DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0164]

Positron Emission Tomography Drug Products; Draft Guidance for Industry on Content and Format of an Abbreviated New Drug Application; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 27, 1997, the comment period on the agency's draft guidance entitled ''Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of April 23, 1997 (62 FR 19767). FDA is extending the comment period in response to a request by the Institute for Clinical PET for additional time for the PET community to review the agency's proposed guidance on the submission of ANDA's for PET drugs.

DATES: Written comments by August 27, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter Rickman, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5862.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 23, 1997, FDA published a notice announcing the availability of a draft guidance document entitled ''Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products.'' The draft guidance is intended to assist applicants who wish to submit ANDA's for Fludeoxyglucose F18 injection. The notice invited interested persons to submit written comments on the draft guidance by June 28, 1997.

On May 5, 1997, FDA received a letter from Ernest V. Garcia, President of the Institute for Clinical PET, requesting that the agency extend the comment period on the draft guidance on ANDA's for PET drug products. FDA has considered this request and is extending the comment period for 60 days.

Interested persons may, on or before August 27, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15760 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice

Request for application, low-cost, high-accuracy DNA sequencing technologies.

NIH GUIDE, Volume 26, Number 16, May 16, 1997.

RFA: HG–97–002.

P.T. 34; K.W. 1215018, 0755045.

National Human Genome Research Institute.

Letter of Intent Receipt Date: August 1, 1997.

Application Receipt Date: October 16, 1997.

Purpose

The purpose of this Request for Applications (RFA) is to stimulate research on next-generation technologies that have the potential to reduce the cost of high-accuracy genomic DNA sequencing by at least an order of magnitude.

Healthy People 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a PHS-led national activity for setting priority areas. This RFA, Low-Cost, High-Accuracy DNA Sequencing Technologies, is related to several priority areas including cancer, heart disease and stroke, diabetes and chronic disability conditions, and maternal and infant health. Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report: Stock No. 017–001–00474–0 or Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone 202–512–1800).

Eligibility Requirements

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, companies, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Applications from foreign institutions will not be accepted. However, subcontracts to foreign institutions are allowable, with sufficient justification.

Mechanism of Support

This RFA will use the National Institutes of Health (NIH) research project grant (R01), First Independent Research Support and Transition (FIRST) (R29) award, exploratory/developmental grant (R21), and program project (P01) mechanisms. The total project period for an R01 or P01 application submitted in response to this RFA may not exceed three years. R29 grants are subject to the usual conditions for the FIRST awards. Exploratory/developmental (R21) grants will be limited to $100,000 direct cost per year for a maximum of three years (one year longer than NHGRI's standard R21 grant). The R21 grant mechanism is used to support highly creative approaches for which substantial preliminary data are not yet available. Specific information about the R21 grant mechanism can be found in the NHGRI Program Announcement PA–97–045, ''Pilot Projects or Feasibility Studies for Genomic Mapping, Sequencing and Analysis'' (available from http://www.nhgri.nih.gov/Grant___info/Funding/Research/pilotpa.html). The R21 grants are not renewable, but future project continuation is possible through other grant mechanisms such as the R01 or P01. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement. The anticipated award date is July 1, 1998. It is anticipated that another RFA related to DNA sequencing

technology will be issued by NHGRI next year.

Funds Available

It is anticipated that approximately $5 million (total costs) will be available for this initiative in Fiscal Year 1998. NHGRI anticipates that projects at very different stages of development will be submitted in response to this RFA. Therefore, the size of awards may vary substantially; accordingly the number of grants funded may be as few as five or as many as 20, depending on the quality and scope of the applications received. Awards pursuant to this RFA are contingent upon the availability of funds for this purpose. The amount of funding for this solicitation may be increased if a large number of highly meritorious applications is received and if funds are available. Only applications found to be of high scientific merit will be considered for funding and all of the funds will not be spent if there are not enough highly meritorious applications. Any applicant planning to submit an application for more than $500,000 direct cost in any one year MUST contact the NHGRI staff listed under inquiries in order for the application to be accepted by NIH.

Research Objectives

Background

NHGRI is currently engaged, along with several other federal, private, and international organizations, in a fifteen year research program called the Human Genome Project (HGP). The goals are to characterize the genomes of human and selected model organisms, to develop technologies to analyze the human genome, to examine the ethical, legal, and social implications of human genetics research, and to train scientists who will be able to utilize the tools and resources developed through the HGP to pursue biological studies that will improve human health.

Significant progress toward completing these goals has been made in the past seven years, with several having already been achieved. The genetic mapping goals for both the human and the mouse have been met. Progress toward the human and mouse physical mapping goals is steady, with sufficient support in place to allow the achievement of these goals ahead of schedule. There has also been good progress toward meeting the sequencing goals. The genomic sequence of both *E. coli* and *S. cerevisiae* have been determined, the sequence of *C. elegans* is expected to be finished by 1998, and the complete sequence of *D. melanogaster* is expected to be finished shortly after the end of this century.

As a result of recent improvements in sequencing technology and strategies, confidence is high that current technology, enhanced by foreseeable improvements, will be sufficient to complete a reference human genomic DNA sequence by the target date, 2005. To this end, pilot projects for large-scale production of human genomic DNA sequence were initiated in 1996. However, even with anticipated improvements, DNA sequencing is likely to remain too expensive to meet the scientific demand for sequence information. For example, additional sequencing will be needed to understand the sequence variation between individuals that is associated with individual differences in inherited susceptibility to disease. Such studies may require obtaining the sequence of much of the genomic DNA from large numbers (tens to possibly thousands) of individuals. Similarly, the utility of the initial complete genomic sequence of a few organisms for understanding their biology will increase the incentive to collect genomic sequence information for many other organisms to study their biology and evolutionary and symbiotic relationships. DNA sequencing of that magnitude can only be contemplated when sequencing techniques have been made considerably more cost-effective and robust than they are today, or will be in the foreseeable future. The purpose of this RFA is to stimulate the development of the technologies needed to achieve these goals.

Objectives and Scope

Technologies for *de novo* sequencing and re-sequencing are needed. It should be noted that the conceptual distinction between these DNA sequencing technologies is not fundamental, but is instead a function of the limitations of the technologies as currently implemented. As novel methods are introduced and sequencing technologies mature, throughput and accuracy will increase and cost will decrease, and the distinction may not persist. However, at least for the present, the capabilities of these approaches and their potential near-term applications are sufficiently different to justify distinguishing between them for the purpose of this RFA.

De novo sequencing involves determining DNA sequence without any prior knowledge of that sequence. The initial reference human sequence will be determined by *de novo* sequencing, as were the sequences of yeast, *H. influenzae*, *M. genitalium*, *M. jannaschii*, and *E. coli*. Technology for *de novo* sequencing will continue to be needed to determine the complete sequence of the genomes of numerous other organisms including pathogens, agriculturally important organisms, and those that have utility as model organisms and sources of pharmaceutical products.

Technology is also needed for re-sequencing or rapidly comparing sequences to identify differences. Re-sequencing takes advantage of sequence information obtained from one sample, to design a more efficient approach to determining the sequence of another, similar sample. Today's re-sequencing technologies are effective for samples that are extremely similar (e.g., for identifying single-base differences in a particular gene isolated from two individuals). With additional development, however, the data quality and throughput of re-sequencing technology my be improved, and expanded to allow determination of sequence in cases such as insertions or deletions relative to a reference sequence. Re-sequencing technology may be the most cost-effective way, for example, to collect the large amounts of sequence data from large numbers of individuals that is needed to understand the sequence variations associated with individual differences in inherited susceptibility to disease.

This RFA seeks to stimulate research on next-generation technologies (including those for *de novo* sequencing, re-sequencing, or both) that have the potential to reduce the cost of high-accuracy genomic DNA sequencing by at least an order of magnitude. State-of-the-art technology can currently generate *de novo* sequence data containing less than 1 error per 10,000 base pairs at a total cost (including machines, personnel, supplies, and overhead) of approximately $0.50 per base pair. The goal of research under this RFA will be to drive the total cost of obtaining accurate (<1 error in 10,000 bp) *de novo* sequence to well below $0.05 per base pair; re-sequencing should cost considerably less.

Applications responsive to this RFA will include those designed to:

Conduct research on novel scientific or engineering principles which have promise for being applicable to the development of cost-effective DNA sequencing technologies;

Study the application to DNA sequencing of principles that are well established in other fields of science or engineering, and that have strong potential for application to DNA sequencing, but for which such application may not have been demonstrated; and

Further develop technologies for which proof of principle for DNA sequencing may already have been demonstrated, but for which substantial additional work is required to achieve high throughput and low cost for genomic sequencing (examples include mass spectrometry, sequencing by hybridization, and micromachined and micro-electro-mechanical systems [MEMS]).

This list is not intended to be all-inclusive, but instead to provide examples of responsive projects. Potential applicants who have questions about the responsiveness of specific ideas are encouraged to contact NHGRI staff listed under Inquiries before submitting an application.

Applicants should directly address the advantages of the proposed approach over existing approaches, and justify their assertion that successful development of the technology will result in a ten-fold decrease in the cost of sequencing. Applicants proposing to develop technologies for which proof of principle for DNA sequencing has not yet been demonstrated should describe clearly the manner in which the proposed technology might be applied to sequencing. For such projects, it will be difficult to predict with confidence the cost of sequencing using the technology. It is therefore particularly important to present a clear conceptual overview of the entire system in which the technology would be used and if possible to estimate the cost of developing, producing, and using such a system.

Current DNA sequencing approaches require some combination of steps, including the isolation of DNA from biological samples, biochemical amplification of the DNA within the sample, incorporation of fluorescent label into the sample, determination of the nucleotide sequence of each sample, ''assembly'' of data from numerous overlapping and redundant determinations into a continuous dataset, and analysis of the sequence data. As new technologies are developed, some or all of these steps may still be required. Research on all of these steps, and particularly on the integration of steps into a continuous process, will be supported under this RFA. For projects whose aim is to develop integrated systems, applicants should address the throughput of the various system components, and how the entire system will support the achievement of the cost and quality goals of this RFA.

The RFA will also accept applications to develop computational tools needed in support of systems or in conjunction with components eligible for funding under this RFA. Support for development of computational tools may be included as part of the technology development application. An application to develop computational tools that is submitted independently of a proposal to develop hardware systems should describe how the results of the independent research will be integrated with existing or planned technology.

The following types of research will NOT be supported under this RFA: projects to improve slab gels, microchannels, and capillary array electrophoresis, in systems in which the well-to-read distance is measured in tens of centimeters. This type of research is currently receiving support from NHGRI as a result of recent RFAs. However, NHGRI continues to encourage this type of technology development for DNA sequencing; applications for such studies should be submitted under the Program Announcement PA–97–044 ''Technologies for Genomic Mapping, Sequencing, and Analysis'' (available from http://www.nhgri.nih.gov/Grant__info/Funding/Research/techpa.html).

Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization ACT of 1993 (Section 492B of Public Law 103–43).

All investigators proposing research involving human subjects should read the ''NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research,'' which have been published in the **Federal Register** of March 28, 1994 (FR 59 14508–14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Special Requirements

Statement of milestones: It has been the experience of NGHRI that technology development projects that establish a clear statement of their milestones, and benchmarks by which attainment of those milestones can be measured, make more rapid progress toward achieving their short- and long-range goals. Therefore, applicants should present a clear timetable for the achievement of specific milestones, and should define the benchmarks by which progress toward those milestones will be measured. Both the milestones and benchmarks should be stated as quantitatively as possible.

Dissemination of the results of technology development research: Proposals should address the issue of access by groups other than the developers to any instruments or software developed through this program.

Post-award management: During the course of the grant period, technologies will improve and the rate of progress and focus of work supported by the grants may change. It is expected that the principal investigators will make any necessary adjustments in scientific direction to accommodate the changing environment. During the award period, the principal investigators may be invited to meet with NIH program staff in Bethesda, MD, or at the grantee site, to review scientific progress. Other scientists external to and knowledgeable about these studies may also be invited to participate. Applicants should include travel funds for the P.I. to meet annually with NIH staff in the Washington, D.C. area, should such meetings be advisable.

Special human subjects issues: Recently, it has become evident that special human subjects issues are raised by the large-scale sequencing of human genomic DNA because large amounts of DNA sequence information from single individuals may be generated. Similar issues can be anticipated in projects in which sequence variations are identified in individuals. The NHGRI and the DOE have recently issued a document, ''Guidance on Human Subjects Issues in Large-Scale DNA Sequencing'' to address these issues. This document can be found on the NHGRI web site at (http://www.NHGRI.nih.gov/Grant__infor/Funding/Statements/large__scale.html). Any application submitted in response to this RFA that includes a plan to sequence at least 1 megabase of human DNA during the period of the grant, or to determine a large number of human sequence polymorphisms, in the context of testing the technology under development, should address these special human subjects issues.

Letter of Intent

Prospective applicants are asked to submit, by August 1, 1997, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of

other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, it can help establish an early dialogue with NHGRI staff, and the information that it contains allows NHGRI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to: Jeffery A. Schloss Ph.D., Division of Extramural Research, National Human Genome Research Institute, Building 38A, Room 614, Bethesda, MD 20892–6050, Telephone: (301) 496–7531, FAX: (301) 480–2770, E-mail: Jeff__Schloss@nih.gov.

Application Procedures

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892–7910, telephone 301/435–0714, e-mail: ASKNIH@odrockml.od.nih.gov; and from the program administrator listed under Inquiries.

The RFA label available in the application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to: Division of Research Grants, National Institutes of Health, 6701 Rockledge Drive, Room 1040, Bethesda, MD 20892–7710, Bethesda, MD 20817 (for express/courier service).

At the time of submission, two additional copies of the application, including appendices, must also be sent to: Rudy Pozzatti, Ph.D, Office of Scientific Review, National Human Genome Research Institute, Building 38A, Room 613, Bethesda, MD 20892–6050.

Applications must be received by October 16, 1997. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique. The applicants should also ensure that their revised applications respond to the review criteria by which applications received in response to this RFA will be evaluated.

Review Considerations

Upon receipt, applications will be reviewed for completeness by DRG and for responsiveness to the RFA by NHGRI program staff. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIH staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Those applications that are complete and responsive will be evaluated for scientific and technical merit in accordance with the criteria stated below by an appropriate peer review group convened by the NHGRI. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit will be discussed and assigned a priority score. All applications will receive a second level of review by the National Advisory Council for Human Genome Research.

Review criteria will include:

Scientific and technical merit of the proposed research;

Potential of the proposed technology to achieve the cost and quality goals of this RFA;

Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;

Adequacy with which critical technical issues have been identified, and solutions proposed;

Appropriateness of the timeline and milestones established by the investigator to ensure continued progress toward the specific aims, and adequacy of the specific benchmarks proposed for measuring progress toward the milestones;

Adequacy of plans to integrate the proposed technology with other components of a process required to accomplish DNA sequencing;

Qualifications and research experience of the principal investigator and staff in the area of the proposed research;

Availability of the resources necessary to perform the reseach;

Adequacy of plans for dissemination of technical advances and software tools developed under grant support:

Appropriateness of the proposed budget and duration in relation to the proposed research; and

Adequacy of plans to protect human subjects and to include women and minorities, if applicable.

For R21 applications, preliminary data are not required. However, the applicant does have the responsibility for developing a sound research plan and for presenting any other information that can be considered as evidence of feasibility.

Award Criteria

Factors that will be used to make award decisions are:

Quality of the proposed project as determined by peer review:

Balance among the projects received in response to the RFA in addressing different experimental approaches and their complementarity to other ongoing efforts, and value of the proposed research for achieving the goals of the National Human Genome Research Institute;

Adequacy of plans to manage and share data, resources and technology in a timely manner; and

Availability of funds.

Inquiries

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to: Jeffery A. Schloss, Ph.D., Division of Extramural Research, National Human Genome Research Institute, Building 38A, Room 614, Bethesda, MD 20892–6050, Telephone: (301) 496–7531, FAX: (301) 480–2770, E-mail: Jeff__Schloss@nih.gov.

Direct inquiries regarding fiscal matters to: Ms. Jean Cahill, Grants Management Office, National Human Genome Research Institute, Building 38A, Room 613, Bethesda, MD 20892–6050, Telephone: (301) 402–0733, FAX: (301) 402–1951, E-mail: Jean__Cahill@mih.gov.

Authority and Regulations

This program is described in the Catolog of Federal Domestic Assistance No. 93.172. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Pub. L. 78–410, as amended by Public Law 99–158, 42 U.S.C. 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Elke Jordan,

Deputy Director.

[FR Doc. 97–15744 Filed 6–13–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting of the National Cancer Advisory Board and Its Subcommittees

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Cancer Advisory Board, National Cancer Institute, and its Subcommittees on June 16–18, 1997. The meetings of the Board and its Subcommittees will be open to the public as indicated below. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public in accordance with the provisions set forth in secs. 552b(c)(4), 552b(c)(6), and 552(c)(9)(B), Title 5, U.S.C and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications and for discussion of issues pertaining to programmatic areas and/or NCI personnel. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning the individuals associated with the applications or programs, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy and premature disclosure of recommendations which would inhibit the final outcome and subsequent implementation of recommendations.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 630E, 6130 Executive Boulevard, MSC 7410, Rockville, Maryland 20892–7410, (301) 496–5708 will provide summaries of the meetings and rosters of the Board members, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mrs. Linda Quick-Cameron, Committee Management Officer, at (301) 496–5708 in advance of the meeting.

Name of Committee: Subcommittee on Cancer Centers.

Contact Person: Dr.Brian Kimes, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room 502, 6130 Executive Blvd., MSC 7383, Bethesda, MD. 20892–7383, (301) 496–8537.

Date of Meeting: June 16, 1997.

Place of Meeting: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Rhode Island Room, Washington, D.C. 20012.

Open: 7:00 p.m. to 8:00 p.m.

Agenda: To discuss policies and procedures of cancer programs.

Name of Committee: Ad Hoc Subcommittee on Clinical Trials.

Contact Person: Dr. Robert Wittes, Executive Secretary, National Cancer Institute, NIH, 9000 Rockville Pike, Bldg 31, Room 3A44, Bethesda, MD. 20892–2440, (301) 496–4291.

Date of Meeting: June 16, 1997.

Place of Meeting: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, N.W., Pennsylvania Room, Washington, D.C. 20012.

Open: 8:00 p.m. to 9:30 p.m.

Agenda: To discuss NCAB resolutions relating to Managed Care and the NCAB resolutions and Draft Bypass Budget section relating to Clinical Research.

Name of Committee: Subcommittee on Planning and Budget.

Contact Person: Ms. Cherie Nichols, Executive Secretary, National Cancer Institute, NIH, 7550 Wisconsin Avenue, Room 312, MSC 9010, Bethesda, MD. 20892–9010, (301) 496–5515.

Date of Meeting: June 17, 1997.

Place of Meeting: Building 31, Conference Room 10/C Wing, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. 20892.

Open: 12:25 p.m. to 1:35 p.m.

Agenda: To discuss the NCI Budget and various planning issues.

Name of Committee: Subcommittee on Special Actions for Grants

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room 600, 6130 Executive Blvd., MSC 7410, Bethesda, MD. 20892–7410, (301) 496–5147.

Date of Meeting: June 17, 1997.

Place of Meeting: Building 31, Conference Room 10/C Wing, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. 20892.

Closed: 3:45 p.m. to Adjournment.

Agenda: For review and discussion of grant applications and extramural/intramural, programmatic and personnel policies.

Name of Committee: National Cancer Advisory Board.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Institutes of Health, NIH, Executive Plaza North, Room 600, 6130 Executive Blvd., MSC 7410, Bethesda, MD. 20892–7410, (301) 496–5147.

Dates of Meeting: June 17–18, 1997.

Place of Meeting: Building 31, Conference Room 10/C Wing, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. 20892.

Open: June 17 8:30 a.m. to 3:20 p.m., June 18 8:30 a.m. to 1:30 p.m.

Agenda: Report of the Director, National Cancer Institute; Legislative Update; Report of the President's Cancer Panel; Topics for the National Cancer Policy Board; Report of the Prevention Program Review Group; New Initiatives in Communication; NCAB Outreach Activities; 25th Anniversary of the National Cancer Act; Subcommittee Reports; discussion of NCI Budget; Mini-Symposium; Managed Care's Impact on Clinical Investigations; Cancer Surveillance Update; Mammography Update; Future Research; Proposed Modifications of NIH Review and Award Policies; Office of Liaison Activities and other Council business.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers: (93.393, Cancer Cause and Prevention Research; 93.392, Cancer Detection and Diagnosis Research; 93.394, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: June 11, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–15740 Filed 6–13–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart,