow-up Survey. *Type of Information collection Request:* New. *Need and Use of Information Collection:* NCI SEP is a five-week summer residential program on university campuses that services under-represented minority and under-served students who have just completed ninth grade. The program goals are to (1) Encourage student participants to select careers in science, mathematics, and/or research, and (2) broaden and enrich students' science, research, and sociocultural backgrounds. The proposed data collection is a follow-up survey of SEP students who participated in the program during one of three different funding cycles between 1990 and 2003, and a control group of students who did not participate in the program. The information from the proposed data collection will supplement previous evaluation results, which have been and will continue to be used to judge program process and outcomes. *Frequency of Response:* One time. *Affected Public:* Individuals or households. *Type of Respondents:* High school and college students, and young adults. *Cost to Respondents:* $5,872. The annual reporting burden is as follows:

ESTIMATES OF HOUR BURDEN: BURDEN REQUESTED

Type of respondents	Number of respondents	Frequency of response	Average time per response	Average annual hour burden
Former SEP Participants (1990–2003):				
SEP participants 1990–1997	644	1	0.25	161
SEP participants 1998–2002	479	1	0.25	119.75
SEP participants 2003	100	1	0.25	25
Control Group Participants	245	1	0.25	61.25
Total	1,468			367

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: 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. Frank Jackson, Center to Reduce Cancer Health Disparities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Suite 602, Rockville, MD 20852, or call non-toll-free number (301) 496–8589, or e-mail your request, including your address to *fj12i@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: July 28, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–17705 Filed 8–3–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Commercializing Instruments, Reagents and Related Products Used for Sequencing of Single Nucleic Acid Molecules on a Substrate, Based on High Speed Parallel Molecular Nucleic Acid Sequencing Method

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. § 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in Patent Applications US 60/151,580, filed August 29, 1999; PCT/US00/23736, filed August 29, 2000 and US 10/070,053, filed June 10, 2002; entitled ''High Speed Parallel Molecular Nucleic Acid Sequencing'', to Helicos BioSciences Corporation, having a place of business in Cambridge, MA. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before October 4, 2004 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Cristina Thalhammer-Reyero, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: *ThalhamC@mail.nih.gov*; Telephone: 301–435–4507; Facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The invention relates to a method and apparatus for DNA sequencing, also known as Two Dye Sequencing (TDS). This invention is based on Fluorescence Resonance Energy Transfer (FRET), a technology increasingly in use for

several molecular analysis purposes. In particular, the method consists of: (1) Attachment of engineered DNA polymerases labeled with a donor fluorophore to the surface (chamber) of a microscope field of view, (2) addition to the chamber of DNA with an annealed oligonucleotide primer, which is bound by the polymerase, (3) further addition of four nucleotide triphosphates, each labeled on the base with a different fluorescent acceptor dye, (4) excitation of the donor fluorophore with light of a wavelength specific for the donor but not for any of the acceptors, resulting in the transfer of the energy associated with the excited state of the donor to the acceptor fluorophore for a given nucleotide, which is then radiated via FRET, (5) identification of the nucleotides most recently added to the primer by recording the fluorescent spectrum of the individual dye molecules at specific locations in the microscope field, and (6) converting the sequential spectrum into a DNA sequence for each DNA molecule in the microscope field of view.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to ''commercializing instruments, reagents and related products used for sequencing of single nucleic acid molecules on a substrate'.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. § 552.

Dated: July 28, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–17704 Filed 8–3–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Preliminary List of Drugs for Which Pediatric Studies Are Needed

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is providing notice of a ''Preliminary List of Drugs for Which Pediatric Studies Are Needed.'' The NIH developed the list in consultation with the Food and Drug Administration (FDA) and pediatric experts, as mandated by the Best Pharmaceuticals for Children Act (BPCA). This list identifies 23 drugs that will be reviewed at a scientific meeting on October 25 and 26, 2004, in Bethesda, Maryland. At that time, the drugs will be discussed by the NIH, FDA, and a group of scientific experts to help identify those in most urgent need of study. It is anticipated that the final listing of drugs most in need of study for use by children to ensure their safety and efficacy will be selected from this preliminary listing and will be published in the **Federal Register** in January 2005. This will be the third annual list published by NIH. NIH will continue to update the list at least annually until the Act expires on October 1, 2007.

DATES: The list is effective upon publication.

FOR FURTHER INFORMATION CONTACT: Dr. Tamar Lasky, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Suite 5C01G, Bethesda, MD 20892–7510, e-mail <*BestPharmaceuticals@mail.nih.gov*>, telephone 301–594–8670 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The NIH is providing notice of a ''Preliminary List of Drugs for Which Pediatric Studies Are Needed,'' as authorized under Section 3, Pub. L. 107–109 (42 U.S.C. 409I). On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that not later than one year after the date of enactment, the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (2) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider, for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in pediatric populations; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in pediatric populations; and (4) whether reformulation of the drug is necessary. In developing this list, the NIH consulted with the FDA and experts in pediatric research and practice. A preliminary list of drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

Following are the drugs and indications that will be reviewed at a scientific meeting on October 25 and 26, 2004, to select drugs and indications to add to the list for which pediatric studies are most urgently needed:

Acetylcysteine—acetaminophen poisoning
Aclometasone diproprionate cream—dermatitis
Acyclovir—herpetic infections
Albendazole—Giardia infection
Amantadine—influenza
Cefuroxime—infections in children with sickle cell anemia
Cephalexin—acute, oral infections
Chlorothiazide—hypertension
Clarithromycin—oral infections in dental patients
Clonidine—autism, attention deficit disorder
Cyclosporine—heart transplant patients
Desonide ointment—dermatitis
Ethambutol—tuberculosis
Flecainide—life threatening ventricular arrhythmias
Griseofulvin—tinea capitis
Hydrochlorothiazide—hypertension
Hydrocortisone valerate ointment and cream—dermatitis
Hydroxychloroquine—lupus
Ivermectin—scabies
Malathion—lice
Methadone—opiate addicted neonates
Rimantidine—influenza
Sulfasalazine—juvenile rheumatoid arthritis

Twelve additional drugs have been identified as having a sizeable number of studies published since 1990. These twelve drugs will receive extensive