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

systematic literature reviews and meta-analysis to assess the safety and efficacy questions that remain unstudied. The twelve drugs are:

Amoxicillin
Amoxicillin clavulanate potassium
Cefixime
Chloral Hydrate
Dexamethasone
Epinephrine
Fluconazole
Mebendazole
Methylprednisolone
Prednisolone
Prednisone
Trimethoprim

The Foundation for the NIH, Inc., has referred four on-patent drugs to NIH. The feasibility and public health importance of studying these drugs will be reviewed at the scientific meeting on October 25 and 26, 2004. The four on-patent drugs that have been referred by the Foundation for the NIH, Inc., for consideration for study are:

Bupropion
Morphine
Sevelamer
Zonisamide

Individuals or organizations with comments, information, and current data regarding these drugs are requested to contact Dr. Tamar Lasky at NICHD (contact information above).

Dated: July 28, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 04–17703 Filed 8–3–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

National Outcomes Performance Assessment of the Collaborative Initiative to Help End Chronic Homelessness—(OMB No. 0930–0247; Revision)—This Initiative is coordinated by the U.S. Interagency Council on the Homeless and involves the participation of three Council members: the Department of Housing and Urban Development (HUD), the Department of Health and Human Services (HHS), and the Department of Veterans Affairs (VA). Within HHS, SAMHSA's Center for Mental Health Services is the lead agency.

This project will monitor the implementation and effectiveness of the Initiative. A national assessment of client outcomes is needed to assure a high level of accountability and to identify which models work best for which people, using the same methods for all sites. To this end, this project will provide a site-by-site description of program implementation, as well as descriptive information on clients served; services received; housing quality, stability, and satisfaction; and, client outcomes in health and functional domains. The VA Northeast Program Evaluation Center (NEPEC), based at the VA Connecticut Healthcare System in West Haven, Connecticut, is responsible for conducting this project.

Data collection will be conducted over a 36-month period. At each site, a series of measures will be used to assess (1) program implementation (*e.g.,* number and types of housing units produced and intensity and type of treatment and supportive services provided), (2) client descriptive information (*e.g.,* demographic and clinical characteristics, and housing and treatment services received) and, (3) client outcomes.

Client outcomes will be measured using a series of structured instruments administered by evaluation personnel employed and funded by the local VA medical center or outpatient clinic involved at each Initiative site who will work closely with central NEPEC staff. Assessment will be conducted through face-to-face interviews and, when needed, telephone interviews. Interviews (approximately one hour in length) will be conducted at baseline, defined as the date of entry into the clinical treatment program leading to placement into permanent housing, and quarterly (every 3 months) thereafter for up to three years. Discharge data will be collected from program staff at the time of official discharge from the program, or when the client has not had any clinical contact from members of the program staff for at least 6 months. In addition to client interviews, key informant interviews with program managers at each site will be conducted annually.

At most Initiative sites, it is expected that more people will be screened and or evaluated for participation in the program than receive the full range of core housing and treatment services. Entry into the Initiative is conceptualized as a two-phase process involving an Outreach/Screening/Assessment Phase (Phase I), and an Active Housing Placement/Treatment Phase (Phase II) that is expected to lead to exit from homelessness; in some programs these two phases may be described as the Outreach and Case Management Phases. It will be important to have at least some minimal information on all clients so as to be able to compare those who enter Housing/Treatment with those who do not.

Client-level data at the time of first contact with the program (*i.e.*, before the client receives more intensive treatment or housing services) will be collected using a screener form. The screener form will be completed by a member of the clinical staff when prospective clients are first told about the program, and express interest in participating in the program (*i.e.*, when they enter Phase I). The purpose of this form is to identify the sampling frame of the evaluation at each site, or the pool of potential clients from which clients are then selected. Program implementation will be measured using a series of progress summaries.

Initiative sites will be responsible for screening potential participants, assessing homeless and disabling condition eligibility criteria for the program, and documenting eligibility as part of the national performance assessment. Each site will identify a limited number of portals of entry into the program in a relatively small geographic area, so that the evaluator can practically and systematically contact clients about participating in the evaluation. VA evaluation staff, clinical program staff, and NEPEC will work together to establish systematic procedures for assessing eligibility, enrolling clients into the Housing/Treatment Activity of the Initiative, obtaining written informed consent to participate in the national performance assessment, and other evaluation activities.

The revisions being made are the addition of a comparison group to be recruited from all participating sites. A relatively small number (N = 61, on average) of individuals can be served at each site due to the considerable cost of providing persons who are chronically homeless with permanent housing and a comprehensive array of supportive services needed to sustain housing tenure and to promote self-sufficiency among the target population and limited federal funds available for the program. Those in the comparison group (N = 39, on average) will be enrolled after client recruitment/enrollment for program