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Positron Emission Tomography Drug Products; Draft Guidance for Industry on Content and Format of an Abbreviated New Drug Application; Availability; Extension of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is extending to August 27, 1997, the comment period on the agency's draft guidance entitled ''Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products.'' FDA published a notice of availability of the draft guidance in the **Federal Register** of April 23, 1997 (62 FR 19767).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INFORMATION: In the **Federal Register** of April 23, 1997, FDA published a notice announcing the availability of a draft guidance document entitled ''Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products.'' The draft guidance is intended to assist applicants who wish to submit ANDA's for Fludeoxyglucose F18 injection. The notice invited interested persons to submit written comments on the draft guidance by June 28, 1997.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V. Garcia, President of the Institute for Clinical PET, requesting that the agency extend the comment period on the draft guidance on ANDA's for PET drug products.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may, on or before August 27, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance.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]

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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